

DANA ROHRBACHER  
46th District, California

## Committees:

## FOREIGN AFFAIRS

Ranking Republican, Subcommittee on  
International Organizations, Human  
Rights and Oversight

Subcommittee on  
Asia, the Pacific, and  
the Global Environment

Subcommittee on the  
Middle East and South Asia

## SCIENCE AND TECHNOLOGY

Subcommittee on  
Space and Aeronautics



Congress of the United States  
House of Representatives

## WASHINGTON OFFICE:

2300 Rayburn House Office Building  
Washington, DC 20515-0546  
(202) 225-2415 FAX: (202) 225-0145

## DISTRICT OFFICE:

101 Main Street, Suite 380  
Huntington Beach, CA 92648-8118  
(714) 960-6483 FAX: (714) 960-7806

South Bay: (310) 377-9493

<http://rohrbacher.house.gov>

## FAX TRANSMISSION FORM

To: CMS  
Attn: Dave Lewandowski  
Fax: 202-690-8168

FROM:

RECEIVED  
AUG 2 2010  
OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

- |   |   |
|---|---|
| <input type="checkbox"/> Congressman Dana Rohrabacher | <input checked="" type="checkbox"/> Kip Payne |
| <input type="checkbox"/> Justin Ahn                   | <input type="checkbox"/> James Schmidt        |
| <input type="checkbox"/> Paul Berkowitz               | <input type="checkbox"/> Tara Setmayer        |
| <input type="checkbox"/> Fess Cassels                 | <input type="checkbox"/> Jeff Vanderslice     |
| <input type="checkbox"/> Tony DeTora                  |   |
| <input type="checkbox"/> Rick Dykema                  |   |
| <input type="checkbox"/> Other: _____                 |   |

NUMBER OF PAGES (INCLUDING TRANSMISSION SHEET): 2

COMMENTS:

Dave,  
Please pass the attached  
on to the appropriate party.  
Best, Kip

IF THERE ARE PROBLEMS WITH THIS TRANSMISSION, CALL (202) 225-2415

IR#3 000001

DANA ROHRBACHER  
46th District, California

## Committees:

## FOREIGN AFFAIRS

Ranking Republican, Subcommittee on  
International Organizations, Human  
Rights and Oversight  
Subcommittee on  
Asia, the Pacific, and  
the Global Environment

## SCIENCE AND TECHNOLOGY

Subcommittee on  
Space and Aeronautics  
Subcommittee on  
Investigations and Oversight



Congress of the United States  
House of Representatives

July 29, 2010

## WASHINGTON OFFICE:

2300 Rayburn House Office Building  
Washington, DC 20515-0546  
(202) 225-2415 FAX: (202) 225-0145

## DISTRICT OFFICE:

101 Main Street, Suite 380  
Huntington Beach, CA 92648-8118  
(714) 960-6483 FAX: (714) 960-7806

South Bay: (310) 377-9493

<http://rohrbacher.house.gov>

Dr. Donald Berwick, MD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Ave., SW  
Washington, DC 20201  
Via facsimile: (202) 690-8168

RE: National Coverage Analysis for Autologous Cellular Immunotherapy Treatment of  
Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Berwick,

I respectfully request the Centers for Medicare and Medicaid Services' careful consideration of inquiries for a national coverage determination pertaining to a Sipuleucel T treatment called Provenge. A uniquely effective prostate cancer treatment, Provenge is FDA-approved and manufactured by an American biotechnology company called Dendreon.

As the available literature regarding Provenge attests, this treatment is a significant alternative to chemotherapy for those people battling prostate cancer. Dendreon, which was founded in California in 1992, is constructing a production facility for this treatment in Seal Beach, California, which will be a welcome partner in my district's economy.

Thank you for your attention to this matter. I trust you will keep this information in mind as you weigh the relevant evidence as to whether Provenge is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

Sincerely,

Dana Rohrabacher  
Member of Congress



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C1-09-06  
Baltimore, Maryland 21244-1850



**AUG 30 2010**

Patti A. Davenport  
Government Relations Liaison  
Alabama Cancer Congress  
8805 N. 145<sup>th</sup> East Ave. (Suite 203)  
Owasso, OK 74055

Dear Ms. Davenport:

Thank you for your letter on behalf of Stephen L. Davidson, M.D. to the Administrator regarding Dendreon Corporation's PROVENGE® product. Dr. Davidson believes that since PROVENGE® is approved for marketing by the Food and Drug Administration, CMS does not have the authority to deny coverage for labeled indication.

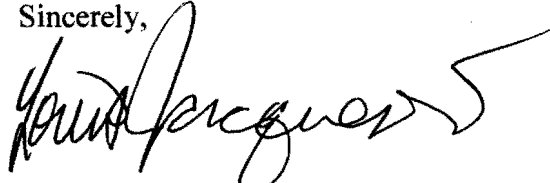
Shortly after Dendreon was given FDA approval to market PROVENGE® it was being covered on a case-by-case basis by some local Medicare administrative contractors. We became aware of differences in coverage policy across contractors as well as questions about whether this cellular immunotherapy would most appropriately be classified as a drug for Medicare purposes. We had also received several inquiries on this subject from members of Congress or their staffs.

These factors contributed to CMS' decision to open a NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes, which implies that NCDs should be considered to promote greater consistency in coverage across local contractors. While our analysis is progressing, local contractors retain their statutory authority to cover or not cover PROVENGE® within their jurisdictions. Upon publication of the NCD they must all comply with the national policy.

Page 2 cont. Patti A. Davenport

Based on the statutory time frames we expect that the proposed decision will be published on the CMS website by March 30, 2011 and that the final decision will be published no later than 60 days after the close of the public comment period on the proposed decision. We appreciate your interest in this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Louis Jacques", with a long, sweeping horizontal stroke extending to the right.

Louis Jacques, MD  
Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality

**CENTERS FOR MEDICARE AND MEDICAID SERVICES****Correspondence Cover Sheet***Doc ID:* **082320104040***Date Due:**Corr. From:* **Patti Davenport***Task Date:**On Behalf Of:**Letter Date:* **7/29/2010***Folder Created:* **8/23/2010***Subject:* **Provenge National Coverage Analysis***Synopsis:* **Provenge National Coverage Analysis***Primary Issues:* **Medicare Coverage***Program Office**Assigned:**Action Required:* **Direct Reply***Signature Level:* **Div Dir Sig***Coordinator:* **Linda Howard***Data Entry By:* **Brenda McCray***Instructions:* None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

Clark, Apryl C. (CMS/OP)

0823201040400059

**From:** Patti Davenport [patti@mjexecmgmt.com]  
**Sent:** Thursday, July 29, 2010 5:52 PM  
**To:** Berwick, Donald (CMS/OA)  
**Subject:** FW: Provenge Commentary  
**Attachments:** Provenge ACC.pdf

RECEIVED

AUG 10 2010

OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

Dr. Berwick – attached please find a copy of Dr. Stephen L. Davidson's CMS commentary on Provenge.

Sincerely,

*Patti A. Davenport*

Government Relations Liaison  
Alabama Cancer Congress

On behalf of Stephen L. Davidson, M.D.  
President, Alabama Cancer Congress

8805 N. 145th East Ave. (Suite 203)  
Owasso, OK 74055

Ph (918) 274-8374  
Fx (918) 274-8354

Confidentiality Notice: This message and the accompanying document or attachments may contain information which is privileged and/or confidential. If you are not the intended recipient, you may not review, discuss, disclose, copy, or distribute the contents of this message. If you have received this information in error, please immediately contact 918-274-8374 and destroy all evidence of this correspondence. Thank you.



## Alabama Cancer Congress

Education. Advocacy & Community

7/29/10

Donald Berwick, M.D., Administrator  
Centers for Medicare & Medicaid Services  
Donald.Berwick@CMS.hhs.gov

Dear Dr. Berwick,

Now that Provenge has been cleared by the FDA, eligible patients are understandably anxious to have access to it. CMS' National Coverage Analysis has the potential to delay treatment to patients with little to no options left in their fight against prostate cancer. Provenge is FDA approved; there is no legal or medical basis to deny Medicare coverage for the approved FDA indication. Provenge has shown a clear survival advantage over chemotherapy with a much lower side effect profile. Provenge also reduced the risk of death by 22.5 percent compared to the control group. This new bioengineered targeted therapy has a median survival of 25.9 months, and a 3-year survival rate of 34.1%. This is a clear benefit over standard care. Those that feel the price is not justified by the incremental survival are not factoring in the quality of life aspect. Provenge side effect profile includes flu-like symptoms. Plus, many of the study subjects are still alive today.

Customized treatment is the way of the future. My hope is that CMS does not choose to delay or impede access to this new innovative therapy.

Sincerely,

Stephen L. Davidson, MD  
President, Alabama Cancer Congress  
Montgomery Cancer Center  
4145 Carmichael Road  
Montgomery, AL 36106

PH: 334 273-7000  
FAX: 334 273-2282

**Ashby, Lori M. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/CCSQ)  
**Sent:** Friday, September 03, 2010 10:50 AM  
**To:** (b)(6)  
**Subject:** Provenge

Dear Dr. DiBenedetto:

Thank you for your email to the Administrator regarding the national coverage analysis (NCA) for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N) that includes PROVENGE®.

Shortly after Dendreon was given FDA approval to market PROVENGE® it was being covered on a case-by-case basis by some local Medicare administrative contractors. We became aware of differences in coverage policy across contractors as well as questions about whether this cellular immunotherapy would most appropriately be classified as a drug for Medicare purposes. We had also received several inquiries on this subject from members of Congress or their staffs.

These factors contributed to CMS' decision to open a NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes, which implies that NCDs should be considered to promote greater consistency in coverage across local contractors. While our analysis is progressing, local contractors retain their statutory authority to cover or not cover PROVENGE® within their jurisdictions. Upon publication of the NCD they must all comply with the national policy.

We have posted a tracking sheet to announce the opening of the NCA. It is available on the CMS website at <https://www4.cms.gov/mcd/viewtrackingsheet.asp?id=247>, and will be updated periodically. The first 30 day comment period ended on July 30, 2010. Based on the statutory time frames we expect that the proposed decision will be published on the CMS website by March 30, 2011 and that the final decision will be published no later than 60 days after the close of the public comment period on the proposed decision. We appreciate your interest in this issue.

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Mailstop C1-09-06  
7500 Security Blvd  
Baltimore MD 21244  
(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

**CENTERS FOR MEDICARE AND MEDICAID SERVICES****Correspondence Cover Sheet**

*Doc ID:*           **082320104015**           *Date Due:*  
*Corr. From:*     **Joseph DiBenedetto**   *Task Date:*  
*On Behalf Of:*  
*Letter Date:*     **7/20/2010**           *Folder Created:*   **8/23/2010**

*Subject:*           **Provenge National Coverage Analysis**  
*Synopsis:*          **Provenge National Coverage Analysis**  
*Primary Issues:*   **Medicare Coverage; Medicare Coverage**

*Program Office  
Assigned:*

*Action Required:* **Direct Reply**           *Signature Level:* **Div Dir Sig**  
*Coordinator:*     **Linda Howard**       *Data Entry By:*   **Brenda McCray**

*Instructions:* None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

082320104015

OCSSA

Clark, April C. (CMS/OP)

**From:** Joseph DiBenedetto (b)(6)  
**Sent:** Tuesday, July 20, 2010 3:14 PM  
**To:** Berwick, Donald (CMS/OA)  
**Subject:** Provenge National Coverage Analysis

RECEIVED

AUG 10 2010

OSORA DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

Dear Dr. Berwick,

The following are my comments on Provenge.

Provenge is a FDA approved therapy and the proposed course of action is inconsistent with the Medicare statute in treating patients. Provenge has shown a clear survival advantage over standard chemotherapy, and the patients experience less side effects than the chemotherapeutic drugs available. There is no basis to deny Medicare coverage for the approved FDA indication. This is an anti-cancer treatment, not a vaccine and should not be confused with such. The proposed National Coverage Analysis could take several months and may delay treatment to our patients with cancer of the prostate.

Respectfully submitted,

Joseph DiBenedetto Jr., M.D.



**CENTERS FOR MEDICARE AND MEDICAID SERVICES**

**Correspondence Cover Sheet**

*Doc ID:* **090920104003**

*Date Due:*

*Corr. From:* **Jeff Bingaman**

*Task Date:*

*On Behalf Of:* (b)(6)

*Letter Date:* **8/24/2010**

*Folder Created:* **9/9/2010**

*Subject:* **Two New FDA Approved Treatments Provenge and Jevtana.**

*Synopsis:* **Expediting Billing Code Two New FDA Approved Treatments Provenge and Jevtana.**

*Primary Issues:* **Medicare Coverage**

*Program Office Assigned:*

*Action Required:* **Direct Reply**

*Signature Level:* **RA Sig**

*Coordinator:* **LaShawn Reese**

*Data Entry By:* **Brenda McCray**

*Instructions:* None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

090920104003

United States Senate

August 24, 2010

Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue SW  
Room 314 G Humphrey Building  
Washington, District of Columbia 20201-0001

Dear Ms. Frizzera:

I have been contacted by my constituent, (b)(6), regarding his request for assistance in expediting the billing code of two new FDA approved treatments, Provenge and Jevtana.

Because of the desire of this office to be responsive to all inquiries, I would appreciate it if you would look into this matter and advise me of your findings so that I may respond to my constituent. Please send your response to the attention of Gabe Long at the address checked on the bottom of this letter.

Thank you for your assistance in this matter.

Sincerely,



Jeff Bingaman  
United States Senator

JB/sgl

PLEASE REPLY TO:

☐ 625 SILVER AVENUE, SW, SUITE 130  
ALBUQUERQUE, NM 87102  
(505) 346-6601

☐ 106-B WEST MAIN  
FARMINGTON, NM 87401  
(505) 325-5030

☐ 148 LORETTO TOWNE CENTRE  
505 SOUTH MAIN, SUITE 148  
LAS CRUCES, NM 88001  
(575) 523-6561

☐ 200 EAST 4TH STREET, SUITE 300  
ROSWELL, NM 88201  
(575) 622-7113

☒ 119 EAST MARCY, SUITE 101  
SANTA FE, NM 87501  
(505) 988-6647  
IR#3 000012

## United States Senate

Due to the Enactment of the "Right to Privacy Act," it is necessary for you to complete and sign this form authorizing me and members of my staff to obtain the information needed to respond to your request for assistance. The information obtained will be only that which is relative to the problem you presented to my office.

**Date:** AUGUST 4, 2010

**Name:** (b)(6)

**Address:** (b)(6)

**City:** (b)(6) **Zip Code:** (b)(6)

**Telephone:** (b)(6)

**Email:** (b)(6)

U.S. Senator Jeff Bingaman has my permission to make inquiries into my personal records and/or files as necessary to assist me in the matter I have presented to his office.

**Signature:** (b)(6)

**Date of Birth:** (b)(6)

**Social Security Number:** (b)(6)

Do you currently have a case pending before a local, state, of federal court in regard to this matter?: NO

Is another Congressional office assisting you in this matter?: no.

If so, which office?: We have sent letters to Sen. Udall & Cong. Lujan but have not received responses to date.

PLEASE REPLY TO:

☐ 625 SILVER AVENUE, SW, SUITE 130  
ALBUQUERQUE, NM 87102  
(505) 346-6601

☐ 148 LORETTO TOWNE CENTRE  
505 SOUTH MAIN, SUITE 148  
LAS CRUCES, NM 88001  
(505) 523-6561

☐ P.O. BOX 1977  
118 BRIDGE STREET, SUITE 3  
LAS VEGAS, NM 87701  
(505) 454-8824

☐ 200 EAST 4TH STREET, SUITE 300  
ROSWELL, NM 88201  
(505) 622-7113

☐ 119 EAST MARCY, SUITE 101  
SANTA FE, NM 87501  
(505) 996-4647

July 30, 2010

Senator Jeff Bingaman  
Santa Fe, New Mexico

Re: Recent approval by FDA of two new treatments for advanced prostate cancer and failure of Medicare to issue billing codes so patients can be covered financially

Dear Senator Bingaman,

I am writing on behalf of (b)(6). (b)(6) is a Medicare/AARP supplemental insurance patient of 68 who has been treated for prostate cancer in New Mexico since 2006. His oncologist is (b)(6) in Los Alamos, NM. (b)(6) has been treated with all of the standard treatments for his disease and his cancer continues to progress.

This summer the FDA approved an exciting immunotherapy treatment called Provenge, made by Dendreon and shortly thereafter a new chemotherapy called Jevtana, made by Sanofi Aventis. (b)(6) is a good candidate for both treatments.

No medical center in New Mexico has been approved as a treatment site for Provenge so we have traveled to Dallas, TX to Texas Oncology at Baylor University to try and get him treated with Provenge. In Dallas we would have to pay the \$93,000 up front because Trailblazer, the Medicare Administrative Contractor for TX and NM, has not issued a billing code and is not likely to do so for a year. We checked into two centers in Colorado, and they both require up front payment for the same reason.

With Jevtana, the new chemotherapy, the billing code hasn't been issued yet, and there is no date when it might be. We are caught in an impossible situation right now. Time is of the essence in getting (b)(6) treated right away. Jevtana is \$8,500 a treatment & it is given every 3 weeks. Our income is not low enough to qualify for patient assistance from the drug companies.

It was our understanding that we would be financially covered for FDA approved treatments when those treatments are approved specifically for a medical condition. Is there any way you can assist us in getting Trailblazer to speed up their issue of the billing codes so Los Alamos Medical Center and Texas Oncology at Baylor can treat (b)(6) (b)(6) and hundreds of other men with advanced prostate cancer this summer?

Sincerely,

(b)(6)

(b)(6)

and

(b)(6)

c.c. (b)(6), Los Alamos Medical Center



091620104022

September 21, 2010

The Honorable Saxby Chambliss  
416 Russell Senate Office Building  
Washington, DC 20510-1007

Dear Senator Chambliss:

Thank you for your inquiry on behalf of your constituent, (b)(6). (b)(6) has expressed concern about the potential for discrimination of Georgia residents by Medicare. Specifically, he wants to know when Medicare will allow coverage of a new drug called Provenge for Georgia residents. Provenge was recently approved by the Food and Drug Administration to treat prostate cancer.

Medicare does not yet have a national policy for this treatment. The Centers for Medicare and Medicaid Services (CMS) is considering all currently available evidence regarding the impact of labeled and unlabeled use of autologous cellular immunotherapy treatment of patients with metastatic prostate cancer. In absence of a national policy, our Medicare contractor, Cahaba GBA, has the authority to determine if this treatment is covered in the states of Georgia, Florida and Mississippi. The decision to allow coverage is based on local medical practice patterns, medical and scientific documentation.

If a claim is submitted for payment, Cahaba will determine if the drug is medically necessary. If the drug is determined to be medically necessary, Medicare will allow reimbursement. After a claim is filed, (b)(6) physician may be asked to submit additional supporting medical documentation.

I hope this information has been helpful. If you have further questions, please feel free to contact me by telephone at (404) 562-7368.

Sincerely,

Kristen Dixon  
Medicare Fee for Service Operations  
Division of Financial Management  
& Fee for Service Operations

# United States Senate

WASHINGTON, DC 20510-1007

September 7, 2010

RECEIVED

SEP 15 2010

OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

Maria Martino  
Centers for Medicare and Medicaid Services  
U.s. Department Of Health And Human Services  
Hubert Humphrey Building, Room 314  
Washington, D.C. 20201

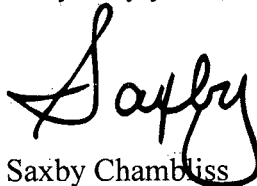
Dear Maria:

I have enclosed a copy of a letter from my constituent, (b)(6), of Acworth, Georgia, who has contacted me concerning the prostate cancer drug, Provenge.

I would very much appreciate your review of (b)(6) concerns.

If you need further information, please contact Mark Olsen of my staff at 202-224-3521. I look forward to your response.

Very truly yours,

  
Saxby Chambliss

SC:mo

**E-Mail Viewer**

Message	Details	Attachments	Headers	Source
---------	---------	-------------	---------	--------

HTML

From: "WebServer Reserved UID" <webservd@p-ess-www6.senate.gov>  
Date: 8/18/2010 12:22:50 PM  
To: "webmail@chambliss-iq.senate.gov" <webmail@chambliss-iq.senate.gov>  
Cc:  
Subject: Discrimination of Georgia residents by Medicare

(b)(6)

<ISSUE>hlth</ISSUE>  
<AFFL>reply</AFFL>  
<MSG>I am having a issue with Medicare. The FDA has approved a prostate cancer drug called Provenge made by Dendreon.

Medicare is reviewing to what extent they will pay for the treatment, which is very unusual given itâ€™s FDA approval. What is more unusual and the subject of my email is that Medicare has left the interim decision on payments to the regional CMS contractors.


The local carrier in GA, Cahaba, has refused to give my physican a local coverage determination, so we donâ€™t yet know if they will cover the Provenge. My physician will not treat me unless it is covered. The local carrier in North Carolina is covering treatments and I am forced to travel to Charlotte for multiple treatment events.

My question is how can Medicare discriminate based on geographic location? Do I have legal recourse here?

</MSG>  
</APP>

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**REPORT OF CONTACT**

<b>Name/Organization/Telephone Number of Person Contacted:</b> Marilyn Jones Seator Mark Warner <a href="mailto:jones@warner.senate.gov">jones@warner.senate.gov</a>		<b>MTN#: 69526</b> <b>Swift Doc ID #:</b> 072620104007
<b>Constituent Name /Address/Telephone Number:</b>  Paul F. Schellhammer, MD Medical Director, Sentara Interstate Corporate Center, Bld. 16 Norfolk, VA 23502 757.457.5100		<b>Date of Contact:</b> 08/17/2010 via email <hr/> <b>Phone:</b>  <b>In Person:</b>
<b>SUBJECT:</b>  Medicare Coverage of Provenge		
<b>DISCUSSION/STATUS:</b>  Dr. Shellhammer wanted to speak with the Medical Director of Trailblazer to discuss coverage of his prostate cancer drug so Sentara Health Plan can also cover drug. Trailblazer will discuss this matter with Dr. Shellhammer as requested.		
<b>ACTION REQUIRED:</b>  N/A		
<b>Prepared By:</b> 	<b>Phone Number:</b> 215-861-4194	<b>Date Closed:</b> 8/17/2010



**CENTERS FOR MEDICARE AND MEDICAID SERVICES****Correspondence Cover Sheet**

*Doc ID:* **072620104007** *Date Due:*  
*Corr. From:* **Mark R. Warner** *Task Date:*  
*On Behalf Of:* **Paul Schellhammer**  
*Letter Date:* **7/12/2010** *Folder Created:* **7/26/2010**

*Subject:* **Medicare Coverage For the Drug Provenge.**  
*Synopsis:* **Medicare Coverage For the Drug Provenge.**  
*Primary Issues:* **Medicare Coverage**

*Program Office  
Assigned:*

*Action Required:* **Direct Reply** *Signature Level:* **RA Sig**  
*Coordinator:* **Linda Howard** *Data Entry By:* **Brenda McCray**

*Instructions:* None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

07252010 4007

United States Senate

WASHINGTON, DC 20510-4606

COMMITTEES:  
BANKING, HOUSING, AND  
URBAN AFFAIRS

COMMERCE, SCIENCE, AND  
TRANSPORTATION

BUDGET

RULES AND ADMINISTRATION

JOINT ECONOMIC COMMITTEE

July 12, 2010

Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department Of Health And Human Services  
200 Independence Avenue, Sw, Room 341h  
Washington, DC 20201-0001

Dear Ms. Frizzera:

I am writing to bring to your attention the enclosed comments from my constituent, Dr. Paul F. Schellhammer.

I would appreciate your reviewing this correspondence and preparing a reply on the stated concerns. Please send your reply to my state office:

The Honorable Mark R. Warner  
919 E. Main Street, Suite 630  
Richmond, Virginia 23219

My constituent and I appreciate your assistance in this matter. I am grateful for all you can do to resolve this matter within the existing laws, rules and regulations of the Centers for Medicare and Medicaid Services.

Thank you for your time and courtesy.

Sincerely,



MARK R. WARNER  
United States Senator

RECEIVED

JUL 19 2010

OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

MRW/mj

Enclosure(s)

☐ 180 WEST MAIN STREET  
ABINGDON, VA 24210  
PHONE: (276) 628-8158  
FAX: (276) 628-1036

☐ 101 WEST MAIN STREET  
SUITE 4900  
NORFOLK, VA 23510  
PHONE: (757) 441-3079  
FAX: (757) 441-6250

☒ 919 EAST MAIN STREET  
SUITE 630  
RICHMOND, VA 23219  
PHONE: (804) 775-2314  
FAX: (804) 775-2319

☐ 129B SALEM AVENUE, SW  
ROANOKE, VA 24011  
PHONE: (540) 857-2676  
FAX: (540) 857-2800

☐ 8000 TOWERS CRESCENT DRIVE  
SUITE 200  
VIENNA, VA 22182  
PHONE: (703) 442-0670  
FAX: (703) 442-0408

**Urology of Virginia**  
Sentara Medical Group

June 11, 2010

Senator Mark R. Warner  
8000 Towers Crescent Drive  
Suite 200  
Vienna, Virginia 22182

Fax: 703-442-0408 / 757-441-6250 (Norfolk)

Dear Senator Warner:

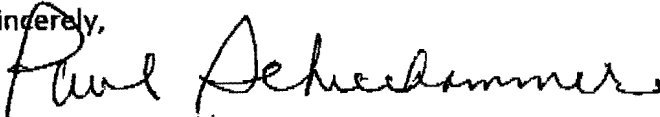
I am enclosing several e-mails that are self-explanatory with regard to the position of Trailblazers, our geographic Medicare carrier, concerning coverage of a recently improved immunotherapy for men with advanced prostate cancer. The product is called **PROVENGE**<sup>®</sup>. It was approved in late April by the FDA. Our patients in Tidewater Virginia have been denied coverage, and our efforts to meet the medical director have also led to a denial. On discussing coverage in other geographic locations, I have obtained feedback that coverage approval by Medicare carrier has been forthcoming.

Patients with metastatic androgen independent prostate cancer face chemotherapy as their only current strategy to improve survival. **PROVENGE**<sup>®</sup> also improve survival but with much lower toxicity than chemotherapy.

I would like very much to be able to provide immunotherapy, **PROVENGE**<sup>®</sup>, to patients in our practice who have advanced metastatic prostate cancer.

I would appreciate any help that you might give.

Sincerely,

  
Paul F. Schellhammer, MD

PFS/kk

Interstate Corporate Center, Bldg. 16  
Norfolk, VA 23502 Tel: 757.457.5100

400W. Brambleton Avenue, Suite 100  
Norfolk, VA 23510 Tel: 757.457.5170

1200 First Colonial Road, Suite 100G  
Virginia Beach, VA 23454 Tel: 757.481.3556

9536 Hospital Avenue  
Nassawadox, VA 23413 Tel: 757.442.8050

113 Gainsborough Square, Suite 202  
Chesapeake, VA 23320 Tel: 757.457.5480

3150 Western Branch Boulevard  
Chesapeake, VA 23321 Tel: 757.686.1873

100 Kingsley Lane, Suite 404  
Norfolk, VA 23505 Tel: 757.489.411

www.sentara.com

Victor M. Brugh, III, M.D.\*

Jack R. Drucker, M.D.\*

Gregg R. Eura, M.D., F.A.C.S.\*

Michael D. Fabrizio, M.D., F.A.C.S.\*

Robert W. Given, M.D., F.A.C.S.\*

Nathan P. Goldin, M.D.\*

Jose E. Gonzales, M.D.\*

Gerald H. Jordan, M.D., F.A.C.S., F.A.A.P. (Hon)\*

William A. Julian, M.D.\*

P. Gary Katz, M.D.\*

Joseph J. Konefal, M.D.\*

Peter O. Kwong, M.D.\*

Raymond S. Lance, M.D.\*

John S. Liu, M.D. F.A.C.S.\*

Donald F. Lynch, Jr., M.D. F.A.C.S.\*

Kurt A. McCammon, M.D., F.A.C.S.\*

Guillermo H. Mosquera, M.D., F.A.C.S.\*

William H. Rawls, M.D., F.A.C.S.\*

Edwin L. Robey, M.D., F.A.C.S.\*

Paul F. Schellhammer, M.D., F.A.C.S.\*

Steven M. Schlossberg, M.D., F.A.C.S.\*

James D. Young, M.D.\*

Carol A. Ascher, M.S.N., F.N.P., B.C.

Stephanie C. Oldfield, N.P.C.

Bonnie L. Gallo, M.S.N., F.N.P., B.C.

Cheryl S. Oscar, M.S.N., F.N.P., B.C.

Valerie A. Paschang, A.P.R.N., B.C.

\*Diplomate of the American Board of Urology



SENTARA

Subj: **FW: Provenge - Medicare's response to inquiry**  
Date: 5/19/2010 9:15:55 A.M. Eastern Daylight Time  
From: [DPROSENB@sentara.com](mailto:DPROSENB@sentara.com)  
To: [CMVAUGH1@sentara.com](mailto:CMVAUGH1@sentara.com), [KDRAMSEY@sentara.com](mailto:KDRAMSEY@sentara.com), (b)(6)

(b)(6)

(b)(6) [CSOSCAR@sentara.com](mailto:CSOSCAR@sentara.com), [JPESPINO@sentara.com](mailto:JPESPINO@sentara.com)

FYI--The SMG CBO has made contact with our local Medicare carrier, Trailblazers, to see their position on Provenge. Please read below.

Thanks

Dana

---

**From:** CINDY A TAYLOR  
**Sent:** Wednesday, May 19, 2010 9:11 AM  
**To:** DANA ADAMS; DORIS G PRINCE  
**Subject:** Provenge - Medicare's response to inquiry

Good morning,

Per CMS, there is no payment policy for Provenge. Since Provenge is a vaccine, it is considered a preventive service and will not be covered at this time. The patient will be liable for any charges incurred relating to receiving this treatment.

Despite the fact that it is considered a non-covered service, an ABN will still be required in order for SMG to bill the patient.

Please let me know if you have any questions.

Thank you  
Cindy

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. This message contains confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.

Friday, June 11, 2010 AOL: PSchellham

IR#3 000022

Subj: Meeting with Trailblazers to discuss Provenge  
Date: 6/10/2010 2:12:12 P.M. Eastern Daylight Time  
From: DPROSENB@sentara.com  
To: (b)(6)  
CC: KDRAMSEY@sentara.com, CMVAUGH1@sentara.com

As you can see, SMG has attempted to get the contact information for the Medicare Medical Director for a discussion on Provenge. Below is the response. I am surprised by this, as we have always been able to contact the Medical Director in the past.

Dana

---

From: CINDY A TAYLOR  
Sent: Thursday, June 10, 2010 1:40 PM  
To: DANA ADAMS  
Cc: DORIS G PRINCE  
Subject: Contact Information - In follow up for Trailblazer Health

Dana,

I just receive the following from Carolyn McNamar at Trailblazer Health:

" Hello, I just spoke to Dr. Haley. He regrets he is unable to meet with Dr. Schlossberg but suggested he attend one of our Open CAC meetings, the next one will be in September. The date for this meeting has not been set yet but the registration is on our web-site around the second week of September. You may also send Dr. Haley any informational materials for him to review. His schedule until December is completely taken."

For your records, Ms McNamar's email address is: [carolyn.mcnamar@trailblazerhealth.com](mailto:carolyn.mcnamar@trailblazerhealth.com)

I am a little unsure of her response related to the fact that Dr Haley "is unable to meet with Dr. Schlossberg" . . . here is my original inquiry to her:

Good day Ms. McNamar,  
I am in need of some assistance. One of our Medical Directors, Steven Schlossberg, MD, would like to talk to Charles Haley, MD at Trailblazer Health. I have been unable to locate a phone number that I can provide to Dr Schlossberg. Would you please let me know what phone number he should use in order to call Dr Haley?

Dr Schlossberg would like to discuss a newly FDA approved autologous cellular immunotherapy biologic manufactured by Dendreon called Provenge (NDC# 30237-8900-6). Medicare currently does not have any coverage policies pertaining to this biologic and we have Medicare patients interested in receiving the treatment.

I look forward to hearing from you.

Thank you for your assistance regarding this matter,

Cindy

Friday, June 11, 2010 (b)(6)

IR#3 000023

At this point, I feel that I have exhausted all means at my level. You may have more success if one of the physicians were to make a call to them as the suggestion to attend an Open CAC meeting in September does not seem conducive to our plan to begin treating Medicare patients immediately.

Thank you  
Cindy

Friday, June 11, 2010 (b)(6)

IR#3 000024



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

JUL 28 2010

7500 Security Boulevard  
Baltimore, MD 21244-1850

The Honorable Jim Webb  
United States Senate  
222 Central Park Avenue  
Suite #120  
Virginia Beach, VA 23462

Dear Senator Webb:

Thank you for your letter concerning the issue raised by Dr. Shellhammer, #610031, regarding the local Medicare Administrative Contractor (MAC) decision to deny coverage for PROVENGE®, an autologous cellular immunotherapy used to treat some patients with metastatic prostate cancer.

Each MAC has authority under statute (section 1869(f)(2)(B) of the Social Security Act) to cover or not cover particular items or services within its jurisdiction. We understand that, in light of the available scientific evidence, some local Medicare contractors are covering it while others are not. We also understand that there has been some discussion as to whether the constituent parts of the PROVENGE® regimen, for the purposes of the Medicare program, are most appropriately characterized singly or collectively as a drug, biologic, immunotherapy, vaccine or other item or service.

The Centers for Medicare and Medicaid Services has opened a National Coverage Analysis (NCA) to make a National Coverage Determination (NCD) to address these issues. We will evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of PROVENGE® for prostate cancer. We are aware that this is a novel type of anticancer treatment, and that the Food and Drug Administration is requiring post approval clinical studies. It is our hope that the opening of the NCD, the commissioning of an external technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ), and the convening of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

We have posted a tracking sheet to announce the opening of the NCA. It is available on the CMS website at <https://www4.cms.gov/mcd/viewtrackingsheet.asp?id=247>, and will be updated periodically. While our analysis is progressing, local MACs retain their statutory authority to cover or not cover PROVENGE® within their jurisdictions. Upon publication of the NCD they must all comply with the national policy.

We invite Dr. Shellhammer to provide public comment on the NCA. The public comment portal is available on the tracking sheet.

Sincerely,

A handwritten signature in cursive script that reads "Barry M. Straube, M.D.".

Barry M. Straube, M.D.  
CMS Chief Medical Officer  
Director, Office of Clinical Standards and Quality

cc:  
Jeanne Evans

Enclosure



JIM WEBB  
VIRGINIA

COMMITTEE ON  
ARMED SERVICES  
COMMITTEE ON  
FOREIGN RELATIONS  
COMMITTEE ON  
VETERANS' AFFAIRS

JOINT ECONOMIC COMMITTEE

WASHINGTON OFFICE:  
WASHINGTON, DC 20510  
(202) 224-4024

# United States Senate

WASHINGTON, DC 20510-4605

June 18, 2010

RECEIVED

JUN 28 2010

OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

Ms. Carleen Talley  
Director, Congressional Affairs Group  
Centers for Medicare and Medicaid Services  
Department of Health And Human Services  
200 Independence Avenue, SW, Room 341 H  
Washington, DC 20201

Dear Ms. Talley:

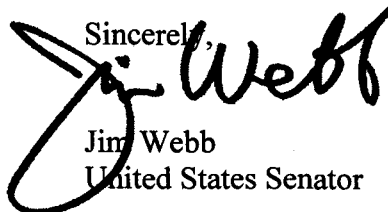
Enclosed is correspondence from my constituent in reference to a matter involving your agency.

Please give this letter every appropriate consideration and review my constituent's case in accordance with all rules, regulations and laws applicable to your agency. Your immediate attention and expeditious assistance would be greatly appreciated.

Please reply in duplicate to my 222 Central Park Ave. # 120, Va. Beach, Va. 23462, Attn: Jeanne Evans, Regional Representative (757-518-1678 or [Jeanne\\_Evans@webb.senate.gov](mailto:Jeanne_Evans@webb.senate.gov)) office and return the enclosure. In your reply, please reference Shellhammer # 610031.

Thank you so much for your assistance to my constituent.

With warm regards, I remain

Sincerely,  
  
Jim Webb  
United States Senator

JW: je  
Enclosure

Urology of Virginia  
Sentara Medical Group  
6333 Center Drive, Bldg 16  
Norfolk, VA 23502

Phone: (757) 457-5182  
FAX: (757) 627-3573  
Email: [schellpf@evms.edu](mailto:schellpf@evms.edu); [pfschell@sentara.com](mailto:pfschell@sentara.com)

**Paul F. Schellhammer, M. D.**

# Fax

**To:** Senator Webb  
**From:** Dr. Schellhammer/Kathy Katana  
**Fax:** 518-1679  
**Pages:** 5  
**Phone:**  
**Date:** June 14, 2010  
**Re:**  
**CC:**

☐ Urgent    ☐ For Review    ☐ Please Comment    ☐ Please Reply    ☐ Please Recycle

• **Comments:**

**Urology of Virginia**  
Sentara Medical Group

June 14, 2010

Senator Jim Webb  
222 Central Park Ave.  
Suite 120  
Virginia Beach, VA 23462

Fax: 757-518-1679

Dear Senator Webb:

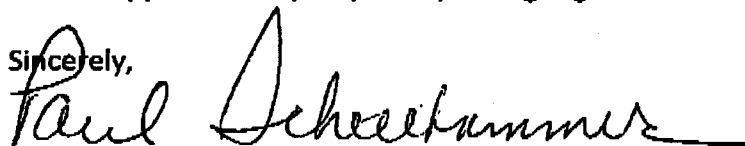
I am enclosing several e-mails that are self-explanatory with regard to the position of Trailblazers, our geographic Medicare carrier, concerning coverage of a recently improved immunotherapy for men with advanced prostate cancer. The product is called **PROVENGE®**. It was approved in late April by the FDA. Our patients in Tidewater Virginia have been denied coverage, and our efforts to meet the medical director have also led to a denial. On discussing coverage in other geographic locations, I have obtained feedback that coverage approval by Medicare carrier has been forthcoming.

Patients with metastatic androgen independent prostate cancer face chemotherapy as their only current strategy to improve survival. **PROVENGE®** also improve survival but with much lower toxicity than chemotherapy.

I would like very much to be able to provide immunotherapy, **PROVENGE®**, to patients in our practice who have advanced metastatic prostate cancer.

I would appreciate any help that you might give.

Sincerely,



Paul F. Schellhammer, MD

PFS/kk

Interstate Corporate Center, Bldg. 18  
Norfolk, VA 23502 Tel: 757.457.5100

400W. Brambleton Avenue, Suite 100  
Norfolk, VA 23510 Tel: 757.457.5170

1200 First Colonial Road, Suite 100G  
Virginia Beach, VA 23454 Tel: 757.481.3556

9536 Hospital Avenue  
Nassawadox, VA 23413 Tel: 757.442.6050

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Chesapeake, VA 23320 Tel: 757.457.5480

3150 Western Branch Boulevard  
Chesapeake, VA 23321 Tel: 757.686.1973

100 Kingsley Lane, Suite 404  
Norfolk, VA 23505 Tel: 757.489.411

www.sentara.com

Victor M. Brugh, III, M.D.\*  
Jack R. Drucker, M.D.\*  
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Michael D. Fabrizio, M.D., F.A.C.S.\*  
Robert W. Given, M.D., F.A.C.S.\*  
Nathan P. Goldin, M.D.\*  
Jose E. Gonzales, M.D.\*  
Gerald H. Jordan, M.D., F.A.C.S., F.A.A.P. (Hon)\*  
William A. Julian, M.D.\*  
P. Gary Katz, M.D.\*  
Joseph J. Konetel, M.D.\*  
Peter O. Kwong, M.D.\*  
Raymond S. Lance, M.D.\*  
John S. Liu, M.D. F.A.C.S.\*  
Donald F. Lynch, Jr., M.D. F.A.C.S.\*  
Kurt A. McCammon, M.D., F.A.C.S.\*  
Guillermo H. Mosquera, M.D., F.A.C.S.\*  
William H. Rawls, M.D., F.A.C.S.\*  
Edwin L. Robey, M.D., F.A.C.S.\*  
Paul F. Schellhammer, M.D., F.A.C.S.\*  
Steven M. Schlossberg, M.D., F.A.C.S.\*  
James D. Young, M.D.\*  
Carol A. Ascher, M.S.N., F.N.P., B.C.  
Stephanie C. Oldfield, N.P.C.  
Bonnie L. Gallo, M.S.N., F.N.P., B.C.  
Cheyl S. Oscar, M.S.N., F.N.P., B.C.  
Valerie A. Paschang, A.P.R.N., B.C.

\* Diplomate of the American Board of Urology



SENTARA.

Subj: **FW: Provenge - Medicare's response to inquiry**  
Date: 5/19/2010 9:15:55 A.M. Eastern Daylight Time  
From: DPROSENB@sentara.com  
To: CMVAUGH1@sentara.com, KDRAMSEY@sentara.com, (b)(6)

(b)(6)

(b)(6)

CSOSCAR@sentara.com, JPESPINO@sentara.com

FYI---The SMG CBO has made contact with our local Medicare carrier, Trailblazers, to see their position on Provenge. Please read below.

Thanks  
Dana

---

**From:** CINDY A TAYLOR  
**Sent:** Wednesday, May 19, 2010 9:11 AM  
**To:** DANA ADAMS; DORIS G PRINCE  
**Subject:** Provenge - Medicare's response to inquiry

Good morning,

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Despite the fact that it is considered a non-covered service, an ABN will still be required in order for SMG to bill the patient.

Please let me know if you have any questions.

Thank you  
Cindy

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. This message contains confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.

Friday, June 11, 2010 (b)(6)

Subj: Meeting with Trailbalzers to discuss Provenge  
Date: 6/10/2010 2:12:12 P.M. Eastern Daylight Time  
From: DPROSENB@sentara.com  
To: (b)(6)  
CC: KDRAMSEY@sentara.com, CMVAUGH1@sentara.com

As you can see, SMG has attempted to get the contact information for the Medicare Medical Director for a discussion on Provenge. Below is the response. I am surprised by this, as we have always been able to contact the Medical Director in the past.

Dana

---

From: CINDY A TAYLOR  
Sent: Thursday, June 10, 2010 1:40 PM  
To: DANA ADAMS  
Cc: DORIS G PRINCE  
Subject: Contact Information - In follow up for Trailblazer Health

Dana,

I just receive the following from Carolyn McNamar at Trailblazer Health:

" Hello, I just spoke to Dr. Haley. He regrets he is unable to meet with Dr. Schlossberg but suggested he attend one of our Open CAC meetings, the next one will be in September. The date for this meeting has not been set yet but the registration is on our web-site around the second week of September. You may also send Dr. Haley any informational materials for him to review. His schedule until December is completely taken."

For your records, Ms McNamar's email address is: [carolyn.mcnamar@trailblazerhealth.com](mailto:carolyn.mcnamar@trailblazerhealth.com)

I am a little unsure of her response related to the fact that Dr Haley "is unable to meet with Dr. Schlossberg" . . . here is my original inquiry to her:

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I am in need of some assistance. One of our Medical Directors, Steven Schlossberg, MD, would like to talk to Charles Haley, MD at Trailblazer Health. I have been unable to locate a phone number that I can provide to Dr Schlossberg. Would you please let me know what phone number he should use in order to call Dr Haley?

Dr Schlossberg would like to discuss a newly FDA approved autologous cellular immunotherapy biologic manufactured by Dendreon called Provenge (NDC# 30237-8900-6). Medicare currently does not have any coverage policies pertaining to this biologic and we have Medicare patients interested in receiving the treatment.

I look forward to hearing from you.

Thank you for your assistance regarding this matter,

Cindy

Friday, June 11, 2010 (b)(6)

At this point, I feel that I have exhausted all means at my level. You may have more success if one of the physicians were to make a call to them as the suggestion to attend an Open CAC meeting in September does not seem conducive to our plan to begin treating Medicare patients immediately.

Thank you  
Cindy

Friday, June 11, 2010 AOL: PSchellham



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

SEP 02 2010

7500 Security Boulevard  
Baltimore, MD 21244-1850

The Honorable Sam Brownback  
United States Senate  
11111 West 95<sup>th</sup>, Suite 245  
Overland Park, KS 66214  
Attention to: Shawn Cowing  
Re: Kelli White letter

Dear Senator Brownback:

Thank you for your letter of August 2, 2010 to Charlene Frizzera concerning the various issues raised by your constituent (b)(6) regarding PROVENGE®. (b)(6) asked why CMS opened a national coverage analysis (NCA) for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N) that includes PROVENGE®.

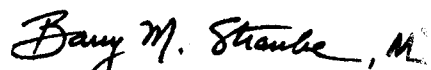
Shortly after Dendreon was given FDA approval to market PROVENGE® it was being covered on a case-by-case basis by some local Medicare administrative contractors. We became aware of differences in coverage policy across contractors as well as questions about whether this cellular immunotherapy would most appropriately be classified as a drug for Medicare purposes. We had also received several inquiries on this subject from members of Congress or their staffs.

These factors contributed to CMS' decision to open a NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes, which implies that NCDs should be considered to promote greater consistency in coverage across local contractors. While our analysis is progressing, local contractors retain their statutory authority to cover or not cover PROVENGE® within their jurisdictions. Upon publication of the NCD they must all comply with the national policy.

We have posted a tracking sheet to announce the opening of the NCA. It is available on the CMS website at <https://www4.cms.gov/mcd/viewtrackingsheet.asp?id=247>, and will be updated periodically. The first 30 day comment period ended on July 30, 2010. Based on the statutory time frames we expect that the proposed decision will be published on the CMS website by March 30, 2011 and that the final decision will be published no later than 60 days after the close of the public comment period on the proposed decision. We cannot comment on her broader allegations of actions or omissions by Dendreon, the Securities and Exchange Commission or the Food and Drug Administration (FDA) and (b)(6) will need to follow up with those agencies on those issues outside of CMS jurisdiction.

Thank you very much for bringing this issue to our attention. If you have any additional questions or if I can be of further assistance please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Barry M. Straube, MD". The signature is written in a cursive style with a large, stylized 'B' and 'M'.

Barry M. Straube, MD  
CMS Chief Medical Officer  
Director, Office of Clinical Standards and Quality



SAM BROWNBACK  
KANSAS

(202) 224-6521 PHONE  
(202) 228-1265 FAX

United States Senate  
WASHINGTON, DC 20510-1604

COMMITTEES:  
APPROPRIATIONS  
COMMERCE, SCIENCE  
AND TRANSPORTATION  
ENERGY AND  
NATURAL RESOURCES  
JOINT ECONOMIC  
AGING

August 2, 2010

Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Room 314 G Humphrey Building  
Washington, DC 20201

RECEIVED

AUG 9 2010

GOVERNMENT DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

Dear Mrs. Frizzera:

Enclosed please find a letter sent to my office from (b)(6) regarding her concerns over the CMS's review of Provenge, a cancer treatment developed by Dendreon. I believe you will find the letter to be self-explanatory.

I would appreciate it if you would review the enclosed letter and provide my office with any information that may be helpful in addressing (b)(6)'s concerns. Specifically, I would be grateful if you could advise as to why the CMS is conducting this review of Provenge. Please direct your response to Shawn Cowing in my Overland Park office at (913) 492-6378.

I am grateful for any assistance you may be able to provide in this matter.

Sincerely,



Sam Brownback  
United States Senator

612 SOUTH KANSAS AVENUE  
TOPEKA, KS 66603  
(785) 233-2503 PHONE  
(785) 233-2616 FAX

1001-C NORTH BROADWAY  
PITTSBURG, KS 66762  
(620) 231-6040 PHONE  
(620) 231-6347 FAX

811 NORTH MAIN STREET, SUITE A  
GARDEN CITY, KS 67846  
(620) 275-1124 PHONE  
(620) 275-1837 FAX

245 NORTH WACO, SUITE 240  
WICHITA, KS 67202  
(316) 264-8066 PHONE  
(316) 264-9078 FAX

11111 WEST 95TH, SUITE 245  
OVERLAND PARK, KS 66214  
(913) 492-6378 PHONE  
(913) 492-7253 FAX

[www.brownback.senate.gov](http://www.brownback.senate.gov)

IR#3 000035

## Casework

4978-10P

## Details

<b>Case Information</b>	
Description	
Category	Health Care
Subcategory	
Subject	casework
<b>Dates</b> <b>Elapsed Days</b> 0	
Opened	08/02/2010
Due	09/01/2010
Modified	08/02/2010
Closed	

<b>Classification</b>	
Received Via	Letter
Region	
Status	Open
Closed By	Indicator

<b>Web Mail Message</b>
<p>I write yet again about the Federal government's malfeasance in dealing with Dendreon's Provenge, a new cancer treatment. My previous complaints to you have centered on the FDA and the SEC's dealings with Provenge. The FDA was unprofessional, if not unethical, in its approval process for Provenge. The SEC ignores Dendreon's outright stock manipulation. How can a stock drop from \$23.00 to less than \$8.00 in 75 seconds?</p> <p>Now I have complaints about CMS (Medicare and Medicaid) which has unnecessarily called for a review of Provenge. Why? The CMS announcement of this review was unprofessionally vague. The FDA (finally) has approved the use of Provenge. It is not within the CMS purview to question FDA approvals. The American Society of Clinical Oncologists (ASCO) has now called for CMS to back off this review.</p> <p>Please find out why CMS is conducting this review of Provenge.</p> <p>Dendreon is a small company which developed a revolutionary form of treatment for cancer, it uses the body's own immune system. Yet at every turn the Federal government has thrown up roadblocks.</p> <p>I'm appalled and ashamed at the lack of supportive actions from these Federal agencies. And, I am also ashamed that you, and Congress have failed to address the issues.</p> <p>(b)(6)</p>

<b>Results</b>
----------------

<b>Contact</b>
(b)(6)
<b>Agency</b>
<b>Key Players</b>

Outcome
Results
Disposition
<b>Work Flow</b>
Assigned To: Shawn Cowing
<b>Notes</b>
<b>Communications</b>
<b>Follow-up</b>
<b>Follow-Up Entries</b>
Due Date      Status      Assigned To      Subject



Dp/072320104041.69170

August 10, 2010

The Honorable Bill Nelson  
225 East Robinson Street, Suite 410  
Orlando, FL 32801

Dear Senator Nelson:

Thank you for your inquiry on behalf of your constituent, (b)(6). (b)(6) wants to know when Medicare will allow coverage for the drug, Provenge. Provenge is a new drug approved by the Food and Drug Administration to treat prostate cancer.

Medicare does not have a national policy for this treatment. In absence of a national policy, our Medicare contractor, CIGNA DME, has the authority to determine if this treatment is covered. The decision to allow coverage is based on local medical practice patterns, medical and scientific documentation.

If a claim is submitted for payment, CIGNA will determine if the drug is medically necessary. If the drug is determined to be medically necessary, Medicare will allow reimbursement. After a claim is filed, (b)(6) physician may be asked to submit additional supporting medical documentation.

I hope this information has been helpful. If you have further questions, please feel free to contact me by email at [Denita.Pryor@cms.hhs.gov](mailto:Denita.Pryor@cms.hhs.gov).

Sincerely,

Denita Pryor, RN, MPA  
Medicare Fee for Service Operations  
Division of Financial Management  
& Fee for Service Operations

# **CENTERS FOR MEDICARE AND MEDICAID SERVICES**

## **Correspondence Cover Sheet**

*Doc ID:* **072320104041**

*Date Due:*

*Corr. From:* **Bill Nelson**

*Task Date:*

*On Behalf Of:* (b)(6)

*Letter Date:* **7/2/2010**

*Folder Created:* **7/23/2010**

*Subject:* **Medicare Coverage For the Drug Provenoe.**

*Synopsis:* **Medicare Coverage For the Drug Provenoe.**

*Primary Issues:* **Medicare Coverage**

*Program Office  
Assigned:*

*Action Required:* **Direct Reply**

*Signature Level:* **RA Sig**

*Coordinator:* **Sheila Duvall**

*Data Entry By:* **Brenda McCray**

*Instructions:* None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

pe 4

07232010 4041



United States Senate  
WASHINGTON, DC 20510-0905

BILL NELSON  
FLORIDA

July 2, 2010

Mr. Al Chadwick  
Florida Congressional Liason  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Room 341H  
Washington, District of Columbia 20201

Dear Mr. Chadwick:

Please find enclosed correspondence I received from one of my constituents. It involves an important matter under the jurisdiction of your agency.

Your review and response to the issues raised would be greatly appreciated. Please send your correspondence directly to my office and reference (b)(6) for our records. I look forward to a response at your earliest convenience and thank you in advance for your assistance with this matter.

Sincerely,

Bill Nelson

BN/pg  
98480-2RV

Enclosure

RECEIVED

JUL 19 2010

OSORA, DIVISION  
OF CORRESPONDENCE  
MANAGEMENT

BILL NELSON  
FLORIDAUnited States Senate  
Washington, DC 20510-0905

## Consent For Release Of Information

The Privacy Act of 1974 requires that written consent be obtained from the constituent before information can be disclosed from a government agency's record. So that I can legally act on your behalf, please complete and sign the following statement and return it to me. *This form is available to the public free of charge.*

*Please note, if you are inquiring on behalf of someone, that person must sign the release.*

Today's Date 6/26/10 Social Security Number (b)(6)

☒ Mr. ☐ Mrs. ☐ Ms. ☐ Dr. (b)(6)  
First Middle Last

Mailing Address (b)(6)Home Phone (b)(6) Cell Phone (b)(6) Work Phone \_\_\_\_\_Date of Birth \_\_\_\_\_ E-mail Address (b)(6)

I hereby authorize Senator Nelson or his representative to make inquiries into my personal records and or files, and to obtain information about me pertaining to my request for assistance.

Signature (b)(6) For The Attention Of \_\_\_\_\_

## Please return form to:

## By Mail:

Office of Senator Bill Nelson  
225 East Robinson Street, Suite 410  
Orlando, Florida 32801

## By Fax:

Fax: (407) 872-7165

## Questions:

Telephone: (407) 872-7161  
Toll-Free in Florida Only:  
(888) 671-4091

FOR OFFICE USE ONLY

IT: ☐ Yes ☐ No IT # \_\_\_\_\_ (Caseworker Only) Cross Reference Name 3347461Referral: ☐ FTL ☐ FTM ☐ JAX ☐ MIA ☐ ORL ☐ TAL ☐ TPA ☐ WPB ☐ BN ☐ GN ☐ PM ☐ BS

Web Tracking # \_\_\_\_\_

PLEASE COMPLETE PAGE 2 OF THIS FORM

Please complete the sections that apply to your case.

## Military or Veteran's Issues

Military ID/VA ID/Other ID Number \_\_\_\_\_ Sponsor's ID / SSN \_\_\_\_\_

Rank / Unit \_\_\_\_\_ Duty Station \_\_\_\_\_

## Immigration Issues

Receipt Number \_\_\_\_\_ Alien Registration Number A - \_\_\_\_\_

Date of Birth \_\_\_\_\_ Place of Birth \_\_\_\_\_

Type of Application Filed \_\_\_\_\_

## Social Security Administration Issues

Type of file claimed? \_\_\_\_\_

Initial Claim	Date Filed _____	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied
Reconsideration	Date Filed _____	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied
ALJ Hearing	Date Filed _____	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied
Appeals Council	Date Filed _____	<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied

## Case Details

Please briefly explain your problem. (In writing, provide my office with a detailed account. Include any additional relevant correspondence that you have initiated or received concerning your problem.)

PROVENGE IS A VACCINE-TYPE TREATMENT FOR PROSTATE CANCER, APPROVED BY THE FDA ABOUT 6 WEEKS AGO. MEDICARE HAS NOT YET DETERMINED A BILLING CODE (WHAT % WILL BE COVERED). A LOT OF MEN ARE WAITING FOR THEIR ANSWER.

Please state how you would like Senator Nelson to help you.

PROVIDE CLARIFICATION AS TO WHEN MEDICARE WILL MAKE A DECISION.

Consent For Release Of Information/4.28.06

06/28/2010 10:56AM

IR#3 000042



## MEMORANDUM

**Subject:** Clinical Team Leader BLA review memo  
**From:** Peter Bross, Clinical Oncology Team Leader, OCTGT/CBER  
**To:** STN 125197 Sipuleucel-T/Provenge® BLA file  
**Through:** Celia Witten, Office Director OCTGT/CBER  
**Date:** May, 4, 2007

**Background:** PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF). This cellular product is then re-infused intravenously into the patients, and is thought to activate T cells to create an immune response against the patients' prostate cancer. This product was studied in the treatment of men with asymptomatic metastatic androgen independent prostate cancer. The efficacy claim of this BLA submission is based on an observed survival difference by log rank test favoring the Sipuleucel T treatment seen in one completed phase 3 study of 127 patients. The primary efficacy endpoint was time to objective disease progression, defined as the time from randomization to the first observation of disease progression. This study failed to achieve its primary objective of an increase in time to progression, however, a survival difference of 4.5 months favoring the treatment arm was noted following 36 months follow up. Review of the submitted data including review of study conduct, baseline disease characteristics, therapeutic interventions, and statistical sensitivity analyses supported the findings of a survival difference in this study, however there was no evidence of an effect upon time to progression, tumor shrinkage, or delay in onset of disease related pain. The conservative statistical conclusion in this situation would be to assume that in the setting of a failed primary objective, any positive statistical findings are attributable to chance, however the novel mechanism of action and the clinically meaningful 4.5 month survival finding led to CBER filing and reviewing the BLA. Docetaxel, given every 3 weeks, has a 2.4 month median survival advantage over mitoxantrone and is the only therapy which has demonstrated a conclusive survival advantage in hormone refractory prostate cancer.

**Study design:** Two similarly designed, randomized, double-blind, placebo-controlled phase 3 trials, D9901 and D9902A, and evidence from additional non randomized studies are submitted in support of efficacy and safety in this BLA. The stated primary objective of D9901 and D9902A was to test whether the treatment with Sipuleucel T could increase the time to disease progression by 3.7 months in patients with asymptomatic metastatic AIPC compared with treatment by APC placebo. For details regarding the manufacture of these products, please see the CMC review by Dr Wonnacott. Disease progression was defined by objective radiographical criteria, clinical progression and pain progression criteria. Prostate-Specific Antigen (PSA) was measured, but not used as a criterion for disease progression. The trials were not powered to detect a survival difference and the primary method for survival analysis was not pre-defined, but survival data were collected as part of the safety evaluation. Major eligibility criteria included histologically documented adenocarcinoma of the prostate, >25% of tumor cells staining positive for PAP, asymptomatic metastatic disease either in the soft tissue or bone, and evidence of tumor progression after hormonal therapy either by radiographic or PSA criteria. Subjects were stratified by study center and bisphosphonate use, centrally randomized in a 2:1 ratio of APC 8015 to APC-Placebo, and scheduled to receive three intravenous infusions of either Sipuleucel T or APC-placebo preceded by leukapheresis 2 to 3 days prior to the infusion date on weeks 0, 2 and 4. Patients were evaluated

at weeks 2, 4, 12, and clinical evaluations were combined with radiographic tumor staging at baseline, weeks 8, 16, 24, and 32, and every 12 weeks thereafter until disease progression. Staging scans were reviewed by an independent radiology facility to confirm objective disease progression. Subjects were monitored for delayed treatment-related adverse events (AEs) and for survival for 36 months or until death. For details regarding the study design, please see Dr Ke Liu's clinical BLA review.

### **Study Results:**

**D9901:** Study D9901 screened 186 patients to enroll 127 subjects. Eighty two were randomized to the Sipuleucel T arm and 45 to the APC-Placebo arm. Some imbalances were noted in the baseline demographic and prognostic characteristics including Gleason grading and disease location (bone, soft tissue or both) between the two arms. Sensitivity analyses did not suggest that these imbalances confounded the survival results. African-American and Hispanic subjects were underrepresented in this patient population.

### **Primary efficacy analysis of time to progression:**

**Progression events:** Out of 127 subjects randomized, 114 developed disease progression. Ninety-eight subjects were documented to have disease progression based on the imaging studies. Ten subjects had clinical events of disease progression and 7 subjects developed new onset of disease pain correlated with imaging studies. There were 12 censored events (13.4%) for Sipuleucel T arm and 1 (2.2%) censored event for APC-placebo. Although the curves appeared to separate at week 10, there was no overall statistical difference between the two curves; Estimated median time to disease progression was 11.0 weeks (ranging from 2.1 weeks to 57.4) for Sipuleucel T and 9.1 weeks (ranging from 3.9 weeks to 52.1) for placebo. In the June 2002 analysis after unblinding of the locked database, the difference in the time to disease progression (TTP) seen between the two arms in the ITT population did not reach statistical significance ( $p = 0.085$  by log-rank test). Subsequently, a complete clinical audit was performed to compare source documentation at the clinical study centers to the clinical database, resulting in the changes of progression dates in six subjects. Based upon this unblinded audit and revision of progression dates, the applicant re-analyzed the primary endpoint results and reported a p-value of 0.052 for the primary TTP endpoint difference. FDA's review of the revised progression dates from case report forms and sponsor's additional information showed that the changes in the progression dates from two subjects were primarily responsible for lowering p-value to 0.052. The FDA concluded that the sponsor's claimed p-value is derived from an analysis resulting from an unblinded study audit. This audit was not prespecified in the imaging charter or study protocol. The reduction in the p-value was primarily driven by the revision of progression dates or censoring from two subjects in a study with a small sample size. A review of case report forms revealed that the FDA disagreed with the sponsor with respect to 18 progression dates in the active arm and 7 progression dates in the placebo arm. In almost all of these cases the FDA judged that the progression event occurred earlier than the sponsor's estimate.

Since the BLA claim was based on a survival advantage in favor of Sipuleucel T treatment, not on the results of the primary endpoint, and there were so many uncertainties regarding the endpoint, FDA did not require a complete reassessment of the time to disease progression data. FDA considers a p-value of 0.085 by log-rank test to be the result from the primary analysis specified in the protocol, and the p-value of 0.052 by log-rank test to be derived from an exploratory analysis. Although the

BLA claim was based on survival, time to progression was important because it was the primary endpoint. The primary efficacy analysis of D9901 results showed that the study did not achieve its primary objective of prolonged time to objective disease progression or any other pre-specified efficacy endpoint. The failure of the study to achieve its primary objective makes it very difficult to determine if additional positive findings could be attributable to chance.

**Survival analysis:** A 3-year survival analysis of D9901 was performed as part of the follow up, although a primary method for survival analysis was not pre-specified in the protocol. The analysis showed that the median survival times in the subjects treated with Sipuleucel T and APC-Placebo were 25.9 and 21.4 months, respectively, a difference of 4.5 months. This difference reached statistical significance ( $p = 0.010$ ) by log rank test. The unadjusted HR was 1.71 [95% confidence interval (CI): 1.13, 2.58]. Therefore, study D9901 failed in achieving its primary objective, but a *post hoc* analysis demonstrated an apparent survival increase in sipuleucel T-treated subjects, the basis for the efficacy claim in this BLA submission.

**Possible confounders of Survival:** There were a number of baseline imbalances in disease characteristics noted between study arms. Specifically there were more patients with bone only disease in the treatment arm (42% vs. 24%) and more patients with soft tissue disease in the placebo arm (71% vs. 57%). Sensitivity analyses described in the statistical reviewer's AC briefing document adjusting for single baseline covariate effects did not demonstrate confounding, but several analyses adjusting for multiple covariates including: one that incorporated Localization of disease, Gleason Score ( $\leq 6$ , 7,  $\geq 8$ ), PSA ( $< 20$ , 20 -  $< 100$ ,  $\geq 100$ ) resulted in  $p$  values  $> 0.05$  (Table 1, statistical reviewer's AC briefing document).

**Concomitant medications:** Non-steroidal antiandrogen (e.g., flutamide, nilutamide or bicalutamide) use was not reported during the study however 2 patients received chemotherapy during the study. Nineteen (23%) of patients on the sipuleucel T group vs. 4 (9%) of patients on the placebo group received corticosteroids. Ketoconazole use was reported by the sponsor in only 4 patients on the active arm; however review of CRF's revealed 3 additional patients on the active arm and 4 additional patients on the placebo arm who were receiving ketoconazole.

**Subsequent chemotherapy:** Chemotherapy subsequent to progression could potentially have confounded chemo effects however more patients received chemotherapy on the placebo arm compared with the sipuleucel T arm. An analysis of survival data in D9901 comparing patients who received chemotherapy following progression versus other patients showed that those who received chemotherapy had better survivals, however after removal of patients who received docetaxel the  $p$  value of the survival results was still  $< 0.05$ , suggesting that subsequent therapy with docetaxel did not confound the survival results.

**D9902A:** The D9902A trial was originally designed to be a companion trial to D9901: eligibility, endpoints, treatment plan, monitoring, accrual goals and statistical analysis plans were initially the same in both studies. Study D9902A was terminated early because of the overall negative findings from D9901. Ninety-eight patients were enrolled out of a planned 120 patients: 65 were randomized to receive sipuleucel T and 33 to APC-Placebo. As a result of this early termination, D9902A was underpowered to reach its primary objective of improved time to progression. The estimated median time to disease progression in D9902A was 10.9 weeks in the sipuleucel T arm compared with 9.9

weeks in the APC- Placebo arm ( $p=0.72$ ); median survival times were 19.0 months and 15.7 months, respectively ( $p = 0.331$ , log rank test). Efficacy results for the two trials are summarized below. Please note that there is an overlap in the 95% CI of the median survivals in the two treatment arms of study 9901:

**Table 1: Combined Summary of Efficacy, D9901 and D9902A**

Study	Median TTP (weeks)		Median Survival (months) (95% CI)	
	Sipuleucel-T	APC Placebo	Sipuleucel-T	APC Placebo
D9901	11.0	9.1 ( $p = 0.085$ )	25.9 (20.0, 32.4)	21.4 (12.3, 25.8) ( $p = 0.01$ )
D9902A	10.9	9.9 ( $p = 0.72$ )	19.0	15.7 ( $p = 0.33$ )

**Conclusions regarding treatment effect on survival:** Most sensitivity analyses supported the finding of a survival difference between study treatment arms, and the findings of 9902A, although underpowered, at least were in the same direction. The 4.5 month estimated difference in median survivals between treatment arms greatly exceeds the known 2.5 month survival benefit reported in the docetaxel study in a similar population, and is therefore of unquestioned clinical benefit. However, questions remain regarding the persuasiveness of these survival findings. There were many baseline imbalances and although most sensitivity analyses supported the survival advantage, there were some sensitivity analyses that did not.

**Safety results:** The safety database was mainly derived from 147 patients who received sipuleucel T and 78 patients who received APC-placebo; a total of 225 subjects in trials D9901 and D9902A. Since these studies were similar in design and eligibility, safety results were pooled from the two studies. More than 88% of the subjects received the scheduled 3 infusions of either sipuleucel T or APC-Placebo. Overall, sipuleucel T treatment was relatively well tolerated. Most sipuleucel T treated patients developed Adverse Events (AEs), but most of these were grade 1 to 2 and resolved within 48 hours. Chills, fatigue pyrexia, and back pain were the most common AE's (> 25% of subjects who received sipuleucel T). These events generally occurred within 1 day of an infusion with sipuleucel T, were Grade 1 or 2, were managed on an outpatient basis, and had median durations of 24 to 48 hours. No deaths were reported to be related to the infusion of sipuleucel T and no deaths occurred within 30 days after the infusion. Twenty-four percent (23.8%) of sipuleucel T treated subjects developed Serious Adverse Events (SAEs) other than death, not different from 23% of APC-Placebo treated subjects. These SAEs included life-threatening adverse events, inpatient hospitalization or prolongation of existing hospitalization, or a persistent or significant disability/incapacity. However, 5.4% (8 out of 147) sipuleucel T treated subjects experienced CVA-related SAEs, compared to none in APC-Placebo treated subjects in D9901 and D9902A. The sponsor subsequently submitted summarized results for CVA events observed in all the phase 3 trials, including p-11 in androgen dependent prostate cancer and D9901, D9902A and ongoing study D9902B in the proposed indication. Eighteen out of 461 (3.9%) subjects treated with sipuleucel T developed CVA events compared to 6 out of 231 (2.6%) in the APC-Placebo treated subjects, an absolute increase of 1.3% (odds ratio = 1.5). Two percent (7/345) of subjects in the sipuleucel T arm died from CVA events compared to 1.2 % of subjects in the APC- Placebo arm (2/172), an absolute increase of 0.8%. In the proposed indication, approximately three times as many subjects experienced CVA's in the treatment group compared with controls. Although these differences did not reach statistical significance, the increased CVA frequency in sipuleucel T treated subjects is a potential safety concern.

**FDA Advisory Committee meeting:** On March 29, 2007, FDA held an advisory committee meeting of the Cellular, Tissue and Gene Therapies Advisory Committee, supplemented by members of the Oncology Drugs Advisory Committee and several prostate cancer specialists, to seek advice on the persuasiveness of submitted sipuleucel T efficacy and safety results. Several questions regarding product potency, variability and mechanism of action were also discussed. After extensive discussions regarding the significance of the CVA's reported in the 2 efficacy studies and additional studies with sipuleucel T, the committee voted unanimously (17-0) that safety had been established. The Committee recommended that post-marketing pharmacovigilance studies be performed to monitor the incidence of CVA's with attention to the African- American population and other minorities. The Committee was asked to vote whether or not submitted data established the efficacy of sipuleucel-T (APC-8015) in the intended population. The official record shows that the vote was 13 yes and 4 no in favor of evidence of efficacy. However, most of the advisory committee members expressed misgivings about the persuasiveness of the efficacy data. After two members initially voted against efficacy, the committee requested clarification, and the question was changed from 'establish efficacy' to 'substantial evidence.' The two members then changed their vote from no to yes and an additional member stated that he would have voted no to the original question but yes to the revised question. Only seven out of the 17 voting Committee members voiced an opinion that the data clearly demonstrated efficacy, and one member stated that he voted yes to "promote this type of research." The interpretation of the advisory committee vote on efficacy is therefore problematic, however, Committee members did agree that the confirmatory phase 3 study 9902B must be completed, and that the under representation of the African American population should be addressed.

**Conclusions:** It is difficult to quantify the persuasiveness of the survival findings, given the effects of multiplicity; therefore no p value could be applied to the survival difference. The submitted studies are very small compared with successful studies in hormone refractory prostate cancer. The statistical simulation performed using --b(4)---distributions suggests that the chance that the survival findings could be attributable to chance in such a small study population may actually be as high as 15%. As mentioned previously, there is an overlap in the 95% CI of the median survivals in the two treatment arms of study 9901. The lack of a treatment effect on tumor responses, PSA responses, delays in time to progression or delays in time to onset of pain despite the striking survival findings do not lead credence to attribution of the survival effects to the therapy. The reported study results are clearly clinically meaningful, however they do not meet the regulatory criteria for licensure as described in the guidance on Clinical Evidence of Effectiveness for Human Drug and Biological Products, which states: "In order for a single trial to support registration, the trial must be well conducted, and the results of the trial must be internally consistent, clinically meaningful, and statistically very persuasive." Statistically highly persuasive has been interpreted variously, as a one-sided  $p \leq 0.0025$ - $0.005$  but in no case has a  $p > .01$  been accepted. The submitted single study results are much less persuasive, particularly since they are based on a single small trial which failed its primary endpoint. The advisory committee recommendations regarding efficacy are difficult to interpret, however committee members did agree that additional information from ongoing study 9902B will provide definitive evidence of efficacy. If Sipuleucel-T were to be licensed now on the basis of a survival advantage, it may be logistically and ethically problematic to finish the study 9902B.

**Accelerated Approval:** 'Accelerated approval' has been considered to be an option, due to the increased regulatory authority to require post marketing studies and to withdraw marketing approval if the studies are not performed or do not support the efficacy of the product. Under 21CFR 601.40 Subpart E : Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses: These regulations describe approval of 'certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).' In the proposed indication, available therapy is considered to be docetaxel, which is approved, in combination with prednisone for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer. (see Guidance for Industry, Available therapy, <http://www.fda.gov/cber/gdlns/availther.htm>) In oncology drug regulation, 'meaningful therapeutic benefit' is defined by a population that is clearly refractory to or intolerant of available therapy, which in this case would be docetaxel. Since only 8% of patients had received prior chemotherapy, this population could not be considered refractory to available therapy, and since over 50% of patients received chemotherapy following progression, the population could not be considered intolerant of chemotherapy.

In addition, 21CFR 601.41 specifies that Accelerated Approval can be "based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity," and further states that "FDA may grant marketing approval for a biological product on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Since the BLA claim was based on a survival finding, approval based on a surrogate would appear to have no regulatory basis. Because CD54, a cell surface marker on dendritic cells, was a potency release criterion, all sipuleucel T subjects had CD54 expression and cell count data. Kaplan Meier survival was analyzed by 3 groups: patients who received placebo and those who received sipuleucel T whose CD54 upregulation ratio was below the median and those who received sipuleucel T whose CD54 upregulation were at or above the median. These results suggest that there may be a relationship between CD54 and some clinical effect, however since these results are again *post hoc* and could be considered responder analyses, reflecting patient prognostic factors rather than the effects of therapy, the further validation of this biomarker will await the analysis of the ongoing study 9902B. There is insufficient evidence provided in the BLA to support use of this biomarker in support of accelerated approval.

**Clinical Team Leader's Recommendations:** Due to uncertainties surrounding the treatment effect, I recommend waiting for additional efficacy data from 9902B: either the interim or final analysis, prior to licensure. The sponsor estimates that the interim analysis for 9902B, based on 180 events, will occur in August 2008 and the final analysis, based on 360 events, will occur around the end of 2010. An earlier interim analysis would not be recommended, since it could compromise the power of the study to detect a survival difference. Accelerated Approval is not an option, as noted above and given the survival claim.

**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, May 19, 2010 2:53 PM  
**To:** Hambrick, Edith L. (CMS/CMM)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

Sent from my Blackberry

---

**From:** Hambrick, Edith L. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Warren, John F. (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Simon, Kenneth B. (CMS/CMM)  
**Sent:** Wed May 19 14:36:56 2010  
**Subject:** Provenge

Hi,

(b)(5) - Predecisional

(b)(5) - Predecisional

What would you think about that? Thanks.

Edith

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, May 05, 2010 9:05 AM  
**To:** DEUTSCH, PAUL G  
**Cc:** COSTANTINO, GEORGE; Cunningham, Carolyn; Warren, John F. (CMS/CMM); Bassano, Amy (CMS/CMM); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Coverage for Provenge

P, G and C,

Have CC's a few CMSers on this reply.

Provenge made a presentation here months ago and we are familiar with their technology. It may be administered as a vaccine, but it is not a preventive vaccination. I believe it is coverable, but will defer to CMM for a benefit category discussion.

Louis

**From:** DEUTSCH, PAUL G [<mailto:Paul.Deutsch@Empireblue.com>]  
**Sent:** Tuesday, May 04, 2010 6:06 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** COSTANTINO, GEORGE; Cunningham, Carolyn  
**Subject:** Coverage for Provenge  
**Importance:** High

Louis,



We have been discussing the new anti-prostate-cancer therapy, Provenge.

The product is described as an autologous vaccine, and is manufactured by harvesting patient antigen presenting cells, then incubating them with prostatic acid phosphatase and GM-CSF and then returning the product to the patient in an infusion. The purpose is to stimulate the host immune system into recognizing prostate cancer cells as foreign. This appears to be some form of immunotherapy.

Is there Medicare coverage for this? Would this be considered under the drug/biologicals benefit (?? vaccine)? Since this requires the incorporation of cells retrieved from patients, is this a biological or immunotherapy?

Thank you for looking at this.

Paul

Paul Deutsch, MD  
Medical Director, MAC J-13  
National Government Services, Inc  
PO Box 7108  
Indianapolis, IN 46206-7108  
tel: 914-801-3567  
fax: 914-801-3600

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## Jacques, Louis B. (CMS/OCSQ)

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, May 28, 2010 8:34 AM  
**To:** Bernice Hecker  
**Subject:** Provenge

I'm here all day to chat

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
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Centers for Medicare & Medicaid Services  
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(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

## **Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, June 01, 2010 2:59 PM  
**To:** Warren, John F. (CMS/CMM)  
**Subject:** Provenge

Any thoughts on the pricing of this bundled service?

## **From Oncology Stat**

# **Provenge Poised for Broad Insurance Coverage, Despite Grumbles on Price**

**The Pink Sheet Daily. 2010 May 24, E Hayes**

After a strong endorsement in the National Comprehensive Cancer Network guidelines, Dendreon's first-of-its-kind prostate cancer vaccine Provenge appears well positioned for broad insurance coverage and take-up with physicians.

Commercial carriers that had been left gasping at the autologous cellular immunotherapy's \$93,000 annual price tag may now feel obliged to provide coverage after a May 12 update to the NCCN practice guidelines.

According to the update, Provenge (sipuleucel-T) is recommended as a salvage therapy for patients with castrate recurrent prostate cancer. Furthermore, Provenge received the NCCN's highest endorsement - a "Category 1" rating, which signifies uniform agreement of experts based on a high level of evidence.

The treatment had only just been approved April 29 for treating asymptomatic or minimally symptomatic prostate cancer that is metastatic and resistant to standard hormone treatment.

The recommendation applies to patients who have an ECOG performance status of 0 to 1, which means patients are either fully active and able to carry on all pre-disease performance without restriction or restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature.

Provenge is not recommended for patients with visceral disease and a life expectancy less than six months, the guidelines advise.

A "Category 1" rating is highly significant, said Lee Blansett, senior vice president-oncology market access at the global consulting company Kantar Health. On top of the approval, the rating will also make it very difficult for commercial carriers to refuse coverage of the drug, Blansett added. Commercial carriers that have endorsed the NCCN compendia, such as UnitedHealthcare, should automatically pay, he said.

Most Provenge use in the U.S. will likely end up being covered by Medicare, since about 75 percent of the target population for Provenge receives government-sponsored health care. Dendreon had met with CMS officials as planned during the first week of May to discuss reimbursement and confirmed that it will have a specific J-code assigned in January 2012, consistent with other medications approved by the FDA after March 31, 2010. Until then, it will use a temporary J-code.

Having a temporary code has the potential to cause delays to reimbursement, but in the company's investors' call on April 29, execs said they would provide physicians with 120-day payment terms for the first several months of launch.

Dendreon has indicated its capacity will be restrained in the first year, so wide insurance coverage is unlikely to affect revenues right away, but the NCCN stamp of approval bodes very well for the future.

"Given that Provenge was approved on April 29, the speed with which these guidelines were updated is notable and attests to the product's acceptance within the medical community," wrote J.P. Morgan's Cory Kasimov in a May 20 note.

### **Payers Question Pricing Strategy**

Dendreon's pricing of \$93,000 per patient per year, unveiled soon after approval, had "dwarfed expectations," analysts said at the time (1 'The Pink Sheet,' May 3, 2010). Dendreon explained that the price was derived based on the number of months of the survival benefit offered with the treatment, a concept that was unfamiliar to payers interviewed (prior to the NCCN development).

"That statement doesn't feel right. It's the first time I have heard about putting a price on one month of life," said Eric Cannon, director of pharmacy at SelectHealth.

The \$93,000 price is on the high end of oncology treatments, but payers will feel pressure to cover it, just as they do for other expensive therapies, Cannon added.

Following the NCCN endorsement, commercial carriers can "try to negotiate with Dendreon on price, but I don't know how much success they will have," Blansett said.

### **Getting To The Bottom Of Pricing**

Provenge is a personalized therapeutic cancer vaccine, as opposed to an off-the-shelf product that could be given to any patient. Each dose is produced specifically for a particular patient using the patient's own immune cells. These cells are altered via leukapheresis to boost their ability to fight prostate cancer. Then the activated immune cells are delivered back intravenously to the patient. Treatment will be administered in three infusions over the course of one month.

The process of tailoring the product to the individual patient and the unique challenges of distribution were expected to contribute to a hefty price.

But Dendreon's price calculations also were based in their valuation of the product's benefits, which departs from the standard Quality Adjusted Life Year metric commonly used in cost effectiveness calculations; the UK's NICE, for instance, considers £50,000 (\$76,700) per QALY to be acceptable for end-of-life treatments that extend life.

Data supporting the Provenge NDA suggest that patients treated with Provenge live on average four months longer than without it. Dendreon divides the total cost of \$93,000 by extra life made possible with treatment, or 4.1 to 4.5 months.

"When you consider these benefits, the price for a full course of treatment equates to a cost per month of survival of just under \$23,000, which compares very favorably to many other widely used oncology products in similar advanced disease settings," COO Hans Bishop maintained during an investor's call.

Dendreon has pledged to offer a patient assistance program to help patients make co-payments. In an interview, Bishop declined to give any figures for the program but asserted that no patient will be turned away from treatment due to inability to pay.

### **Exec Draws Parallels With Other Cancer Drugs**

During an interview, Bishop also elaborated on the comparative figures for widely used cancer treatments that Dendreon considered in its pricing process.

The standard of care in late-stage prostate cancer is Sanofi's chemotherapy treatment Taxotere. Direct per patient costs for Taxotere amount to only \$18,000 per patient, but when indirect costs are included, such as supportive care, the total is actually about \$60,000, according to Dendreon. Yet the survival benefit is 2.4 extra months lived, so by Dendreon's calculations, the cost for each month of life equates to about \$25,000.

Provenge is atypical in that there are nominal premedication and supportive care costs, meaning the overall cost is essentially its list price. On top of Provenge, patients might need only acetaminophen and an antihistamine for infusion-related reactions like chills or fever, the company points out.

Whereas Provenge has a low rate of serious side effects, Taxotere is more toxic and patients sometimes require hospitalization, an additional raft of costs.

When extra costs for adjuvant therapies and supportive care are included, Provenge's price is actually lower than oncology therapies, Dendreon argues. In front-line breast cancer, the total cost for Genentech's Avastin (bevacimumab) is about \$120,000. Given with chemotherapy, that drug had a 1.7 month overall survival benefit compared to chemotherapy alone.

"You can do the math in terms of cost versus benefit." Bishop said.

In first-line metastatic colon cancer, total costs for Avastin can amount to about \$110,000, Dendreon noted. Data suggest that given in combination with chemotherapy, the drug offers about five months overall survival benefit over chemotherapy alone. That equates to a cost of \$22,000 per month.

Genentech disputed the figures reached by Dendreon, noting that it caps its wholesale costs for Avastin at \$56,000 per year for FDA-approved uses in insured patients with less than \$100,000 a year in income. Genentech also pointed out that the breast cancer indication was supported by data showing a doubling in progression-free survival, rather than on overall survival.

Dendreon also highlighted Celgene's blockbuster Revlimid (lenalidomide) in second-line multiple myeloma, which it said costs \$120,000 yearly when associated treatments and services are included. Given along with dexamethasone, the drug was shown to offer a time to progression benefit of 6.5 months. That equates to a cost of about \$18,000 per month of life. Direct costs for Revlimid for 12 months of therapy in the U.S. amount to \$78,000, according to Celgene.

### **How Much Will The Market Bear?**

Basing price on the amount of time lived has negative implications for society, in the view of Helen Sherman, Chief Pharmacy Officer at the Regence Group, a tech assessment specialist that provides services to Blue Cross Blue Shield carriers in the Northwest of the U.S.

"We would hope that cost would not be about how much the market will bear, because that will break the system," said Sherman.

She noted that there are other therapeutics with higher prices, including Novartis' Ilaris (canakinumab) and Regeneron's Arcalyst (rilonacept), both approved for Cryopyrin Associated Periodic Syndrome, at \$120,000 and \$300,000 a year respectively. But CAPS is very rare, afflicting about 300 in the U.S., which minimizes the cost to the system, she said. In contrast, some 100,000 men in the U.S. have late-stage prostate cancer and about 30,000 die from it every year. "The greatest strain will be on Medicare," Sherman said.

Regence said it has not received requests for coverage of Provenge as yet. To inform its coverage decisions, the payer plans to perform its own analysis of the data and advisory committee discussion supporting approval. Regence has also requested additional data from Dendreon beyond what has been made publicly available so far. For example, Regence wants more information about how blinding was done, drop-out rates, and how patients who discontinued therapy fared.

"We will press the manufacturer to give us the data," Sherman said.

Such reviews are routine for Regence. The goal is to determine the actual clinical benefit in practice, as opposed to accepting a treatment based on data showing a statistically significant effect.

In the past, Regence's reviews have often been at odds with FDA approval decisions, Sherman said. For example, FDA approved GlaxoSmithKline's Tykerb (lapatinib) for advanced breast cancer. But while Tykerb showed improvements of progression-free survival, its impact on overall survival and/or quality of life are unknown and the drug has not been compared to other treatment options for advanced breast cancer, Sherman observed.

## Price Sounds Right To Other Sponsors

In contrast with the surprised reaction from payers and analysts, biotechs working in cancer immunotherapy said Dendreon's high price was in line with their expectations, due to the complexity of the product's manufacturing process.

"It's very labor intensive," commented Eric von Hofe, president of Antigen Express, a subsidiary of Genex. Antigen Express has developed synthetic therapeutic vaccines for HER-2/neu expressing tumors. An immunotherapeutic peptide is ready for Phase III, pending a partnership deal.

But Antigen Express' product, as well as other non-autologous active immunotherapies, can be made at a fraction of the cost of Provenge, he said. "It's much more of an off-the-shelf drug," von Hofe noted, which makes it "a much less expensive therapy."

Still, while successive entries in the space may have different price points based on their production realities, Dendreon's setting of a high price for Provenge - and the potential acceptance by payers - could have downstream effects for future drugs.

Bernice Hecker MD, MHA, FACC  
Medicare, Contractor Medical Director  
AK, ID, OR, MN, WA & Jur. 3 (AZ, MT, ND, SD, UT, WY)

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Sunday, June 06, 2010 9:14 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge

(b)(5) - Predecisional



**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 8:53 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** Provenge

Thinking we may need to open an NCD on this one. Let's chat later today. We met with them quite awhile ago, I don't remember who was the team from CAG.

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Mailstop C1-09-06  
7500 Security Blvd  
Baltimore MD 21244  
(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 8:57 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** Provenge label  
**Attachments:** Provenge prescribing-information.pdf

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
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7500 Security Blvd  
Baltimore MD 21244  
(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)



**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 10:36 AM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge

BCBS is fine, since we'll need it quickly.

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Monday, June 07, 2010 10:36 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge

BCBSA already sent me an email volunteering to do this "if you asked for it". I think that means they are already doing it internally.

Do you want BCBSA to do it or one of the TA EPCs?

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 10:34 AM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Provenge

Elise,

Close hold, but might want a TA on this new prostate immunotherapy.

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 12:13 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge

Joan,

We've been following Provenge for some time. There is no NCD or LCD at this time. There are outstanding benefit category issues that would need to be addressed before coverage policy could realistically be implemented. Provenge is several different types of services strung together.

Louis

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
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Mailstop C1-09-06  
7500 Security Blvd  
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(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

Let me know when it is OK to talk to them about it.

---

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Elise,

Close hold, but might want a TA on this new prostate immunotherapy.

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 6:54 PM  
**To:** Bassano, Amy (CMS/CMM)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)  
**Subject:** Re: F/U New Tech call: Provenge

Amy

(b)(5) - Predecisional



Louis  
Sent from my Blackberry

---

**From:** Bassano, Amy (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)  
**Sent:** Mon Jun 07 17:48:24 2010  
**Subject:** FW: F/U New Tech call: Provenge

Louis,

Can you send Dr. Hecker a message similar to what you just sent Dr. Lurvey? She seems to misunderstand how coverage works.

Thanks.  
Amy

---

**From:** Medicare Contractor Medical Directors [mailto:MEDICARE-CMDS@LIST.NIH.GOV] **On Behalf Of** Bernice Hecker  
**Sent:** Friday, June 04, 2010 12:42 PM  
**To:** MEDICARE-CMDS@LIST.NIH.GOV  
**Subject:** F/U New Tech call: Provenge

As requested, I had a discussion with CAG regarding potential Provenge coverage with evidence development. Bottom-line: how can anyone cover anything when we are not yet sure what it is? See below.

The CM (Center for Medicare, formerly CMM – the Center for Medicare Management) is the CMS authority on benefit category determination, i.e. , whether or not an item or service falls within the Medicare insurance benefit, and if so, which one(s). The Provenge autologous immunotherapy program comprises multiple discrete elements including the collection of the patient's blood, the processing of the patient's cells , and the subsequent infusion of the processed cells back into the patient. At the current time, CM is trying to determine the preferred benefit category allocation for the elements of Provenge. It is entirely unclear whether the elements would be treated as a single bundled service or not, or how they should be coded and priced yet. This being the case, it seems to me that we inform those seeking payment that neither we nor CAG has authority to pay at this time and won't until CM decides what it is we are paying. Interested parties might be directed to CMS.

Bernice Hecker MD, MHA, FACC  
Medicare, Contractor Medical Director  
AK, ID, OR, MN, WA & Jur. 3 (AZ, MT, ND, SD, UT, WY)

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 5:51 PM  
**To:** Bassano, Amy (CMS/CMM)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)  
**Subject:** Re: F/U New Tech call: Provenge

Just called her  
Sent from my Blackberry

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**From:** Bassano, Amy (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)  
**Sent:** Mon Jun 07 17:48:24 2010  
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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 5:21 PM  
**To:** Warren, John F. (CMS/CMM)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

Sent from my Blackberry

---

**From:** Warren, John F. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Mon Jun 07 17:15:01 2010  
**Subject:** Re: Provenge

(b)(5) - Predecisional

John Warren, -----  
Sent using BlackBerry

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**To:** Warren, John F. (CMS/CMM)  
**Sent:** Mon Jun 07 17:12:26 2010  
**Subject:** RE: Provenge

(b)(5) - Predecisional

---

**From:** Warren, John F. (CMS/CMM)  
**Sent:** Monday, June 07, 2010 5:06 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

John Warren, -----  
Sent using BlackBerry

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**To:** arthur.lurvey@palmettogba.com <arthur.lurvey@palmettogba.com>  
**Cc:** Warren, John F. (CMS/CMM); Syrek Jensen, Tamara S. (CMS/OCSQ); Bassano, Amy (CMS/CMM)  
**Sent:** Mon Jun 07 17:03:34 2010  
**Subject:** Provenge

Art,

Following up on the case in California. Absent CMS instructions to the contrary, local contractors have discretion to cover or noncover the various components of the Provenge autologous immunotherapy program.

Louis



Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
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Baltimore MD 21244  
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[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

## Jacques, Louis B. (CMS/OCSQ)

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**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)  
**Sent:** Mon Jun 07 17:48:24 2010  
**Subject:** FW: F/U New Tech call: Provenge

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**From:** Medicare Contractor Medical Directors [<mailto:MEDICARE-CMDS@LIST.NIH.GOV>] **On Behalf Of** Bernice Hecker  
**Sent:** Friday, June 04, 2010 12:42 PM  
**To:** [MEDICARE-CMDS@LIST.NIH.GOV](mailto:MEDICARE-CMDS@LIST.NIH.GOV)  
**Subject:** F/U New Tech call: Provenge

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Medicare, Contractor Medical Director  
AK, ID, OR, MN, WA & Jur. 3 (AZ, MT, ND, SD, UT, WY)

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**Subject:** Re: F/U New Tech call: Provenge

Amy

(b)(5) - Predecisional



Louis  
Sent from my Blackberry

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, June 08, 2010 9:19 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge option

(b)(5) - Predecisional



-----Original Message-----

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Tuesday, June 08, 2010 8:48 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Provenge option

Can we talk with the FDA - get some of the data on Provenge - would that help with a CE decision?

Tamara Syrek Jensen  
Deputy Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality, CMS 7500 Security Blvd.  
Baltimore, MD 21244  
(410) 786-3529  
[tamara.syrekjensen@cms.hhs.gov](mailto:tamara.syrekjensen@cms.hhs.gov)

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 8:59 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge option

(b)(5) - Predecisional



**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 14, 2010 8:39 AM  
**To:** 'arthur.lurvet@palmettogba.com'  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge

Art

Let's chat before you all publish the article Sent from my Blackberry

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 14, 2010 9:47 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge

Re: my email to Art Lurvey.

Let's chat about the effect of LCDs on CED, i.e. should the MACs make case by case determinations instead of publishing LCDs?

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
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Centers for Medicare & Medicaid Services  
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**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 14, 2010 4:40 PM  
**To:** Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Re: Provenge

Long time ago  
Sent from my Blackberry

---

**From:** Ashby, Lori M. (CMS/OCSQ)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Anderson, Kelly (CMS/OCSQ)  
**Sent:** Mon Jun 14 16:19:22 2010  
**Subject:** Provenge

Have we met with Dendreon regarding Provenge? Kelly Anderson was asked this question by a reporter.

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, June 23, 2010 3:34 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Fw: Provenge  
**Attachments:** JSM Draft - Provenge is Part B drug (06232010).doc

Fyi  
Sent from my Blackberry

---

**From:** Warren, John F. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ); Hambrick, Edith L. (CMS/CMM); SALIVE, Marcel (CMS/OCSQ)  
**Sent:** Wed Jun 23 15:26:02 2010  
**Subject:** Provenge

Can you please review the attached and let me know your thoughts on this? OGC is reviewing this as well, so it is still subject to their concurrence. Thanks.

John Warren | Director, Division of Ambulatory Services | Hospital and Ambulatory Policy Group | Center for Medicare Management | Centers for Medicare & Medicaid Services | 7500 Security Blvd, Baltimore, MD 21244 | Mail Stop C4-01-26 | voice: (410) 786-3633 | fax: (410) 786-4490 | e-mail: [john.warren@cms.hhs.gov](mailto:john.warren@cms.hhs.gov)

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 8:25 AM  
**To:** Warren, John F. (CMS/CMM)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

Sent from my Blackberry

---

**From:** Warren, John F. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Thu Jun 24 08:19:06 2010  
**Subject:** RE: Provenge

(b)(5) - Predecisional

John Warren| Director, Division of Ambulatory Services | Hospital and Ambulatory Policy Group | Center for Medicare Management | Centers for Medicare & Medicaid Services| 7500 Security Blvd, Baltimore, MD 21244 | Mail Stop C4-01-26 | voice: (410) 786-3633 | fax: (410) 786-4490 | e-mail: [john.warren@cms.hhs.gov](mailto:john.warren@cms.hhs.gov)

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 8:17 AM  
**To:** Warren, John F. (CMS/CMM)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

Sent from my Blackberry

---

**From:** Warren, John F. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thu Jun 24 07:44:49 2010  
**Subject:** RE: Provenge

(b)(5) - Predecisional

John Warren| Director, Division of Ambulatory Services | Hospital and Ambulatory Policy Group | Center for Medicare Management | Centers for Medicare & Medicaid Services| 7500 Security Blvd, Baltimore, MD 21244 | Mail Stop C4-01-26 | voice: (410) 786-3633 | fax: (410) 786-4490 | e-mail: [john.warren@cms.hhs.gov](mailto:john.warren@cms.hhs.gov)

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 6:57 AM  
**To:** Warren, John F. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); SALIVE, Marcel (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Provenge

(b)(5) - Predecisional

Sent from my Blackberry

---

**From:** Warren, John F. (CMS/CMM)  
**To:** Jacques, Louis B. (CMS/OCSQ); Hambrick, Edith L. (CMS/CMM); SALIVE, Marcel (CMS/OCSQ)

**Sent:** Wed Jun 23 15:26:02 2010

**Subject:** Provenge

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John Warren | Director, Division of Ambulatory Services | Hospital and Ambulatory Policy Group | Center for Medicare Management | Centers for Medicare & Medicaid Services | 7500 Security Blvd, Baltimore, MD 21244 | Mail Stop C4-01-26 | voice: (410) 786-3633 | fax: (410) 786-4490 | e-mail: [john.warren@cms.hhs.gov](mailto:john.warren@cms.hhs.gov)

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 9:04 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Provenge

OK. Would like to give FDA a heads up and open the NCD this week before the CMDs start publishing LCDs etc.

-----Original Message-----

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 9:02 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Provenge

Lori is not here today. She is contacting them.

Tamara Syrek Jensen  
Deputy Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality, CMS 7500 Security Blvd.  
Baltimore, MD 21244  
(410) 786-3529  
[tamara.syrekjensen@cms.hhs.gov](mailto:tamara.syrekjensen@cms.hhs.gov)

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 8:23 AM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Provenge

Let's try to talk w FDA today  
Sent from my Blackberry

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 28, 2010 5:22 PM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062810 lbj lf (3).doc  
**Attachments:** Provenge DRAFT track sheet 062810 lbj lf (3).doc

We'll use this version later this week.

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 28, 2010 4:20 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062810 lbj lf.doc  
**Attachments:** Provenge DRAFT track sheet 062810 lbj lf.doc

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, June 29, 2010 11:22 AM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062910 lbj lf (4).doc

Looks fine, Lori pls send to Celia

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Tuesday, June 29, 2010 11:21 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062910 lbj lf (4).doc

REVISED as per discussion this am



**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, June 29, 2010 2:58 PM  
**To:** Dolina, Elaine L. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Thursday after 4 for Provenge

Elaine,

We'll hold til Thurs pending FDA

Louis

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Mailstop C1-09-06  
7500 Security Blvd  
Baltimore MD 21244  
(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

**Cc:** Beckerman, Peter  
**Subject:** coverage tracking sheet

Hi Celia,

Thank you for talking with us this morning. We greatly appreciate it and are happy to have future conversations with you and your colleagues. The attendees from the Coverage and Analysis Group (CAG) were:

Louis Jacques, MD, Director, CAG  
Tamara Syrek-Jensen, JD, Deputy Director, CAG  
James Rollins, MD, PhD, Director, Division of Items and Devices, CAG  
Lori Paserchia, MD, Medical Officer, CAG (and Coverage Liaison for the FDA-CMS Collaboration Initiative)

As noted by you, an agenda and list of CAG attendees will be sent to you prior to future conversations.

As promised, attached please find the draft tracking sheet for this National Coverage Determination (NCD). Please let us know if you have any comments/concerns. We will post it for public consumption by COB this Thursday.

Regards,

Lori

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, June 30, 2010 12:32 PM  
**To:** Dolina, Elaine L. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ)  
**Subject:** Provenge tracking sheet  
**Attachments:** Provenge DRAFT track sheet 062910 lbj lf (4).doc

Elaine,

We expect to hear from FDA this afternoon and would like to post after 4 today if possible, but tomorrow is OK if necessary. This is the current version, the requestor is CMS internally generated. The Benefit category is intentionally left blank.

Louis

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 8:44 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Fw: Provenge Question - Investment Community  
**Attachments:** image001.gif

We are calling peter at 9  
Sent from my Blackberry

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thu Jul 01 08:34:45 2010  
**Subject:** FW: Provenge Question - Investment Community

Here's more

---

**From:** Hellman, Peter [<mailto:PHellman@rwbaird.com>]  
**Sent:** Wednesday, June 30, 2010 6:10 PM  
**To:** McLeod, Donald E. (CMS/OEA); Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Provenge Question - Investment Community

Don-

I understand that you are out until July 7<sup>th</sup> but I am trying to reconcile comments you made to the media with today's news of an initiation of a NCD process on Provenge. Is there anyone I can talk with in your absence?

I am just trying to understand the need/rationale for this process.

Your commentary as quoted by Bloomberg.

**Provenge will almost certainly be covered by the government's Medicare insurance plan for the elderly and disabled, said Don McLeod, a Center for Medicare and Medicaid Services spokesman. The agency doesn't typically make formal determinations on cancer drugs. Instead, it pays claims through the local contractors who administer payments.**

**'99.9% Certain'**

**"It is 99.9 percent certain that we will pay for it if somebody files a claim," McLeod said in an e-mail. The agency has yet to determine how much it will reimburse for the drug, McLeod said. Dendreon said yesterday that it plans to meet with the agency next week.**

Regards, Peter

Peter D. Hellman, CFA  
Equity Research/Biotech  
Robert W. Baird & Co.  
414-298-2337

Baird – Nationally recognized as a great place to work six consecutive years 2004-2009

\*\*\*\*\*

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\*\*\*\*\*

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 12:07 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: DNDN MEDCAC

Can u call me now and we can strategizw  
Sent from my Blackberry

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thu Jul 01 12:03:28 2010  
**Subject:** FW: DNDN MEDCAC

You available after 130?

---

**From:** [SHeavey@thomsonreuters.com](mailto:SHeavey@thomsonreuters.com) [<mailto:SHeavey@thomsonreuters.com>]  
**Sent:** Thursday, July 01, 2010 11:59 AM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: DNDN MEDCAC

On way to meeting, can do after 1330  
\*\*\*\*\*

Susan Heavey  
Health Reporter  
Reuters  
202-210-8660 (cell)  
202-354-5848 (office)

---

**From:** Ashkenaz, Peter (CMS/OEABS) <[Peter.Ashkenaz@CMS.hhs.gov](mailto:Peter.Ashkenaz@CMS.hhs.gov)>  
**To:** Heavey, Susan E. (M Edit Ops)  
**Cc:** Richwine, Lisa A. (M Edit Ops)  
**Sent:** Thu Jul 01 11:52:33 2010  
**Subject:** RE: DNDN MEDCAC

Around 1245, ok?

---

**From:** [SHeavey@thomsonreuters.com](mailto:SHeavey@thomsonreuters.com) [<mailto:SHeavey@thomsonreuters.com>]  
**Sent:** Thursday, July 01, 2010 11:34 AM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Cc:** [Lisa.Richwine@thomsonreuters.com](mailto:Lisa.Richwine@thomsonreuters.com)  
**Subject:** DNDN MEDCAC

Peter:

Would someone from CMS be available to talk to me today about its decision to review prostate cancer vaccines?

Many thanks,  
SH

---

**Susan Heavey**  
Health Reporter, Reuters News

Thomson Reuters

Phone: 202-354-5848

Mobile: 202-210-8660

[sheavey@thomsonreuters.com](mailto:sheavey@thomsonreuters.com)  
[www.twitter.com/ReutersDCHealth](http://www.twitter.com/ReutersDCHealth)

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Any views expressed in this message are those of the individual sender, except where the sender specifically states them to be the views of Thomson Reuters.

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 11:20 AM  
**To:** Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Medicare coverage determination

Time by law is 9-12 mos.  
Sent from my Blackberry

----- Original Message -----

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thu Jul 01 11:16:07 2010  
**Subject:** RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----

**From:** Herper, Matthew [mailto:MHerper@forbes.com]  
**Sent:** Thursday, July 01, 2010 11:15 AM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: Medicare coverage determination

Let me know if there are any issues here:

Forbes spoke with Louis Jacques, the director of the Coverage and Analysis Group at the Medicare center, to learn more about the process, called a National Coverage Assessment, and the decision that will result after a period of public comment and the accrual of scientific data, called a National Coverage Determination.

Medicare, though seen as a big government program, is actually structured so that local contractors make many coverage decisions. This system was put in place as part of the compromise that created the agency in 1965. When there is no National Coverage Determination, the local contractors are the ones who decide whether or not a new treatment will be paid for.

Coverage assessments are rare, because by law they must take a year. Jacques says that currently there is only manpower to do 20 to 25 annually. The topics addressed by NCAs tend to be broad. Some recent examples include an assessment of how to pay for genetic tests that were being paired with drugs, who should get anemia drugs made by Amgen and Johnson & Johnson, and whether to pay for costs incurred by hospitals as a result of medical errors.

Individual treatments don't usually get their own NCAs, but Provenge turned out to be a special case not so much because of its newness but because it is raising questions and generating debate.

"We've been getting questions from people," says Jacques. "'Well, what's up with Provenge? Is it a drug? Is it a biologic? Is it something else? Does it really work? It has been interesting to look at the evidence around it."

The extent of conversation, Jacques says, made it seem to make sense to create a national standard for how Provenge is covered. This is rare for an individual product, but it made sense in this case because many of the men who will get Provenge will be Medicare patients.



"I don't know that anybody should be surprised that Medicare would take an interest in a technology that would have an impact on the Medicare population," says Jacques.

On 7/1/10 11:13 AM, "Ashkenaz, Peter (CMS/OEABS)" <Peter.Ashkenaz@CMS.hhs.gov> wrote:

I understand. sorry

-----Original Message-----

From: Herper, Matthew [mailto:MHerper@forbes.com]  
Sent: Thursday, July 01, 2010 11:13 AM  
To: Ashkenaz, Peter (CMS/OEABS)  
Subject: Re: Medicare coverage determination

I'll just email you the relevant paraphrases and quotes, then. I was hoping to read you some of the surrounding context as well, but would rather not email it verbatim.

On 7/1/10 11:10 AM, "Ashkenaz, Peter (CMS/OEABS)" <Peter.Ashkenaz@CMS.hhs.gov> wrote:

Stuck on a conference call for at least an hour

-----Original Message-----

From: Herper, Matthew [mailto:MHerper@forbes.com]  
Sent: Thursday, July 01, 2010 11:09 AM  
To: Ashkenaz, Peter (CMS/OEABS)  
Subject: Re: Medicare coverage determination

Could you give me a quick call? 212-367-4879

On 7/1/10 9:07 AM, "Ashkenaz, Peter (CMS/OEABS)" <Peter.Ashkenaz@CMS.hhs.gov> wrote:

Matthew, would you be available in the next 15 to 30 minutes?

----

Fact & Comment: Our new expanded, multimedia presentation of the column by Steve Forbes:  
<http://cptl.st/FactAndComment>

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 12:04 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: Medicare coverage determination

Call u in 5  
Sent from my Blackberry

----- Original Message -----

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thu Jul 01 11:55:23 2010  
**Subject:** RE: Medicare coverage determination

-----Original Message-----

**From:** Ashkenaz, Peter (CMS/OEABS)  
**Sent:** Thursday, July 01, 2010 11:54 AM  
**To:** Herper, Matthew  
**Subject:** RE: Medicare coverage determination

How about: The extent of conversation, Jacques says, made it seem to make sense to create a national standard for how A TREATMENT LIKE Provenge is covered.

Then I would be able to sleep tonight

-----Original Message-----

**From:** Herper, Matthew [mailto:MHerper@forbes.com]  
**Sent:** Thursday, July 01, 2010 11:52 AM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: Medicare coverage determination

Is this better?

The extent of conversation, Jacques says, made it seem to make sense to create a national standard for how Provenge is covered. "I don't know that anybody should be surprised that Medicare would take an interest in a technology that would have an impact on the Medicare population," says Jacques.

On 7/1/10 11:49 AM, "Ashkenaz, Peter (CMS/OEABS)" <Peter.Ashkenaz@CMS.hhs.gov> wrote:

Matt, we have some major concerns with the last graf. I don't remember him saying " This is rare for an individual product, but it made sense in this case because many of the men who will get Provenge will be Medicare patients" and from our perspective even using this as a paraphrase is troubling. We can't make it appear that we are only looking at this treatment because he said there are others being developed - which you did capture in the last quote.

Thanks.

-----Original Message-----

**From:** Herper, Matthew [mailto:MHerper@forbes.com]  
**Sent:** Thursday, July 01, 2010 11:15 AM

To: Ashkenaz, Peter (CMS/OEABS)  
Subject: Re: Medicare coverage determination

Let me know if there are any issues here:

-----

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Coverage assessments are rare, because by law they must take a year. Jacques says that currently there is only manpower to do 20 to 25 annually. The topics addressed by NCAs tend to be broad. Some recent examples include an assessment of how to pay for genetic tests that were being paired with drugs, who should get anemia drugs made by Amgen and Johnson & Johnson, and whether to pay for costs incurred by hospitals as a result of medical errors.

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The extent of conversation, Jacques says, made it seem to make sense to create a national standard for how Provenge is covered. This is rare for an individual product, but it made sense in this case because many of the men who will get Provenge will be Medicare patients. "I don't know that anybody should be surprised that Medicare would take an interest in a technology that would have an impact on the Medicare population," says Jacques.

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<Peter.Ashkenaz@CMS.hhs.gov> wrote:

I understand. sorry

-----Original Message-----

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Sent: Thursday, July 01, 2010 11:13 AM  
To: Ashkenaz, Peter (CMS/OEABS)  
Subject: Re: Medicare coverage determination

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On 7/1/10 11:10 AM, "Ashkenaz, Peter (CMS/OEABS)"  
<Peter.Ashkenaz@CMS.hhs.gov> wrote:

Stuck on a conference call for at least an hour

-----Original Message-----

From: Herper, Matthew [mailto:MHerper@forbes.com]

Sent: Thursday, July 01, 2010 11:09 AM

To: Ashkenaz, Peter (CMS/OEABS)

Subject: Re: Medicare coverage determination

Could you give me a quick call? 212-367-4879

On 7/1/10 9:07 AM, "Ashkenaz, Peter (CMS/OEABS)"

<Peter.Ashkenaz@CMS.hhs.gov> wrote:

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-----

Fact & Comment: Our new expanded, multimedia presentation of the column by Steve Forbes:  
<http://cptl.st/FactAndComment>

## Jacques, Louis B. (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 1:39 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: Dendreon: Medicare reviewing Provenge coverage

On phone with Dendreon  
Sent from my Blackberry

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Anderson, Kelly (CMS/OCSQ)  
**Sent:** Thu Jul 01 11:09:55 2010  
**Subject:** Dendreon: Medicare reviewing Provenge coverage

Dendreon: Medicare reviewing Provenge coverage

By MARLEY SEAMAN (AP) – 10 minutes ago

NEW YORK — Medicare administrators say they will take a full year to review Dendreon Corp.'s prostate cancer therapy Provenge and decide whether to cover the costly treatment.

Provenge, which costs \$93,000 for a course of treatment, has been widely expected to bring Dendreon billions in revenue in the coming years. But sales will be slashed if Medicare decides not to cover the cost or offers only limited coverage. Medicare's Coverage and Analysis Group will propose a decision in about nine months and make a final ruling about a year from now. That decision will apply to all Medicare contractors.

In morning trading, shares of Seattle-based Dendreon lost \$3.53, or 11 percent, to \$28.75.

The Food and Drug Administration approved Provenge in late April, and some Medicare insurance contractors already are paying for the therapy, but there is no national policy. Contractors can continue to cover Provenge during the agency's review, but must adhere to any final decision.

Medicare is evaluating whether or not it is reasonable and necessary to cover Provenge. Clinical studies have shown that patients treated with Provenge live about a month longer than those who receive traditional chemotherapy treatment.

The Coverage and Analysis Group is a team of medical officers, managers and analysts. A technical panel and a coverage advisory committee also will take part in the review.

The FDA has approved Provenge for patients who have prostate cancer that has spread and that has not responded to hormone-based treatment. Medicare will consider whether it makes sense to cover a costly drug that has a relatively narrow approval. But if it decides to cover Provenge treatment for patients with less advanced cancer, that could help sales.

Medicare will also deal with a deceptively simple question: what is Provenge? Is it a traditional drug, a biologic drug, or something else? The answer could affect the amount that Medicare will cover because different types of drugs are covered at different rates.

Provenge is designed to train a patient's immune system to attack tumors. It is different from traditional drugs and even biotech drugs because it is made by mixing blood cells from the individual patient with a protein found on cancer cells and an immune system-boosting substance.

Wednesday marked the beginning of a 30-day public comment period on coverage. After the comment period ends, the agency will take about nine months to create a proposal. The public will then have 30 days to comment on the proposal, and Medicare will publish a final decision within 60 days of the end of that comment period. The decision goes into effect as soon as it is published.

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## **Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 2:10 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** RE: Dendreon: Medicare reviewing Provenge coverage

Finishing up with Al Chadwick now. Available now

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**Sent:** Thursday, July 01, 2010 2:05 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Dendreon: Medicare reviewing Provenge coverage

Let me know when you are ready to talk

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 01, 2010 1:39 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Re: Dendreon: Medicare reviewing Provenge coverage

On phone with Dendreon  
Sent from my Blackberry

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Anderson, Kelly (CMS/OCSQ)  
**Sent:** Thu Jul 01 11:09:55 2010  
**Subject:** Dendreon: Medicare reviewing Provenge coverage

Dendreon: Medicare reviewing Provenge coverage

By MARLEY SEAMAN (AP) – 10 minutes ago

NEW YORK — Medicare administrators say they will take a full year to review Dendreon Corp.'s prostate cancer therapy Provenge and decide whether to cover the costly treatment.

Provenge, which costs \$93,000 for a course of treatment, has been widely expected to bring Dendreon billions in revenue in the coming years. But sales will be slashed if Medicare decides not to cover the cost or offers only limited coverage. Medicare's Coverage and Analysis Group will propose a decision in about nine months and make a final ruling about a year from now. That decision will apply to all Medicare contractors.

In morning trading, shares of Seattle-based Dendreon lost \$3.53, or 11 percent, to \$28.75.

The Food and Drug Administration approved Provenge in late April, and some Medicare insurance contractors already are paying for the therapy, but there is no national policy. Contractors can continue to cover Provenge during the agency's review, but must adhere to any final decision.

Medicare is evaluating whether or not it is reasonable and necessary to cover Provenge. Clinical studies have shown that patients treated with Provenge live about a month longer than those who receive traditional chemotherapy treatment.

The Coverage and Analysis Group is a team of medical officers, managers and analysts. A technical panel and a coverage advisory committee also will take part in the review.

The FDA has approved Provenge for patients who have prostate cancer that has spread and that has not responded to hormone-based treatment. Medicare will consider whether it makes sense to cover a costly drug that has a relatively narrow approval. But if it decides to cover Provenge treatment for patients with less advanced cancer, that could help sales.

Medicare will also deal with a deceptively simple question: what is Provenge? Is it a traditional drug, a biologic drug, or something else? The answer could affect the amount that Medicare will cover because different types of drugs are covered at different rates.

Provenge is designed to train a patient's immune system to attack tumors. It is different from traditional drugs and even biotech drugs because it is made by mixing blood cells from the individual patient with a protein found on cancer cells and an immune system-boosting substance.

Wednesday marked the beginning of a 30-day public comment period on coverage. After the comment period ends, the agency will take about nine months to create a proposal. The public will then have 30 days to comment on the proposal, and Medicare will publish a final decision within 60 days of the end of that comment period. The decision goes into effect as soon as it is published.

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:14 PM  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** Re: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

Maria

This one's a piece of cake. Will send you a reply when I get back to my desk. Amazing that when we don't have an NCD they ask for one but when we do one they ask why.

Louis  
Sent from my Blackberry

---

**From:** Martino, Maria (CMS/OL)  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Sent:** Tue Jul 06 11:53:14 2010  
**Subject:** autologous cellular immunotherapy treatment of prostate cancer

Hi Louis and Tamara—you guys are the lucky people with respect to Congressional calls!

I got the e-mail below on Friday afternoon re regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

- What caused this review?
- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

Maria

Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

---

**From:** PSC Myers, John (Specter)  
**Sent:** Tuesday, July 06, 2010 11:08 AM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Any progress?

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**From:** Martino, Maria (CMS/OL) [mailto:Maria.Martino@CMS.hhs.gov]  
**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Thanks John. We will start looking into it and will get back to you next week. Is that okay?

Thanks,  
Maria

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**From:** PSC Myers, John (Specter)  
**Sent:** Friday, July 02, 2010 3:04 PM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

Thanks. I appreciate it.

Maria,  
Could you tell me what caused this review?  
Will the drug be available to beneficiaries during the coverage determination?

Thanks  
John

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**From:** Fitzgerald, Erin (HHS/ASL) [mailto:Erin.Fitzgerald@hhs.gov]  
**Sent:** Friday, July 02, 2010 3:00 PM  
**To:** Myers, John (Specter)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

John, thanks for your patience as I got back to you. Cc'ed on this email is Maria Martino from CMS' Office of Legislation. She and her colleagues will be able to help you with this issue.

Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

---

**From:** PSC Myers, John (Specter)  
**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

Here is the coverage determination information I asked about. If you could point me to someone I would appreciate it. I thought it would be better to go through leg affairs rather than to the analyst.

John  
4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)** **COMMENT**

**Issue**

CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.

As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Provenge® has FDA approved labeling for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

**Actions Taken**

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010.

Instructions on submitting public comments can be found at [http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**

## Jacques, Louis B. (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:50 PM  
**To:** OWENS, KAREN M. (CMS/OCSQ)  
**Subject:** FW: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

Already there

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:41 PM  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

Opening this NCD is consistent with Congressional intent. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to foster greater consistency of local coverage through either NCDs (on items or services that have differing LCDs) or some other process to achieve a greater uniformity of coverage policies.

We hope that the opening of the NCD and the commissioning of an external TA and convening of the MEDCAC will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

Local Medicare administrative contractors, pursuant to their statutory authorities, currently retain the ability to cover or noncover Provenge within their jurisdictions until the NCD is finalized, at which point they must all comply with the national policy.

Louis

---

**From:** Martino, Maria (CMS/OL)  
**Sent:** Tuesday, July 06, 2010 11:53 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** autologous cellular immunotherapy treatment of prostate cancer

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I got the e-mail below on Friday afternoon regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

- What caused this review?
- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

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Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

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**Cc:** Lewandowski, David S. (CMS/OL)  
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Any progress?

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**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Thanks John. We will start looking into it and will get back to you next week. Is that okay?

Thanks,  
Maria

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**From:** PSC Myers, John (Specter)  
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**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

Thanks. I appreciate it.

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Thanks

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**Sent:** Friday, July 02, 2010 3:00 PM  
**To:** Myers, John (Specter)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

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Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

---

**From:** PSC Myers, John (Specter)  
**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

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John  
4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N) [REDACTED]**

**Issue**

CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.

As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

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We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD  
[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)  
1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

**Actions Taken**

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

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Instructions on submitting public comments can be found at [http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**



11

**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:52 PM  
**To:** OWENS, KAREN M. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge  
**Attachments:** image001.png

Karen,

Sent you my prior email to Maria. As an aside, it's not unusual, despite the way the writer worded it. Because we do a limited number of NCDs annually it's unusual to do more than a few on any particular topic, absent external requests.

Louis

---

**From:** OWENS, KAREN M. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:44 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** FW: Provenge

Hi there. Can you assist with a response to the email below? Please let me know or if I should direct this to Barry.

Thanks!  
Karen

---

**From:** Guevara, Natalia T. (CMS/OL)  
**Sent:** Tuesday, July 06, 2010 11:37 AM  
**To:** OWENS, KAREN M. (CMS/OCSQ)  
**Subject:** FW: Provenge

Hi Karen –

Could you help me with the inquiry below in Maria's absence, please?

Thanks very much.

Natalia

I understand that CMS is currently undertaking a NCD on Provenge? Do you know why CMS is going this route? Is it to determine whether or not it should be covered? Or is it a question of how to reimburse the treatment? Is the article below accurate, in that patients can still receive this treatment while the NCD is underway?

Thanks,

Dan

Dan Elling

Committee on Ways and Means

# The Science Business

a health care blog

## Why is Medicare Reviewing Dendreon's Provenge?

Dendreon shares are down today on the heels of news that the Centers for Medicare and Medicaid Services (CMS) will undergo a lengthy review of whether or not Provenge "is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act" and should be reimbursed by Medicare.

Most analysts believe that Medicare will ultimately agree to pay for Provenge, because it's FDA-approved, and it was shown to extend survival by 4 months in clinical trials.

So why is Medicare undertaking this review? Nobody knows for sure, but here is what we *do* know.

1. It is unusual for Medicare's "National Coverage Determination" process, as it's called, to be launched to review the reimbursement of a cancer therapy in its FDA-approved indication. It appears that CMS "received informal inquiries for a national coverage determination," which suggests that local Medicare contractors are looking for guidance as to how to proceed.
2. Provenge is not your everyday treatment. It's a customized active immune therapy, in which a patient's own immune cells are extracted from the bloodstream, biologically manipulated at an external site, and then reinserted into the patient. It's quite possible that Medicare is simply trying to figure out the logistics of how to pay for such a complicated and unprecedented therapy.
3. Those with private insurance who have received Provenge therapy appear to be having no problems getting insurers to pay for the treatment; those on Medicare can receive the treatment while the review is under way.
4. Medicare is proscribed by law from considering price in its reimbursement decisions. "The cost of a particular technology," according to CMS, "is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population." In other words, if Dendreon had chosen to charge \$2 million for Provenge, instead of \$93,000, Medicare is not supposed to take that into consideration. CMS has to go by what the FDA has approved—and the FDA can't take cost into account either.
5. The timeline will proceed as follows: CMS has opened up a 30-day public comment period on whether or not Provenge should be covered, which will expire at the end of July. CMS will commission a technology assessment from a third party. The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) will then conduct its own review, and will be expected to produce a decision memorandum by March 30, 2011. Implementation of Medicare's decision will begin no later than June 30, 2011.

So, bottom line: if you are a patient, reimbursement is not likely to be an issue. The biggest challenge is obtaining the therapy itself, which will suffer from manufacturing supply constraints for the next several quarters.

The larger question is: should the government be able consider price in deciding whether or not to pay for a particular treatment? There are pluses and minuses to each answer, but the Dendreon case shows us that the question is not going away.

## Jacques, Louis B. (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 3:06 PM  
**To:** Griffith, Ellen B. (CMS/OEA)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

FYI Peter was dealing with Provenge last week and has written QAs that may help

---

**From:** Griffith, Ellen B. (CMS/OEA)  
**Sent:** Tuesday, July 06, 2010 3:01 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Thanks – can I copy this message and forward it to the reporter? Or are there parts of it that should be treated as Internal Use Only?

Ellen

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 2:59 PM  
**To:** Griffith, Ellen B. (CMS/OEA)  
**Subject:** Fw: autologous cellular immunotherapy treatment of prostate cancer

Ellen let me know if the whole msg didn't attach  
Sent from my Blackberry

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Sent:** Tue Jul 06 12:41:07 2010  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

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Louis

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- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

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Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

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**Sent:** Tuesday, July 06, 2010 11:08 AM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

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---

**From:** Martino, Maria (CMS/OL) [mailto:Maria.Martino@CMS.hhs.gov]  
**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

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**Sent:** Friday, July 02, 2010 3:04 PM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

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**From:** Fitzgerald, Erin (HHS/ASL) [mailto:Erin.Fitzgerald@hhs.gov]  
**Sent:** Friday, July 02, 2010 3:00 PM  
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**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

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Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

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**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

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<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Provenge® has FDA approved labeling for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

**Actions Taken**

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010.

Instructions on submitting public comments can be found at [http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**



## **Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 3:04 PM  
**To:** Griffith, Ellen B. (CMS/OEA)  
**Subject:** Re: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

It was meant for internal use. I'll be back at my desk soon and can call u then  
Sent from my Blackberry

---

**From:** Griffith, Ellen B. (CMS/OEA)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tue Jul 06 15:00:55 2010  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Thanks – can I copy this message and forward it to the reporter? Or are there parts of it that should be treated as Internal Use Only?

Ellen

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 2:59 PM  
**To:** Griffith, Ellen B. (CMS/OEA)  
**Subject:** Fw: autologous cellular immunotherapy treatment of prostate cancer

Ellen let me know if the whole msg didn't attach  
Sent from my Blackberry

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Sent:** Tue Jul 06 12:41:07 2010  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

Opening this NCD is consistent with Congressional intent. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to foster greater consistency of local coverage through either NCDs (on items or services that have differing LCDs) or some other process to achieve a greater uniformity of coverage policies.

We hope that the opening of the NCD and the commissioning of an external TA and convening of the MEDCAC will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

Local Medicare administrative contractors, pursuant to their statutory authorities, currently retain the ability to cover or noncover Provenge within their jurisdictions until the NCD is finalized, at which point they must all comply with the national policy.

Louis

---

**From:** Martino, Maria (CMS/OL)  
**Sent:** Tuesday, July 06, 2010 11:53 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** autologous cellular immunotherapy treatment of prostate cancer

Hi Louis and Tamara—you guys are the lucky people with respect to Congressional calls!

I got the e-mail below on Friday afternoon regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

- What caused this review?
- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

Maria

Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

---

**From:** PSC Myers, John (Specter)  
**Sent:** Tuesday, July 06, 2010 11:08 AM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Any progress?

---

**From:** Martino, Maria (CMS/OL) [mailto:Maria.Martino@CMS.hhs.gov]  
**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Thanks John. We will start looking into it and will get back to you next week. Is that okay?

Thanks,  
Maria

---

**From:** PSC Myers, John (Specter)  
**Sent:** Friday, July 02, 2010 3:04 PM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

Thanks. I appreciate it.

Maria,  
Could you tell me what caused this review?  
Will the drug be available to beneficiaries during the coverage determination?

Thanks  
John

---

**From:** Fitzgerald, Erin (HHS/ASL) [mailto:Erin.Fitzgerald@hhs.gov]  
**Sent:** Friday, July 02, 2010 3:00 PM  
**To:** Myers, John (Specter)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

John, thanks for your patience as I got back to you. Cc'ed on this email is Maria Martino from CMS' Office of Legislation. She and her colleagues will be able to help you with this issue.

Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

---

**From:** PSC Myers, John (Specter)  
**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

Here is the coverage determination information I asked about. If you could point me to someone I would appreciate it. I thought it would be better to go through leg affairs rather than to the analyst.

John  
4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)** **COMMENT**

Issue

CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.

As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Provenge® has FDA approved labeling for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

## Actions Taken

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 4:33 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** RE: Provenge Questions and Answers 070110.docx

I'm not replying to the many assorted stock analysts who've been leaving messages on my phone.

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**Sent:** Tuesday, July 06, 2010 4:32 PM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** FW: Provenge Questions and Answers 070110.docx

Sure, sell me down the river.

---

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Friday, July 02, 2010 1:07 PM  
**To:** Ashkenaz, Peter (CMS/OEABS); McLeod, Donald E. (CMS/OEA); Anderson, Kelly (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge Questions and Answers 070110.docx

Peter/Don/Kelly – attached is the Provenge Q&A document. Hopefully, most of this has died down, but just in case. Let me know if you have any questions – Tamara

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 4:35 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** RE: Provenge Questions and Answers 070110.docx

The 20% copay on \$93K for Provenge will be about \$19k. You'll get a lot of calls on that...

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**Sent:** Tuesday, July 06, 2010 4:34 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Provenge Questions and Answers 070110.docx

I don't blame you. I wouldn't either.

I'm getting beneficiaries asking about the \$250 rebate checks.

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 4:33 PM  
**To:** Ashkenaz, Peter (CMS/OEABS)  
**Subject:** RE: Provenge Questions and Answers 070110.docx

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**To:** Ashkenaz, Peter (CMS/OEABS); McLeod, Donald E. (CMS/OEA); Anderson, Kelly (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
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Peter/Don/Kelly – attached is the Provenge Q&A document. Hopefully, most of this has died down, but just in case. Let me know if you have any questions – Tamara

**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 2:56 PM  
**To:** Rinker, Karen A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

I'm revising it now

---

**From:** Rinker, Karen A. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 2:49 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

Leslye,

I only know of section 731 of MMA that states we should consider NCD topics when LCDs are differing. I added some language in the attached correspondence so hope that will be of help.

Karen

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 4:14 PM  
**To:** Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ)  
**Subject:** Response to Senator Webb

Attached please find the response letter to Senator Webb. Please note that in his letter he asked that the response be sent to his Virginia Beach office, that it be addressed to the attention of Jeanne Evans, and include the reference number assigned to dr. Shellhammer's communication.

I was not able to locate the section of the legislation that addresses the need for CO to address LCD inconsistencies. Either Tamara or Karen should be able to help.

Please copy me on the CAG sanctioned version that goes to OSARA.

Thanks,

Leslye



## **Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 2:58 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

Can someone send me the incoming? Thanx

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 2:57 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

Art Lurvey told me that Palmetto was doing an article, not an LCD

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**Sent:** Friday, July 09, 2010 2:53 PM  
**To:** Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

Thanks Karen. You got it right! Will you send me the version that you revised ?

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**Sent:** Friday, July 09, 2010 2:49 PM  
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**Subject:** RE: Response to Senator Webb

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**Subject:** Response to Senator Webb

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Please copy me on the CAG sanctioned version that goes to OSARA.

Thanks,

Leslye

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:38 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Webb provenge lkf 070810 (2) kr lbj.doc  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj.doc

## **Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:48 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

Leslye,

No worries, the differences are often subtle and I have trouble keeping them straight myself.

LJ

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:12 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

STAND CORRECTED – THANKS

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:11 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

It's an article

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:07 PM  
**To:** Rinker, Karen A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
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**Subject:** RE: Response to Senator Webb

SEE ATTACHED

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**Subject:** RE: Response to Senator Webb

When I did a search last week I didn't find any LCDs in the database but I thought that Leslye did find a LCDs.

---

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**Subject:** Webb provenge lkf 070810 (2) kr lbj.doc  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj.doc



Took out a redundant sentence in para 1.

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**Subject:** RE: Response to Senator Webb  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj.doc

 I edit my own edits too, removed the last sentence in the first para after reading the printed hard copy ☺

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:48 PM  
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**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:12 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

STAND CORRECTED – THANKS

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:11 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Response to Senator Webb

It's an article

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:07 PM  
**To:** Rinker, Karen A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M.

(CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

**Subject:** RE: Response to Senator Webb

SEE ATTACHED

---

**From:** Rinker, Karen A. (CMS/OCSQ)

**Sent:** Friday, July 09, 2010 2:59 PM

**To:** Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

**Subject:** RE: Response to Senator Webb

When I did a search last week I didn't find any LCDs in the database but I thought that Leslye did find a LCDs.

---

**From:** Jacques, Louis B. (CMS/OCSQ)

**Sent:** Friday, July 09, 2010 2:57 PM

**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

**Subject:** RE: Response to Senator Webb

Art Lurvey told me that Palmetto was doing an article, not an LCD

---

**From:** Fitterman, Leslye (CMS/OCSQ)

**Sent:** Friday, July 09, 2010 2:53 PM

**To:** Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)

**Subject:** RE: Response to Senator Webb

Thanks Karen. You got it right! Will you send me the version that you revised ?

---

**From:** Rinker, Karen A. (CMS/OCSQ)

**Sent:** Friday, July 09, 2010 2:49 PM

**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)

**Subject:** RE: Response to Senator Webb

Leslye,

I only know of section 731 of MMA that states we should consider NCD topics when LCDs are differing. I added some language in the attached correspondence so hope that will be of help.

Karen

---

**From:** Fitterman, Leslye (CMS/OCSQ)

**Sent:** Thursday, July 08, 2010 4:14 PM

**To:** Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)

**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ)

**Subject:** Response to Senator Webb



Attached please find the response letter to Senator Webb. Please note that in his letter he asked that the response be sent to his Virginia Beach office, that it be addressed to the attention of Jeanne Evans, and include the reference number assigned to dr. Shellhammer's communication.

I was not able to locate the section of the legislation that addresses the need for CO to address LCD inconsistencies. Either Tamara or Karen should be able to help.

Please copy me on the CAG sanctioned version that goes to OSARA.

Thanks,

Leslye



(b)(5) - Draft Document

*(Do not type date)*

The Honorable Jim Webb,  
United States Senate  
22 Central Park Avenue, #120  
Virginia Beach, VA 23460  
Attention to: Jeanne Evans  
Re: Shellhammer#610031

Dear Senator Webb:

(b)(5) - Draft Document

(b)(5) - Draft Document

Sincerely, v

(b)(5) - Draft Document

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*(Do not type date)*

The Honorable Jim Webb,  
United States Senate  
22 Central Park Avenue, #120  
Virginia Beach, VA 23460  
Attention to: Jeanne Evans  
Re: Shellhammer#610031

Dear Senator Webb:

(b)(5) - Draft Document

(b)(5) - Draft Document

Sincerely, v

(b)(5) - Draft Document

6

*(Tab in 6 times to align correctly)*

*(4 lines)*

*(type name of signer)*

*(2 lines)*

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6", Left + 6.5", Left + 7", Left + 7.5", Left + 8", Lef





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*(Do not type date)*

The Honorable Jim Webb,  
United States Senate  
22 Central Park Avenue, #120  
Virginia Beach, VA 23460  
Attention to: Jeanne Evans  
Re: Shellhammer#610031

Dear Senator Webb:

(b)(5) - Draft Document



(b)(5) - Draft Document

Sincerely, ,

(b)(5) - Draft Document

*(Tab in 6 times to align correctly)*

*(4 lines)*

*(type name of signer)*

*(2 lines)*

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Type the list on the next [or last] page.)*

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3.5", Left + 4", Left + 4.5", Left + 5", Left + 5.5", Left +  
6", Left + 6.5", Left + 7", Left + 7.5", Left + 8", Lef

**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, July 12, 2010 2:45 PM  
**To:** Chadwick, Alpheus K. (CMS/OL)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Ashkenaz, Peter (CMS/OEABS); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Re: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

AI

Agree local contractors unaffected until final NCD. Have worked thru Maria in OL and Peter in OEA on this and she has paper if you have a specific Hill inquirer

Louis  
Sent from my Blackberry

---

**From:** Chadwick, Alpheus K. (CMS/OL)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Mon Jul 12 14:34:43 2010  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Louis, just want to confirm that until the analysis is complete, the LCD will remain in effect, i.e. some contractors will continue to reimburse for Provenge? Also, can you say anymore about the inquiries we received that prompted opening the NCD?

-AI

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:41 PM  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

Opening this NCD is consistent with Congressional intent. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to foster greater consistency of local coverage through either NCDs (on items or services that have differing LCDs) or some other process to achieve a greater uniformity of coverage policies.

We hope that the opening of the NCD and the commissioning of an external TA and convening of the MEDCAC will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

Local Medicare administrative contractors, pursuant to their statutory authorities, currently retain the ability to cover or noncover Provenge within their jurisdictions until the NCD is finalized, at which point they must all comply with the national policy.

Louis

---

**From:** Martino, Maria (CMS/OL)  
**Sent:** Tuesday, July 06, 2010 11:53 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** autologous cellular immunotherapy treatment of prostate cancer

Hi Louis and Tamara—you guys are the lucky people with respect to Congressional calls!

I got the e-mail below on Friday afternoon regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

- What caused this review?
- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

Maria

Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

---

**From:** PSC Myers, John (Specter)  
**Sent:** Tuesday, July 06, 2010 11:08 AM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Any progress?

---

**From:** Martino, Maria (CMS/OL) [mailto:Maria.Martino@CMS.hhs.gov]  
**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)

**Cc:** Lewandowski, David S. (CMS/OL)

**Subject:** RE: RE:

Thanks John. We will start looking into it and will get back to you next week. Is that okay?

Thanks,  
Maria

---

**From:** PSC Myers, John (Specter)  
**Sent:** Friday, July 02, 2010 3:04 PM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

Thanks. I appreciate it.

Maria,  
Could you tell me what caused this review?  
Will the drug be available to beneficiaries during the coverage determination?

Thanks  
John

---

**From:** Fitzgerald, Erin (HHS/ASL) [mailto:Erin.Fitzgerald@hhs.gov]  
**Sent:** Friday, July 02, 2010 3:00 PM  
**To:** Myers, John (Specter)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

John, thanks for your patience as I got back to you. Cc'ed on this email is Maria Martino from CMS' Office of Legislation. She and her colleagues will be able to help you with this issue.

Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

---

**From:** PSC Myers, John (Specter)  
**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

Here is the coverage determination information I asked about. If you could point me to someone I would appreciate it. I thought it would be better to go through leg affairs rather than to the analyst.

John  
4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)** 

**Issue**

CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.

As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Provenge® has FDA approved labeling for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

## Actions Taken

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010.

Instructions on submitting public comments can be found at [http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**



**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 13, 2010 11:36 AM  
**To:** Kelman, Jeffrey A. (CMS/CM)  
**Subject:** Re: Provenge

Yes  
Sent from my Blackberry

---

**From:** Kelman, Jeffrey A. (CMS/CM)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tue Jul 13 11:35:21 2010  
**Subject:** Provenge

Have you publically announced the opening of the NCA?

**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 7:16 AM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

The default would be all of it unless parts are off topic or have phi. The team can make a rec.

Sent from my Blackberry

----- Original Message -----

**From:** Dolina, Elaine L. (CMS/OCSQ)  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thu Jul 29 06:58:09 2010  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Would you like me to add this comment to the database? If so, which attachments (if any) should I include?

Elaine

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, July 28, 2010 11:23 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

-----Original Message-----

**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

On behalf of Dendreon Corporation (Dendreon), I am submitting the following comments on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.[1] Dendreon is the manufacturer of PROVENGE® (sipuleucel-T), an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE is the first in a new class of biological products designed to induce a tumor-specific immune response. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) approved PROVENGE on April 29, 2010 under a biologic license application (BLA, license number 1749). Bringing PROVENGE to market has been a 15-year journey that has involved more than a thousand courageous patients, 15 clinical trials, and nearly one billion dollars of funding of research and development.

Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology. [4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P=0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A [5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate  $\geq$  15%, were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common ( $\geq$  2%) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their

battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

We believe that if CMS does decide to move forward with this NCA, it should conclude the process quickly, without a TA or a MedCAC meeting. We believe that a TA is not needed because none of the conditions listed in the guidance document regarding factors CMS considers in commissioning a TA exist. In particular, there are no "significant differences in opinion among experts," as shown by the fact that soon after PROVENGE was approved by the FDA, the National Comprehensive Cancer Network (NCCN) listed PROVENGE in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>T</sup>) for Prostate Cancer (version 2.2010) and NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>T</sup>) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T," [10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly

reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

2 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

- 3 Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.
- 4 Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.
- 5 Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.
- 6 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6) [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6) .
- 7 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).
- 8 NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.
- 9 NCCN Categories of Evidence and Consensus, [http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp) [http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp) .
- 10 Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.
- 11 SSA § 1861(t)(2)(A)-(B).
- 12 SSA § 1861(t)(2)(B)(ii).
- 13 Medicare Benefit Policy Manual, ch. 15, § 50.4.5.
- 14 NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

#### Attachments

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[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.



- [2] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).
- [3] Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.
- [4] Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.
- [5] Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.
- [6] 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)  
<[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)> .
- [7] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).
- [8] NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.
- [9] NCCN Categories of Evidence and Consensus,  
[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)  
<[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)> .
- [10] Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.
- [11] SSA § 1861(t)(2)(A)-(B).
- [12] SSA § 1861(t)(2)(B)(ii).
- [13] Medicare Benefit Policy Manual, ch. 15, § 50.4.5.
- [14] NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

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## Jacques, Louis B. (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 7:40 AM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Meeting with Dendreon at CMS

I will respond to him and cc the team  
Sent from my Blackberry

---

**From:** Lockett, Chris <[clockett@Dendreon.com](mailto:clockett@Dendreon.com)>  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Thu Jul 29 23:42:14 2010  
**Subject:** RE: Meeting with Dendreon at CMS

Leslye,

When we confirmed our meeting last week you informed us that you would provide us with your questions in advance. Having these questions will allow us to prepare the most relevant slide presentation for your analysis. You also stated that the NCA was initiated to determine the "effectiveness" of Provenge (see Below). We are still struggling to understand the rational CMS has used to initiate the NCA and we were hoping your clarification of "effectiveness" would provide us some of that understanding. Dendreon wants to provide CMS with any additional evidence that the agency needs for this analysis, at this point we are still unclear as to exactly what evidence the agency is seeking. Any further guidance would be greatly appreciated.

Regards,

Chris

---

**From:** Fitterman, Leslye (CMS/OCSQ) [<mailto:Leslye.Fitterman3@CMS.hhs.gov>]  
**Sent:** Thursday, July 22, 2010 4:20 PM  
**To:** Lockett, Chris  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Meeting with Dendreon at CMS

Dear Mr. Lockett:

We have scheduled a meeting with you and your colleagues at our office in Baltimore, MD for August 3, 2010 11:00 am to 12 noon. I will follow-up with you early next week when we have composed questions. I will also clarify what I mean by "effectiveness" and "comparative effectiveness".

We looking forward to meeting with you on August 3<sup>rd</sup>.

Regards, Leslye

**Jacques, Louis B. (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 9:22 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Re: Fwd: NCA Comment re. provenge

No response is needed to him. Nothing we can do about it if they want to go to the Hill. The irony is that if they stop the NCD they will have to deal one by one with the local contractors.  
Sent from my Blackberry

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Thu Jul 29 20:33:27 2010  
**Subject:** Fwd: NCA Comment re. provenge

Sent from my iPhone

Begin forwarded message:

**From:** "steven wilson" (b)(6)  
**Date:** July 29, 2010 6:13:41 PM EDT  
**To:** [Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)  
**Subject:** NCA Comment re. provenge

Dear Dr Fitterman,

I would suggest that you read the public comments about the provenge NCA submitted by Hans Bishop - the COO of Dendreon. He discusses this unprecedented review in great detail. I and others will be asking our elected representatives to halt these new hurdles the government has placed in front of provenge.

Regards, Dr SG Wilson

Leslye Fitterman, PhD.  
Centers for Medicare and Medicaid Services  
Office of Clinical Standards and Quality  
Coverage and Analysis Group  
7500 Security Boulevard  
C1-09-06  
Fax - 410-786-9286  
Phone - 410-786-1806  
Email - [Leslye.Fitterman3@cms.hhs.gov](mailto:Leslye.Fitterman3@cms.hhs.gov)

---

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**Jacques, Louis B. (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 3:56 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 073010 lbj.doc  
**Attachments:** Provenge MEDCAC questions 073010 lbj.doc

We need to get closer to this model. There is room to integrate your questions, which were good. Let's discuss next week.

**MEDCAC –November 17, 2010**

**~~DRAFT QUESTIONS~~**

(b)(5) - Draft Document



(b)(5) - Draft Document



**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 8:57 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** Provenge label  
**Attachments:** Provenge prescribing-information.pdf

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
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(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)



## Rollins, James (CMS/OCSQ)

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**Subject:** Meeting RE: provenge  
**Location:** C4-20-02 (J.Warren, 6-3633, 6/17/2010, 10:30 - 11:30 a.m)  
**Start:** Thu 06/17/2010 10:30 AM  
**End:** Thu 06/17/2010 11:30 AM  
**Show Time As:** Tentative  
**Recurrence:** (none)  
**Meeting Status:** Not yet responded  
**Organizer:** Warren, John F. (CMS/CMM)  
**Required Attendees:** CMS C4-20-02; Simon, Kenneth B. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Dahm, Bonny (CMS/CMM); Gilbreath, Cheryl (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Markowitz, Esther B. (CMS/CMM); McGuirk, Glenn C. (CMS/CMM); Rollins, James (CMS/OCSQ); Hake, Cynthia S. (CMS/CMM); Anderson, Lori L. (CMS/CMM)

To meet with Dendreon to discuss coverage, benefit category, coding, and payment for Provenge.

Please note, this room is kind of on the smallish side. I'll look for another larger room and will update the meeting appointment if I find one.

Following are some background materials, some may have already seen, please disregard if you have.



Dendreon Prostate prescribing-informat  
GL.PDF



ion.pdf



Medispan  
Portal\_Provenge.pdf



First  
Data\_Provenge.pdf



Red Book-  
Provenge.pdf



PROVENGE FDA  
Approval Letter C...

## Rollins, James (CMS/OCSQ)

---

**From:** Stieber, Joan (CMS/OL)  
**Sent:** Monday, June 07, 2010 12:05 PM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ)  
**Subject:** FW: Provenge

Hi Jim. Are you familiar with the prostate cancer drug described below? Would this be open to contractor discretion, and if so, do you have any information on whether it would generally be covered?

thanks – Joan in OL

---

**From:** Hayes, Mark (Finance-Rep) <[Mark\\_Hayes@finance-rep.senate.gov](mailto:Mark_Hayes@finance-rep.senate.gov)>  
**To:** Clapton, Erin M. (CMS/OL)  
**Sent:** Mon Jun 07 11:01:58 2010  
**Subject:** Provenge

Good Morning Erin – I need to find out current CMS coverage for this cancer therapy recently approved by FDA. Someone contacted me this morning to say that CMS had denied coverage and while I'm in the process of collecting information on that I thought I would get the ball rolling to get some basic information as well.

Many Thanks,

Mark

## FDA OKs Provenge for Prostate Cancer Therapy

'Vaccine' Is an Immune Therapy That Treats Advanced Prostate Cancer  
By [Daniel J. DeNoon](#)  
WebMD Health News  
Reviewed by [Laura J. Martin, MD](#)

April 29, 2010 -- The FDA today approved Provenge, Dendreon Corp.'s individualized "vaccine" for the treatment of advanced prostate cancer.

The action comes more than three years after an FDA advisory panel recommended approval, declaring the immune therapy safe and effective. But FDA concerns over efficacy led the FDA to delay a decision until more data became available.

Provenge doesn't cure prostate cancer or prevent it from getting worse over time. But it does extend survival -- by months for most patients, by years for some.

Provenge isn't your everyday vaccine. It's an immune therapy created by harvesting immune cells from a patient, genetically engineering them to fight prostate cancer, and then infusing them back into the patient.

It's approved only for treatment of asymptomatic or minimally symptomatic patients with prostate cancer that has spread outside the prostate and no longer responds to hormone therapy.

In clinical trials, Provenge extended survival by a median 4.1 months -- about half of patients were below that amount and half were above. But some of the patients remain alive years after the treatment. In the most recent trial, 32% of Provenge-treated patients remained alive three years after treatment. Only 23% of placebo-treated patients survived that long.

The approval makes Provenge the first cancer treatment vaccine. It will "re-energize" work in a field that is littered with disappointing failures, says Robert Dreicer, MD, chairman of Cleveland Clinic's department of solid tumor oncology. Dreicer helped run a Provenge clinical trial but has no financial interest in the product.

"If you asked me two years ago if I thought we were on the cusp of a cancer-treatment vaccine, I would have said no -- and I would have been wrong," Dreicer tells WebMD. "Now we are about to see a series of therapeutic vaccines that will not be curative, but which will allow us to manage many advanced cancers in a chronic disease paradigm."

The treatment won't be inexpensive. Industry analysts' estimate of Provenge's cost range from \$40,000 to \$100,000, with most analysts betting on the high end of the range. And the treatment presents a logistical challenge, as cells taken from patients must be transported to Dendreon facilities, treated with Provenge and tested for purity and potency, and then returned to a doctor for infusion.

Ongoing clinical trials are looking at whether Provenge might have more dramatic effects if given earlier in the course of prostate cancer. One of these studies is giving Provenge to men intending to undergo prostatectomy for prostate cancer that is still confined to the prostate gland. Investigators will examine the removed prostate tissue for signs that Provenge is reducing prostate tumors.

---

Mark L. Hayes  
Health Policy Director and Chief Health Counsel  
Senate Finance Committee Republican Staff  
219 Dirksen Senate Office Building  
Washington, D.C. 20510

Phone: 202-224-4515  
Twitter: marklhayes

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 12:13 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge

Joan,

We've been following Provenge for some time. There is no NCD or LCD at this time. There are outstanding benefit category issues that would need to be addressed before coverage policy could realistically be implemented. Provenge is several different types of services strung together.

Louis

Louis B. Jacques, MD  
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[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

**Rollins, James (CMS/OCSQ)**

---

**From:** Stieber, Joan (CMS/OL)  
**Sent:** Monday, June 07, 2010 12:22 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** RE: Provenge

Thanks Louis and Jim. So it sounds like contractors are not covering Provenge at this time pending resolution of those benefit category questions, is that correct?

Can I publicly share this explanation? And/or can I say that we are actively looking at the benefit category questions so coverage could be addressed soon?

Also, have there been any external requests for an NCD or is it one we would initiate internally?

thanks -- Joan

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 12:13 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
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Louis

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[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 1:25 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Re: Provenge

Joan

At this point it is contractor discretion  
Sent from my Blackberry

---

**From:** Stieber, Joan (CMS/OL)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Sent:** Mon Jun 07 12:22:25 2010  
**Subject:** RE: Provenge

Thanks Louis and Jim. So it sounds like contractors are not covering Provenge at this time pending resolution of those benefit category questions, is that correct?

Can I publicly share this explanation? And/or can I say that we are actively looking at the benefit category questions so coverage could be addressed soon?

Also, have there been any external requests for an NCD or is it one we would initiate internally?

thanks -- Joan

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 12:13 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge

Joan,

We've been following Provenge for some time. There is no NCD or LCD at this time. There are outstanding benefit category issues that would need to be addressed before coverage policy could realistically be implemented. Provenge is several different types of services strung together.

Louis

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[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)



## Rollins, James (CMS/OCSQ)

---

**Subject:** Meeting RE: provenge  
**Location:** C4-20-02 (J.Warren, 6-3633, 6/17/2010, 10:30 - 11:30 a.m)  
**Start:** Thu 06/17/2010 10:30 AM  
**End:** Thu 06/17/2010 11:30 AM  
**Show Time As:** Tentative  
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**Meeting Status:** Not yet responded  
**Organizer:** Warren, John F. (CMS/CMM)  
**Required Attendees:** CMS C4-20-02; Simon, Kenneth B. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Dahm, Bonny (CMS/CMM); Gilbreath, Cheryl (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Markowitz, Esther B. (CMS/CMM); McGuirk, Glenn C. (CMS/CMM); Rollins, James (CMS/OCSQ); Hake, Cynthia S. (CMS/CMM); Anderson, Lori L. (CMS/CMM)

**6/7/2010 NOTE: THIS MEETING WILL BE HELD IN CONFERENCE ROOM E ON THE 5<sup>TH</sup> FLOOR. C4-20-02 IS ON THIS APPOINTMENT AS A BACKUP IN CASE WE GET BUMPED. -JFW**

To meet with Dendreon to discuss coverage, benefit category, coding, and payment for Provenge.

Please note, this room is kind of on the smallish side. I'll look for another larger room and will update the meeting appointment if I find one.

Following are some background materials, some may have already seen, please disregard if you have.



Dendreon Prostate prescribing-informat  
GL.PDF



ion.pdf



Medispan  
Portal\_Provenge.pdf



First  
Data\_Provenge.pdf



Red Book-  
Provenge.pdf



PROVENGE FDA  
Approval Letter C...



## **Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, June 09, 2010 7:39 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Ulrich, Madeline M. (CMS/OCSQ); Stiller, Jean M. (CMS/OCSQ); Miller, Susan (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: CMM meeting

Thanks  
Sent from my Blackberry

---

**From:** Rollins, James (CMS/OCSQ)  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Ulrich, Madeline M. (CMS/OCSQ); Stiller, Jean M. (CMS/OCSQ); Miller, Susan (CMS/OCSQ)  
**Sent:** Wed Jun 09 06:55:44 2010  
**Subject:** CMM meeting

Louis, we met with CMM yesterday. Though we discussed a number topics, the majority of the discussion pertained to Provenge. CMM has made no decision on a benefit category grouping for provenge; they say it might fall under biologicals, or blood products, or "incident to" (based on 1847a). John Warren has set up a meeting with the manufacturers (June 17), and a number of DID members will be attending this meeting. CMM said that no decision will be made until after meeting with them. Jarollins

## **Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, June 10, 2010 9:02 AM  
**To:** SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ); Burton, Brijet (CMS/OCSQ); Caplan, Stuart (CMS/OCSQ); Baldwin, JoAnna F. (CMS/OCSQ); Miller, Susan (CMS/OCSQ); Warren, John F. (CMS/CMM); Bassano, Amy (CMS/CMM)  
**Subject:** FW: provenge

Background

Also, this is the clinical team leader's "review memo:"

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>

Take a look at the last paragraph→ "FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Lots of other info available online but I haven't scanned it yet:

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213554.htm>

Summary basis for reg action:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM213114.pdf>

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115

## Rollins, James (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, June 10, 2010 9:08 AM  
**To:** PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Miller, Susan (CMS/OCSQ)  
**Subject:** RE: provenge

This is looking like a CED candidate

---

**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Wednesday, June 09, 2010 2:41 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** provenge

It's regulated by CBER's Office of Cellular, Tissue and Gene Therapies (director= Celia Witten, MD, PhD). Celia may remember me but it would be helpful if Peter could give her a heads up that I'll be contacting her.

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[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115

## **Rollins, James (CMS/OCSQ)**

---

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Thursday, June 10, 2010 10:01 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Miller, Susan (CMS/OCSQ)  
**Subject:** RE: provenge

When we are ready Pete will connect us to the right people at FDA. Let me know

Tamara Syrek Jensen  
Deputy Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality, CMS  
7500 Security Blvd.  
Baltimore, MD 21244  
(410) 786-3529  
[tamara.syrekjensen@cms.hhs.gov](mailto:tamara.syrekjensen@cms.hhs.gov)

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**To:** PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Miller, Susan (CMS/OCSQ)  
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**Cc:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** provenge

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410.786.2115

## **Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, June 11, 2010 4:08 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Miller, Susan (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 061110 lbj.doc  
**Attachments:** Provenge DRAFT track sheet 061110 lbj.doc

Draft TS, note (a)(1)(A) and (a)(1)(E) mentions. Comments invited as always.

Just early strategizing about how this might develop. Likely would have a MEDCAC and a TA eventually. Probably cross-divisional topic

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 14, 2010 7:09 PM  
**To:** Berliner, Elise (AHRQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Ashby, Lori M. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)  
**Subject:** RE: MedCACs and timelines

Elise,

Let's go with BCBS, doesn't look like we have other options that preserve our flexibility for a possible November MEDCAC on Provenge.

Thinking ESA MEDCAC in January, carotid in February.

Louis

-----Original Message-----

**From:** Berliner, Elise (AHRQ)  
**Sent:** Mon 6/14/2010 4:49 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** MedCACs and timelines

Attached is the proposed timeline from BCBS for a report on Provenge, they could be ready by a November MedCAC. (b)(5) - Predecisional

Alberta said that they can't do the diabetic retinopathy report by November. They are still sitting on a lot of the CAG money. This is the second report request that they declined.

Duke is still willing to do the diabetic retinopathy report, but can't do it by November

We are working on the paperwork for Uconn to do the renal transplant project, they can be ready for a MedCAC in January.

If we give the diabetic retinopathy project to Duke and the Provenge project to BCBS, the full amount of the X-account will be spent out. Duke and Tufts would both not have any other money for future projects. McMaster has \$151K and Alberta has \$383K, but they have not been responsive. Frustrating!!

What is your current thinking about MedCAC dates?

Thanks,  
Elise

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 9:04 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Provenge

OK. Would like to give FDA a heads up and open the NCD this week before the CMDs start publishing LCDs etc.

-----Original Message-----

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 9:02 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Provenge

Lori is not here today. She is contacting them.

Tamara Syrek Jensen  
Deputy Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality, CMS 7500 Security Blvd.  
Baltimore, MD 21244  
(410) 786-3529  
[tamara.syrekjensen@cms.hhs.gov](mailto:tamara.syrekjensen@cms.hhs.gov)

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 21, 2010 8:23 AM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Provenge

Let's try to talk w FDA today  
Sent from my Blackberry



**Rollins, James (CMS/OCSQ)**

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Tuesday, June 22, 2010 9:55 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** provenge  
**Attachments:** Provenge.doc

Jim,

Attached is the proposal from BCBSA TEC on Provenge.

Please let me know if you approve this, or if you have any questions or comments. If possible, please send a reply by COB today, we are trying to set up all the paperwork quickly.

Thanks,  
Elise

**Rollins, James (CMS/OCSQ)**

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Wednesday, June 23, 2010 5:49 PM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge

Jim,

Have you had a chance to review this?

THanks,  
Elise

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Tue 6/22/2010 9:55 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** provenge

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Thanks,  
Elise

## **Rollins, James (CMS/OCSQ)**

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Thursday, June 24, 2010 8:46 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge

The budget is around \$120,000, but it is being covered by AHRQ, because the contracts office isn't allowing us to do any new contract modifications. BCBSA TEC is going to use some "old" AHRQ money that is already obligated to their contract that they hadn't used for other projects....

Elise

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 8:29 AM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge

The proposal looks fine. What about the budget? Jarollins

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Tuesday, June 22, 2010 9:55 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** provenge

Jim,

Attached is the proposal from BCBSA TEC on Provenge.

Please let me know if you approve this, or if you have any questions or comments. If possible, please send a reply by COB today, we are trying to set up all the paperwork quickly.

Thanks,  
Elise

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, June 25, 2010 8:54 AM  
**To:** Straube, Barry M. (CMS/OCSQ)  
**Cc:** Hammel, Maria L. (CMS/OCSQ); Lund, Eleanor L. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Wagner, Dennis C. (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062110 lbj.doc  
**Attachments:** Provenge DRAFT track sheet 062110 lbj.doc

Barry,

For OK to post next week. Announces opening of Provenge NCD. We will give FDA a heads up at posting, as they have postmarketing requirements for Provenge. We specifically note we are considering both (a)(1)(A) and (a)(1)(E), i.e. CED.

Louis

**Rollins, James (CMS/OCSQ)**

---

**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Friday, June 25, 2010 8:56 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Lund, Eleanor L. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Manlove, John (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

All-

Who is assigning CAG #s while Maria is out? This will need one.

Thanks!  
Elaine

---

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**Sent:** Friday, June 25, 2010 8:54 AM  
**To:** Straube, Barry M. (CMS/OCSQ)  
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## **Rollins, James (CMS/OCSQ)**

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**Sent:** Friday, June 25, 2010 9:12 AM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Lund, Eleanor L. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Manlove, John (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

John is Maria's backup

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**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Friday, June 25, 2010 8:56 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
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Louis

**Rollins, James (CMS/OCSQ)**

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**From:** Straube, Barry M. (CMS/OCSQ)  
**Sent:** Friday, June 25, 2010 4:17 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Hammel, Maria L. (CMS/OCSQ); Lund, Eleanor L. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Wagner, Dennis C. (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

OK to post from front office. thank you.

Barry

Barry M. Straube, M.D.  
CMS Chief Medical Officer, and  
Director, Office of Clinical Standards & Quality  
Centers for Medicare & Medicaid Services  
Mailstop S3-02-01  
7500 Security Boulevard  
Baltimore, MD 21244  
Phone: 410-786-6841  
FAX: 410-786-6857  
Email: [Barry.Straube@cms.hhs.gov](mailto:Barry.Straube@cms.hhs.gov)

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Louis

## **Rollins, James (CMS/OCSQ)**

---

**From:** Manlove, John (CMS/OCSQ)  
**Sent:** Monday, June 28, 2010 10:07 AM  
**To:** Graves, Patricia A. (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Lund, Eleanor L. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

CAG# for Provenge track sheet: 00422N

---

**From:** Graves, Patricia A. (CMS/OCSQ)  
**Sent:** Friday, June 25, 2010 9:12 AM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
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**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

John is Maria's backup

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**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

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**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

Thank you John.

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**To:** Graves, Patricia A. (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Lund, Eleanor L. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

CAG# for Provenge track sheet: 00422N

---

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**To:** Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
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**Subject:** RE: Provenge DRAFT track sheet 062110 lbj.doc

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**Sent:** Friday, June 25, 2010 8:54 AM  
**To:** Straube, Barry M. (CMS/OCSQ)  
**Cc:** Hammel, Maria L. (CMS/OCSQ); Lund, Eleanor L. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Wagner, Dennis C. (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062110 lbj.doc

Barry,

For OK to post next week. Announces opening of Provenge NCD. We will give FDA a heads up at posting, as they have postmarketing requirements for Provenge. We specifically note we are considering both (a)(1)(A) and (a)(1)(E), i.e. CED.

Louis

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 28, 2010 5:22 PM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge DRAFT track sheet 062810 lbj lf (3).doc  
**Attachments:** Provenge DRAFT track sheet 062810 lbj lf (3).doc

We'll use this version later this week.

**Rollins, James (CMS/OCSQ)**

---

**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Tuesday, June 29, 2010 9:20 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** RE: Provenge DRAFT track sheet 062810 lbj lf (3).doc

I just noticed a typo:

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in November 17, 2010.

I will change "in" to "on".

Elaine

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**Sent:** Monday, June 28, 2010 5:22 PM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Manlove, John (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
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Agree!

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**Subject:** Provenge DRAFT track sheet 062810 lbj lf (3).doc

We'll use this version later this week.

## Rollins, James (CMS/OCSQ)

---

**From:** Ashkenaz, Peter (CMS/OEABS)  
**Sent:** Wednesday, June 30, 2010 6:11 PM  
**To:** Anderson, Kelly (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** FW: Provenge Question - Investment Community

---

**From:** Hellman, Peter [<mailto:PHellman@rwbaird.com>]  
**Sent:** Wednesday, June 30, 2010 6:10 PM  
**To:** McLeod, Donald E. (CMS/OEA); Ashkenaz, Peter (CMS/OEABS)  
**Subject:** Provenge Question - Investment Community

Don-

I understand that you are out until July 7<sup>th</sup> but I am trying to reconcile comments you made to the media with today's news of an initiation of a NCD process on Provenge. Is there anyone I can talk with in your absence?

I am just trying to understand the need/rationale for this process.

Your commentary as quoted by Bloomberg.

**Provenge will almost certainly be covered by the government's Medicare insurance plan for the elderly and disabled, said Don McLeod, a Center for Medicare and Medicaid Services spokesman. The agency doesn't typically make formal determinations on cancer drugs. Instead, it pays claims through the local contractors who administer payments.**

**'99.9% Certain'**

**"It is 99.9 percent certain that we will pay for it if somebody files a claim," McLeod said in an e-mail. The agency has yet to determine how much it will reimburse for the drug, McLeod said. Dendreon said yesterday that it plans to meet with the agency next week.**

Regards, Peter

Peter D. Hellman, CFA  
Equity Research/Biotech  
Robert W. Baird & Co.  
414-298-2337



Baird - Nationally recognized as a great place to work six consecutive years 2004-2009

\*\*\*\*\*

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prohibited. If you received this in error, please contact the sender and delete the material from any computer on which it exists. Baird, in accordance with applicable laws, reserves the right to monitor, review and retain all electronic communications, including e-mails, traveling through its networks and systems. E-mail transmissions cannot be guaranteed to be secure, timely or error-free. Baird therefore recommends that you do not send any sensitive information such as account or personal identification numbers by e-mail.

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**Rollins, James (CMS/OCSQ)**

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**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Friday, July 02, 2010 1:07 PM  
**To:** Ashkenaz, Peter (CMS/OEABS); McLeod, Donald E. (CMS/OEA); Anderson, Kelly (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Subject:** Provenge Questions and Answers 070110.docx  
**Attachments:** Provenge Questions and Answers 070110.docx

Peter/Don/Kelly – attached is the Provenge Q&A document. Hopefully, most of this has died down, but just in case. Let me know if you have any questions – Tamara



**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:41 PM  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

Opening this NCD is consistent with Congressional intent. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to foster greater consistency of local coverage through either NCDs (on items or services that have differing LCDs) or some other process to achieve a greater uniformity of coverage policies.

We hope that the opening of the NCD and the commissioning of an external TA and convening of the MEDCAC will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

Local Medicare administrative contractors, pursuant to their statutory authorities, currently retain the ability to cover or noncover Provenge within their jurisdictions until the NCD is finalized, at which point they must all comply with the national policy.

Louis

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**From:** Martino, Maria (CMS/OL)  
**Sent:** Tuesday, July 06, 2010 11:53 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** autologous cellular immunotherapy treatment of prostate cancer

Hi Louis and Tamara—you guys are the lucky people with respect to Congressional calls!

I got the e-mail below on Friday afternoon regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

- What caused this review?
- Will the drug be available to beneficiaries during the coverage determination period?

Any info you have would be appreciated. Thanks!

Maria

Maria Martino  
Director  
Congressional Affairs Group  
CMS\Office of Legislation  
(202) 690-5512

---

**From:** PSC Myers, John (Specter)  
**Sent:** Tuesday, July 06, 2010 11:08 AM  
**To:** Martino, Maria (CMS/OL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Any progress?

---

**From:** Martino, Maria (CMS/OL) [mailto:Maria.Martino@CMS.hhs.gov]  
**Sent:** Friday, July 02, 2010 3:16 PM  
**To:** Myers, John (Specter); Fitzgerald, Erin (HHS/ASL)  
**Cc:** Lewandowski, David S. (CMS/OL)  
**Subject:** RE: RE:

Thanks John. We will start looking into it and will get back to you next week. Is that okay?

Thanks,  
Maria

---

**From:** PSC Myers, John (Specter)  
**Sent:** Friday, July 02, 2010 3:04 PM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE: RE:

Thanks. I appreciate it.

Maria,  
Could you tell me what caused this review?  
Will the drug be available to beneficiaries during the coverage determination?

Thanks  
John

---

**From:** Fitzgerald, Erin (HHS/ASL) [mailto:Erin.Fitzgerald@hhs.gov]  
**Sent:** Friday, July 02, 2010 3:00 PM  
**To:** Myers, John (Specter)  
**Cc:** Martino, Maria (CMS/OL)  
**Subject:** RE:

John, thanks for your patience as I got back to you. Cc'ed on this email is Maria Martino from CMS' Office of Legislation. She and her colleagues will be able to help you with this issue.

Thanks  
Erin

Erin Fitzgerald  
Office of the Assistant Secretary for Legislation  
U.S. Department of Health and Human Services

---

**From:** PSC Myers, John (Specter)  
**Sent:** Thursday, July 01, 2010 11:10 AM  
**To:** Fitzgerald, Erin (HHS/ASL)  
**Subject:**

Here is the coverage determination information I asked about. If you could point me to someone I would appreciate it. I thought it would be better to go through leg affairs rather than to the analyst.

John  
4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)** **COMMENT**

#### Issue

CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.

As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

"PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

Provenge® has FDA approved labeling for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

We are opening this national coverage analysis to determine whether or not autologous cellular immunotherapy is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

#### Requestor Name(s)

Internally generated by CMS

#### Formal Request Accepted and Review Initiated

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**

Lori Paserchia, MD

**Actions Taken**

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010.

Instructions on submitting public comments can be found at

[http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**

**Rollins, James (CMS/OCSQ)**

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**From:** Brocato-Simons, Patricia M. (CMS/OCSQ)  
**Sent:** Wednesday, July 07, 2010 3:25 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ)  
**Subject:** FW: Joint Signature Memorandum (RO-7092, 07-07-10 ) JSM/TDL-10351  
**Attachments:** JSMTDL-10351.doc

**FYI**

---

**From:** CMS DRI  
**Sent:** Wednesday, July 07, 2010 3:22 PM  
**Subject:** Joint Signature Memorandum (RO-7092, 07-07-10 ) JSM/TDL-10351

Subject(s) included in this note:

**Medicare Part B Payment for PROVENGE® (sipuluecel-T) as an "Incident to" Drug/Biological**  
**Filename(s): JSMTDL-10351.doc**

If you are a carrier and have any questions, please contact John Warren on (410) 786-3633 and Ismael Torres at (410) 786-1864 for questions or concerns related to the distribution/transmission of this document.

/s/

Carlos Simon  
Acting Director, Issuances and Records Management Group  
Office of Strategic Operations and Regulatory Affairs  
Centers for Medicare & Medicaid Services

## **Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 8:58 AM  
**To:** Pencek, Eileen (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** FW: provenge comments

Jim:

Eileen is building the excel spreadsheet for the comments in order to know the number of comments that have been cleared of PHI by Elaine and Jon while Elaine is on vacation.

I have reviewed most of the comments and find that the vast majority are unhappy with the NCA and feel that PROVENGE has been approved for marketing by the FDA, costs less than chemotherapy, has far fewer side effects than chemotherapy and thus improves quality of life, is the only alternative treatment other than chemotherapy, and extends life by 4 months. They are concerned that patients will not have access to PROVENGE in for 1 year while we perform the analysis and feel that Medicare is more concerned with the cost of the treatment than the FDA approval of it as efficacious and safe.

Eileen:

Have you had a chance to review the comments to be able to provide Jim with the answers to the number of comments, the breakdown by affiliation/type of commenters, and add to the summary of the general sentiment of the audience?

Thanks again for your assistance with this huge task.

Leslye

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 7:01 AM  
**To:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** provenge comments

Hello Leslye, hope it's not too hot in Roanoke. Two days ago the temp was 105 here in Baltimore. Being in the mountains it should be a little bit cooler. Just wanted to see how many responses we have had on provenge. Also what is the general sentiment of the audience, and what is the breakdown in terms of who is responding. Take care. Jarollins

**Rollins, James (CMS/OCSQ)**

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**Subject:** RE: provenge comments

Leslye,

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I will send you and excel file this afternoon.

Eileen

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 9:02 AM  
**To:** Pencek, Eileen (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: provege comments

Thanks Eileen.

---

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**Sent:** Thursday, July 08, 2010 9:01 AM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
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**Rollins, James (CMS/OCSQ)**

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**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 9:52 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** FW: See section on Provenge

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**From:** Tillman, Katherine K. (CMS/OCSQ)  
**Sent:** Thursday, July 08, 2010 9:44 AM  
**To:** SCHAFER, JYME H. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** See section on Provenge

<http://notablecalls.blogspot.com/>

*Kate Tillman, RN, MA  
Technical Advisor  
Coverage and Analysis Group  
Office of Clinical Standards and Quality  
(410)786-9252  
[katherine.tillman@cms.hhs.gov](mailto:katherine.tillman@cms.hhs.gov)*

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:38 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rinker, Karen A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Webb provenge lkf 070810 (2) kr lbj.doc  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj.doc

**Rollins, James (CMS/OCSQ)**

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**Sent:** Friday, July 09, 2010 3:38 PM  
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**Subject:** Webb provenge lkf 070810 (2) kr lbj.doc  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj.doc

**Rollins, James (CMS/OCSQ)**

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**From:** Ashby, Lori M. (CMS/OCSQ)  
**Sent:** Monday, July 12, 2010 11:29 AM  
**To:** Schiff, Pamela M. (CMS/OCSQ); Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Debnam, Theresa T. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** FW: Webb provenge lkf 070810 (2) kr lbj.doc  
**Attachments:** Webb provenge lkf 070810 (2) kr lbj (2).doc

Please see attached for our response to the Webb letter. I'll be at training at 7111 all afternoon, but I do not believe that I owe you anything else this afternoon. I'll be around for a bit longer, so please let me know if there's something I need to get to get to you guys today.

Jim: Please give the blue folder with the incoming letter and control documents to Theresa (please be sure to sign the clearance sheet on the front of the folder) so she can get Louis to sign off on it and get it to BOS. Thanks!

**Lori M. Ashby**

Special Assistant  
OCSQ/Coverage and Analysis Group  
410-786-6322  
[Lori.Ashby@cms.hhs.gov](mailto:Lori.Ashby@cms.hhs.gov)

**Notice:** The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Centers for Medicare & Medicaid Services. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use the information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 09, 2010 3:56 PM  
**To:** Ashby, Lori M. (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Webb provenge lkf 070810 (2) kr lbj.doc

## **Rollins, James (CMS/OCSQ)**

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**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Fine with me but we should clarify what we mean by "all other preparatory procedures" in the October 2010 OPPS Update CR.

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**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about?

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Provenge Package Insert  
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Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

RE: Cath, colon, retro imaging

26 characters, including spaces. Fine with me.

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Cc: KUSHNIROVA, MARINA (CMS/CMM)  
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Importance: High

Please review the proposed short and long descriptors for item #1 and #6 below. Item #1 is for the Retroscope device and item #6 is for Provenge. I have provided two proposed long descriptors for Provenge. Let me know which one you prefer. Or, if you would prefer to describe Provenge in some other way, then please let me know. I didn't want use the word "supply of" in the Provenge C-code descriptor because we're identifying this item as a pass-through drug under the OPPS. I would appreciate your comments by this Thursday.

Marina,

Can we assign APC 1749 for C1749?

1) Trade Name: Third Eye Retroscope (Pass-Through Device)  
HCPCS Code: C1749  
Short Descriptor: Cath, imaging colonoscope  
Long Descriptor: Catheter, retrograde imaging/illumination colonoscope device (implantable)  
SI: H  
APC: 1749 (confirm with Marina)  
Effective date: October 1, 2010

2) Trade Name: Berinert  
HCPCS Code: C9269  
Short Descriptor: C-1 esterase, berinert  
Long Descriptor: Injection, C-1 esterase inhibitor (human), Berinert, 10 units  
SI: G  
APC: 9269  
Effective date: October 1, 2010

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HCPCS Code: C9270  
Short Descriptor: Gammaplex IVIG  
Long Descriptor: Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg  
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Effective date: October 1, 2010

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HCPCS Code: C9272  
Short Descriptor: Inj, denosumab  
Long Descriptor: Injection, denosumab, 1 mg  
SI: G  
APC: 9272  
Effective date: October 1, 2010

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HCPCS Code: C9273  
Short Descriptor: Sipuleucel-T, per infusion

Long Descriptor 1: Sipuleucel-T, 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

Or

Long Descriptor 2: Sipuleucel-T, per infusion

SI: G

APC: 9273

Effective date: October 1, 2010

## **Rollins, James (CMS/OCSQ)**

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**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

That is fine - we'll draft some language from the PT app and send to Edith to review. Any hints on what you want "other preparatory procedures" to include - at a minimum?

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APC: 1749 (confirm with Marina)  
Effective date: October 1, 2010

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HCPCS Code: C9269  
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Long Descriptor: Injection, velaglucerase alfa, 100 units  
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APC: 9271  
Effective date: October 1, 2010

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APC: 9272  
Effective date: October 1, 2010

6) Trade Name: Provenge (Pass-Through Drug)  
HCPCS Code: C9273

Short Descriptor: Sipuleucel-T, per infusion

Long Descriptor 1: Sipuleucel-T, 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

Or

Long Descriptor 2: Sipuleucel-T, per infusion

SI: G

APC: 9273

Effective date: October 1, 2010

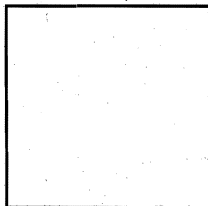
## Rollins, James (CMS/OCSQ)

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 16, 2010 8:15 AM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** FW: [MARKETING EMAIL]ALERT - Your Support Needed!

---

**From:** Thomas A. Farrington [<mailto:thomas@prostatehealthd.org>]  
**Sent:** Friday, July 16, 2010 8:04 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** [MARKETING EMAIL]ALERT - Your Support Needed!



**Thomas A. Farrington**  
**President**  
**July 15, 2010**

**Less than two months ago on April 29th, it was announced that Provenge, the first 'active cellular immunotherapy' treatment for any type of cancer** had been approved for the treatment of prostate cancer. This Federal Drug Administration (FDA) approval came after years of clinical trials to ascertain that this new treatment indeed met the mandatory effectiveness and safety criteria established by the agency. The results of the clinical trials were indisputable.

Once the FDA approves a new treatment the Centers for Medicare and Medicaid (CMS) normally will reimburse for the cost of the treatment. However, for Provenge, CMS has announced that they will make a "national determination" on whether to reimburse for Provenge treatments. This will be a process that could last for up to a year. The first part of the process includes a public comment period which closes on July 30, 2010.

I have posted my comment below and I am requesting that everyone consider making a brief comment to state their position. Comments can be made, and the comments of others reviewed easily and quickly at this link: [Post Your Comment](#)

### **Public Comment of Thomas Farrington:**

The development of new treatments for prostate cancer has lagged behind those for some of the other leading types of cancer. This is in spite of the disease being the leading cause of

cancer among men. Provenge is the first significant new treatment for prostate cancer since chemotherapy, and its approval by the FDA has created a sense of new hope and excitement among those suffering from the disease and those researching new treatments.

Based on the clinical trials data used by the FDA for its approval, there is no question that Provenge provides a greater survival benefit when compared to chemotherapy, with far fewer side effects and for approximately the same overall treatment cost. Using this comparison alone CMS should grant national reimbursement coverage for Provenge.

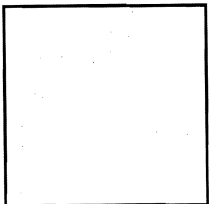
Some of our nation's leading medical researchers have cited Provenge as a "groundbreaking" new type of treatment that could revolutionize the treatment for prostate and other cancers. However, should CMS not allow for reimbursement for this new pioneering treatment then the future of other active cellular immunotherapy treatments would be jeopardized. This would not be in the best interests of patients or taxpayers.

Consistent with its reimbursement policies for chemotherapy treatments for prostate cancer, I urge the CMS to grant national coverage for Provenge. This will immediately benefit prostate cancer patients and support the continued development and evolution of much needed new cancer treatments.

>

**Dendreon News Release on Provenge Approval**  
News Release

You are subscribed as [Louis.Jacques@cms.hhs.gov](mailto:Louis.Jacques@cms.hhs.gov). To unsubscribe please [click here](#).



■



From: Ritter, Christina S. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 3:52 PM  
To: Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I like Barry's revision to the short descriptor. I prefer the long descriptor 1 for Provenge, but am worried that we need to say "a minimum of 50 million autologous .. Doe this addition not fit in the long descriptor limit?

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 2:13 PM  
To: Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Ritter, Christina S. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

What do you all think of the proposed coding for Retroscope and Provenge?

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:55 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

RE: Cath, colon, retro imaging

26 characters, including spaces. Fine with me.

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:54 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about: Cath, colon, retro imaging

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:39 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Barry,

The short descriptor is limited to only 28 characters, and this include spaces. Any recommendation on how it should read?

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:34 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

For the Retroscope, should the short descriptor include reference to the retro view?

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:06 AM  
To: Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: October 2010 Update: C-codes Approved for OPPS Pass-Through Status  
Importance: High

Please review the proposed short and long descriptors for item #1 and #6 below. Item #1 is for the Retroscope device and item #6 is for Provenge. I have provided two proposed long descriptors for Provenge. Let me know which one you prefer. Or, if you would prefer to describe Provenge in some other way, then please let me know. I didn't want use the word "supply of" in the Provenge C-code descriptor because we're identifying this item as a pass-through drug under the OPPS. I would appreciate your comments by this Thursday.

Marina,

Can we assign APC 1749 for C1749?

1) Trade Name: Third Eye Retroscope (Pass-Through Device)  
HCPCS Code: C1749  
Short Descriptor: Cath, imaging colonoscope  
Long Descriptor: Catheter, retrograde imaging/illumination colonoscope device (implantable)  
SI: H  
APC: 1749 (confirm with Marina)  
Effective date: October 1, 2010

2) Trade Name: Berinert  
HCPCS Code: C9269  
Short Descriptor: C-1 esterase, berinert  
Long Descriptor: Injection, C-1 esterase inhibitor (human), Berinert, 10 units

SI: G  
APC: 9269  
Effective date: October 1, 2010

3) Trade Name: Gammaplex (Pass-Through Drug)  
HCPCS Code: C9270  
Short Descriptor: Gammaplex IVIG  
Long Descriptor: Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg

SI: G  
APC: 9270  
Effective date: October 1, 2010

4) Trade Name: Vpriv (Pass-Through Drug)  
HCPCS Code: C9271  
Short Descriptor: Velaglucerase alfa  
Long Descriptor: Injection, velaglucerase alfa, 100 units  
SI: G  
APC: 9271  
Effective date: October 1, 2010

5) Trade Name: Prolia (Pass-Through Drug)  
HCPCS Code: C9272  
Short Descriptor: Inj, denosumab  
Long Descriptor: Injection, denosumab, 1 mg  
SI: G

APC: 9272

Effective date: October 1, 2010

6) Trade Name: Provenge (Pass-Through Drug)

HCPCS Code: C9273

Short Descriptor: Sipuleucel-T, per infusion

Long Descriptor 1: Sipuleucel-T, 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

Or

Long Descriptor 2: Sipuleucel-T, per infusion

SI: G

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Effective date: October 1, 2010

**Rollins, James (CMS/OCSQ)**

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**Sent:** Thursday, July 15, 2010 10:54 AM  
**To:** Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

(b)(5) - Predecisional

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what others think.

Let's see

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**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

That is fine - we'll draft some language from the PT app and send to Edith to review. Any hints on what you want "other preparatory procedures" to include - at a minimum?

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**From:** Baldo, Marjorie D. (CMS/CMM)  
**Sent:** Thursday, July 15, 2010 10:51 AM  
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**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Fine with me but we should clarify what we mean by "all other preparatory procedures" in the October 2010 OPPS Update CR.

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**From:** Hambrick, Edith L. (CMS/CMM)  
**Sent:** Thursday, July 15, 2010 10:49 AM  
**To:** Huq, Alpha-Banu (CMS/CMM); Baldo, Marjorie D. (CMS/CMM)  
**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about?

Long Descriptor 1: Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's, including leukapheresis and all other preparatory procedures, per infusion

-----Original Message-----

From: Huq, Alpha-Banu (CMS/CMM)  
Sent: Thursday, July 15, 2010 8:30 AM  
To: Baldo, Marjorie D. (CMS/CMM); Hambrick, Edith L. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Did we finalize a long descriptor for Provenge?

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From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Wednesday, July 14, 2010 8:06 AM  
To: Hambrick, Edith L. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Third Eye Retroscope: Any suggestion on how the long descriptor should read?

Provenge: If we don't say "per infusion" in the descriptor, will the C-code apply to all 3 infusions of Provenge? Here's what the package insert says about the cells.

How will I get PROVENGE?

Since PROVENGE is made from your own immune cells, your cells will be collected approximately 3 days before each scheduled infusion of PROVENGE. You will need to go to a cell collection center for this collection. The collection is called "leukapheresis" (pronounced loo-kuh-fuh-REE-sis). Your collected cells are sent to a special manufacturing center where they are mixed with a protein to make them ready for your infusion.

You will get PROVENGE in 3 intravenous infusions (put into your veins), about 2 weeks apart. Each infusion takes about 60 minutes. Following each infusion, you will be monitored for at least 30 minutes.

Your doctor will give you a schedule for your cell collection and infusion appointments. It is very important that you arrive on time for your appointments. If you miss an appointment and cannot be infused, your PROVENGE dose will not be usable. Your doctor will work with you to schedule a new appointment at the cell collection center. You may also get a new infusion appointment.

Provenge Package Insert  
<http://www.provenge.com/pdf/prescribing-information.pdf>

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Sent: Wednesday, July 14, 2010 7:54 AM  
To: Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I think this may also include collection of the cells, etc, so I think we should include that in the descriptor. That is part of the cost of the drug. I am not sure about the infusion.

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From: Ritter, Christina S. (CMS/CMM)  
Sent: Wed 7/14/2010 6:59 AM  
To: Baldo, Marjorie D. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I'm good with that - anyone else

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From: Baldo, Marjorie D. (CMS/CMM)  
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To: Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
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**Rollins, James (CMS/OCSQ)**

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**Sent:** Friday, July 16, 2010 9:32 AM  
**To:** Hambrick, Edith L. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
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**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Marina:

Did you confirm that APC 1749 is available for C1749? Thanks.

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**Sent:** Thu 7/15/2010 10:54 AM  
**To:** Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
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To: Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I like Barry's revision to the short descriptor. I prefer the long descriptor 1 for Provenge, but am worried that we need to say "a minimum of 50 million autologous .. Doe this addition not fit in the long descriptor limit?

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 2:13 PM  
To: Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Ritter, Christina S. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

What do you all think of the proposed coding for Retroscope and Provenge?

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:55 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

RE: Cath, colon, retro imaging

26 characters, including spaces. Fine with me.

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:54 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about: Cath, colon, retro imaging

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:39 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Barry,

The short descriptor is limited to only 28 characters, and this include spaces. Any recommendation on how it should read?

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:34 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)

Cc: KUSHNIROVA, MARINA (CMS/CMM)

Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

For the Retroscope, should the short descriptor include reference to the retro view?

From: Baldo, Marjorie D. (CMS/CMM)

Sent: Tuesday, July 13, 2010 9:06 AM

To: Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)

Cc: KUSHNIROVA, MARINA (CMS/CMM)

Subject: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Importance: High

Please review the proposed short and long descriptors for item #1 and #6 below. Item #1 is for the Retroscope device and item #6 is for Provenge. I have provided two proposed long descriptors for Provenge. Let me know which one you prefer. Or, if you would prefer to describe Provenge in some other way, then please let me know. I didn't want use the word "supply of" in the Provenge C-code descriptor because we're identifying this item as a pass-through drug under the OPPS. I would appreciate your comments by this Thursday.

Marina,

Can we assign APC 1749 for C1749?

1) Trade Name: Third Eye Retroscope (Pass-Through Device)

HCPCS Code: C1749

Short Descriptor: Cath, imaging colonoscope

Long Descriptor: Catheter, retrograde imaging/illumination colonoscope device (implantable)

SI: H

APC: 1749 (confirm with Marina)

Effective date: October 1, 2010

2) Trade Name: Berinert

HCPCS Code: C9269

Short Descriptor: C-1 esterase, berinert

Long Descriptor: Injection, C-1 esterase inhibitor (human), Berinert, 10 units

SI: G

APC: 9269

Effective date: October 1, 2010

3) Trade Name: Gammaplex (Pass-Through Drug)

HCPCS Code: C9270

Short Descriptor: Gammaplex IVIG

Long Descriptor: Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg

SI: G

APC: 9270

Effective date: October 1, 2010

4) Trade Name: Vpriv (Pass-Through Drug)

HCPCS Code: C9271

Short Descriptor: Velaglucerase alfa

Long Descriptor: Injection, velaglucerase alfa, 100 units

SI: G

APC: 9271

Effective date: October 1, 2010

5) Trade Name: Prolia (Pass-Through Drug)

HCPCS Code: C9272

Short Descriptor: Inj, denosumab

Long Descriptor: Injection, denosumab, 1 mg

SI: G

APC: 9272

Effective date: October 1, 2010

6) Trade Name: Provenge (Pass-Through Drug)

HCPCS Code: C9273

Short Descriptor: Sipuleucel-T, per infusion

Long Descriptor 1: Sipuleucel-T, 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

Or

Long Descriptor 2: Sipuleucel-T, per infusion

SI: G

APC: 9273

Effective date: October 1, 2010





**Rollins, James (CMS/OCSQ)**

---

**From:** KUSHNIROVA, MARINA (CMS/CMM)  
**Sent:** Friday, July 16, 2010 9:36 AM  
**To:** Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
**Cc:** Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Yes

Marina Kushnirova M.S.  
Health Insurance Specialist  
Centers for Medicare & Medicaid  
Center for Medicare  
Hospital & Ambulatory Policy Group  
Division of Outpatient Care  
marina.kushnirova@cms.hhs.gov

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-----Original Message-----

**From:** Levi, Barry I. (CMS/CMM)  
**Sent:** Friday, July 16, 2010 9:32 AM  
**To:** Hambrick, Edith L. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Marina:

Did you confirm that APC 1749 is available for C1749? Thanks.

-----Original Message-----

**From:** Hambrick, Edith L. (CMS/CMM)  
**Sent:** Thu 7/15/2010 10:54 AM  
**To:** Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
**Cc:** KUSHNIROVA, MARINA (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

(b)(5) - Predecisional

(b)(5) - Predecisional  
what others think.

Let's see

-----Original Message-----

From: Ritter, Christina S. (CMS/CMM)  
Sent: Thursday, July 15, 2010 10:53 AM  
To: Baldo, Marjorie D. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

That is fine - we'll draft some language from the PT app and send to Edith to review. Any hints on what you want "other preparatory procedures" to include - at a minimum?

-----Original Message-----

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Thursday, July 15, 2010 10:51 AM  
To: Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Fine with me but we should clarify what we mean by "all other preparatory procedures" in the October 2010 OPPS Update CR.

-----Original Message-----

From: Hambrick, Edith L. (CMS/CMM)  
Sent: Thursday, July 15, 2010 10:49 AM  
To: Huq, Alpha-Banu (CMS/CMM); Baldo, Marjorie D. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Kasaitis, Edmund E. (CMS/CMM); Warren, John F. (CMS/CMM); Jacques, Louis B. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about?

Long Descriptor 1: Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's, including leukapheresis and all other preparatory procedures, per infusion

-----Original Message-----

From: Huq, Alpha-Banu (CMS/CMM)  
Sent: Thursday, July 15, 2010 8:30 AM  
To: Baldo, Marjorie D. (CMS/CMM); Hambrick, Edith L. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Did we finalize a long descriptor for Provenge?

-----Original Message-----

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Wednesday, July 14, 2010 8:06 AM  
To: Hambrick, Edith L. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Third Eye Retroscope: Any suggestion on how the long descriptor should read?

Provenge: If we don't say "per infusion" in the descriptor, will the C-code apply to all 3 infusions of Provenge? Here's what the package insert says about the cells.

How will I get PROVENGE?

Since PROVENGE is made from your own immune cells, your cells will be collected approximately 3 days before each scheduled infusion of PROVENGE. You will need to go to a cell collection center for this collection. The collection is called "leukapheresis" (pronounced loo-kuh-fuh-REE-sis). Your collected cells are sent to a special manufacturing center where they are mixed with a protein to make them ready for your infusion.

You will get PROVENGE in 3 intravenous infusions (put into your veins), about 2 weeks apart. Each infusion takes about 60 minutes. Following each infusion, you will be monitored for at least 30 minutes.

Your doctor will give you a schedule for your cell collection and infusion appointments. It is very important that you arrive on time for your appointments. If you miss an appointment and cannot be infused, your PROVENGE dose will not be usable. Your doctor will work with you to schedule a new appointment at the cell collection center. You may also get a new infusion appointment.

Provenge Package Insert  
<http://www.provenge.com/pdf/prescribing-information.pdf>

-----Original Message-----

From: Hambrick, Edith L. (CMS/CMM)  
Sent: Wednesday, July 14, 2010 7:54 AM  
To: Ritter, Christina S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Levi, Barry I. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I think this may also include collection of the cells, etc, so I think we should include that in the descriptor. That is part of the cost of the drug. I am not sure about the infusion.

-----Original Message-----

From: Ritter, Christina S. (CMS/CMM)

Sent: Wed 7/14/2010 6:59 AM

To: Baldo, Marjorie D. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)

Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)

Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I'm good with that - anyone else

-----Original Message-----

From: Baldo, Marjorie D. (CMS/CMM)

Sent: Wed 7/14/2010 6:45 AM

To: Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)

Cc: KUSHNIROVA, MARINA (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)

Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

The long descriptor field is limited to 80 characters per line. Some of the E/M codes are over 500 characters, and have to go on multiple lines. I'm perfectly fine with your suggestion. How about this for the long descriptor? This is about 117 characters, and on the HCPCS tape, the long descriptor would take up 2 lines.

Long Descriptor 1: Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

From: Ritter, Christina S. (CMS/CMM)

Sent: Tuesday, July 13, 2010 3:52 PM

To: Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)

Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)

Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

I like Barry's revision to the short descriptor. I prefer the long descriptor 1 for Provenge, but am worried that we need to say "a minimum of 50 million autologous .. Doe this addition not fit in the long descriptor limit?

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Sent: Tuesday, July 13, 2010 2:13 PM  
To: Hambrick, Edith L. (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM); Ritter, Christina S. (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

What do you all think of the proposed coding for Retroscope and Provenge?

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Sent: Tuesday, July 13, 2010 9:55 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

RE: Cath, colon, retro imaging

26 characters, including spaces. Fine with me.

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:54 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

How about: Cath, colon, retro imaging

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:39 AM  
To: Levi, Barry I. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM);  
Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

Barry,

The short descriptor is limited to only 28 characters, and this include spaces. Any recommendation on how it should read?

From: Levi, Barry I. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:34 AM  
To: Baldo, Marjorie D. (CMS/CMM); Ritter, Christina S. (CMS/CMM); Hambrick, Edith L. (CMS/CMM); Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: RE: October 2010 Update: C-codes Approved for OPPS Pass-Through Status

For the Retroscope, should the short descriptor include reference to the retro view?

From: Baldo, Marjorie D. (CMS/CMM)  
Sent: Tuesday, July 13, 2010 9:06 AM  
To: Ritter, Christina S. (CMS/CMM); Levi, Barry I. (CMS/CMM); Hambrick, Edith L. (CMS/CMM);  
Huq, Alpha-Banu (CMS/CMM); Simon, Kenneth B. (CMS/CMM); Bullock, Carrie (CMS/CMM)  
Cc: KUSHNIROVA, MARINA (CMS/CMM)  
Subject: October 2010 Update: C-codes Approved for OPPS Pass-Through Status  
Importance: High

Please review the proposed short and long descriptors for item #1 and #6 below. Item #1 is for the Retroscope device and item #6 is for Provenge. I have provided two proposed long descriptors for Provenge. Let me know which one you prefer. Or, if you would prefer to describe Provenge in some other way, then please let me know. I didn't want use the word "supply of" in the Provenge C-code descriptor because we're identifying this item as a pass-through drug under the OPPS. I would appreciate your comments by this Thursday.

Marina,

Can we assign APC 1749 for C1749?

1) Trade Name: Third Eye Retroscope (Pass-Through Device)  
HCPCS Code: C1749  
Short Descriptor: Cath, imaging colonoscope  
Long Descriptor: Catheter, retrograde imaging/illumination colonoscope device (implantable)  
SI: H  
APC: 1749 (confirm with Marina)  
Effective date: October 1, 2010

2) Trade Name: Berinert  
HCPCS Code: C9269  
Short Descriptor: C-1 esterase, berinert  
Long Descriptor: Injection, C-1 esterase inhibitor (human), Berinert, 10 units  
SI: G  
APC: 9269  
Effective date: October 1, 2010

3) Trade Name: Gammaplex (Pass-Through Drug)  
HCPCS Code: C9270  
Short Descriptor: Gammaplex IVIG



Long Descriptor: Injection, immune globulin (Gammaplex), intravenous, non-lyophilized  
(e.g. liquid), 500 mg

SI: G

APC: 9270

Effective date: October 1, 2010

4) Trade Name: Vpriv (Pass-Through Drug)

HCPCS Code: C9271

Short Descriptor: Velaglucerase alfa

Long Descriptor: Injection, velaglucerase alfa, 100 units

SI: G

APC: 9271

Effective date: October 1, 2010

5) Trade Name: Prolia (Pass-Through Drug)

HCPCS Code: C9272

Short Descriptor: Inj, denosumab

Long Descriptor: Injection, denosumab, 1 mg

SI: G

APC: 9272

Effective date: October 1, 2010

6) Trade Name: Provenge (Pass-Through Drug)

HCPCS Code: C9273

Short Descriptor: Sipuleucel-T, per infusion

Long Descriptor 1: Sipuleucel-T, 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's

Or

Long Descriptor 2: Sipuleucel-T, per infusion

SI: G

APC: 9273

Effective date: October 1, 2010

**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Monday, July 19, 2010 9:08 AM  
**To:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** RE: draft of feature article for Renal & Urology News  
**Attachments:** dy--PROVENGE edit lf 071910.doc

Shanterri:

Attached please find the article for *Renal and Urology News* with comments from CMS that address the timeframe for the NCA. It will occur over 12 months rather nine months as stated in the article for the reasons made in the comment.

Leslye

---

**From:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Sent:** Thursday, July 15, 2010 4:20 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Subject:** FW: draft of feature article for Renal & Urology News

resending

*Shanterri Brown-Jones*  
Correspondence Liaison Specialist  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Email: [SBrownJones@cms.hhs.gov](mailto:SBrownJones@cms.hhs.gov)  
Tel: 410-786-6854  
Fax: 410-786-6857

---

**From:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Sent:** Thursday, July 15, 2010 4:17 PM  
**To:** FITTERMAN, LESLYE K. (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ)  
**Subject:** FW: draft of feature article for Renal & Urology News

Hi Leslie,

Can you take a look at this and check for any factual errors by COB tomorrow?

Thank You

*Shanterri Brown-Jones*  
Correspondence Liaison Specialist  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Email: [SBrownJones@cms.hhs.gov](mailto:SBrownJones@cms.hhs.gov)  
Tel: 410-786-6854  
Fax: 410-786-6857

---

**From:** McLeod, Donald E. (CMS/OEA)  
**Sent:** Thursday, July 15, 2010 3:30 PM  
**To:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Subject:** FW: draft of feature article for Renal & Urology News

Shanterri

Can you have somebody check this for errors? Thanks.  
Don

---

**From:** Jody Charnow [<mailto:Jody.Charnow@HaymarketMedia.com>]  
**Sent:** Thursday, July 15, 2010 3:27 PM  
**To:** McLeod, Donald E. (CMS/OEA)  
**Subject:** draft of feature article for Renal & Urology News

Dear Mr. McLeod:

Attached, for your review, is a draft of a feature article for *Renal & Urology News* that discusses ethical considerations related to Provenge. The article includes quotes from you (although not attributed to you) as reported by staff writer Delicia Honen Yard. If you would like to correct any inaccuracies, please indicate in the attached document where you make changes and e-mail the amended draft to me by July 19. Thank you.

Sincerely,

Jody A. Charnow  
Editor  
Renal & Urology News  
114 W. 26th St. 4th FL  
New York, N.Y. 10001  
(646) 638-6089

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Haymarket Media Group Limited Registered in England no. 267189 Registered Office: 174 Hammersmith Road, London W6 7JP --ES

## **Rollins, James (CMS/OCSQ)**

---

**From:** Clapton, Erin M. (CMS/OL)  
**Sent:** Monday, July 19, 2010 5:34 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Leung, Isabella (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer  
**Importance:** High

Hi everyone. We received some follow-up questions on this issue from the Senate Finance Committee. More specifically, they are interested in the following:

- (1) How many local contractors are currently covering Provenge via their LCD process?
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Thanks for your help on this.

Erin M. Clapton  
Director  
Medicare Part A & Part B Analysis Group  
CMS Office of Legislation

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, July 06, 2010 12:41 PM  
**To:** Martino, Maria (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Lewandowski, David S. (CMS/OL); Stieber, Joan (CMS/OL); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

CMS opened this review to evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of Provenge for prostate cancer. We realize that this is a novel type of anticancer treatment, and that FDA is requiring post approval clinical studies. We understand that some local Medicare contractors were covering it while others were not, both positions not unreasonable, based on the limitations of the current scientific evidence.

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(202) 690-5512

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4-5862

**NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)** **COMMENT**

**Issue**

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As described on the FDA website at

<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>,

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**Requestor Name(s)**

Internally generated by CMS

**Formal Request Accepted and Review Initiated**

6/30/2010

**Expected NCA Completion Date**

6/30/2011

**Public Comment Period**

6/30/2010 - 7/30/2010

**Proposed Decision Memo Due Date**

3/30/2011

**Lead Analyst(s)**

Leslye Fitterman, PhD

[Leslye.fitterman3@cms.hhs.gov](mailto:Leslye.fitterman3@cms.hhs.gov)

1-410-786-1802

**Lead Medical Officer(s)**



Lori Paserchia, MD

## Actions Taken

June 30, 2010

CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

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**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, July 19, 2010 7:56 PM  
**To:** Clapton, Erin M. (CMS/OL); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)  
**Cc:** Leung, Isabella (CMS/OL); Stieber, Joan (CMS/OL)  
**Subject:** RE: autologous cellular immunotherapy treatment of prostate cancer  
**Attachments:** image001.gif

Erin,

I'm offsite tomorrow and Wednesday, so here are some quick replies.

1. This is largely done on a case by case basis rather than by LCD, so any number will be less than fully informative. We did not canvass the MACs.
2. The scientific evidence base is sparse. Provenge failed its initial clinical studies. The Provenge regimen appears to be a collection of discrete services. FDA labeling notes stroke risk and requirement for more research about risk.
3. We don't track this unless it's in the annual report to Congress (I don't know), but maybe a third to a half are CMS initiated. Depends on whether reconsiderations of the same NCD are counted separately. We could try to come up with a better estimate if they really want to know.
4. Yes (Recent examples include Abarelix, Zevalin, Bexxar, 4 GI cancer drugs in NCI trials). Doing 20-25 NCDs total a year would not expect that cancer drugs would necessarily be frequent topics.  
As an aside, Provenge is not a typical drug in the usual sense, since it's really immunotherapy using the patient's cells. So the question itself is a bit presumptive in calling it an NCD about a cancer drug. We do plenty of NCDs on cancer topics.
5. Yes, but TAs don't "meet" so the question doesn't really make sense. We have commissioned the TA from AHRQ.
6. No. November 17. 2010.
7. We are receiving public comment on the opening of the NCD. The next notable event is the MEDCAC. By law (1862(1)) the proposed decision is due in a bit under 9 mos, the final 3 mos after the proposed.

Louis

-----Original Message-----

**From:** Clapton, Erin M. (CMS/OL)  
**Sent:** Mon 7/19/2010 5:34 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
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Medicare Part A & Part B Analysis Group

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Lead Analyst(s)

Leslye Fitterman, PhD

Leslye.fitterman3@cms.hhs.gov <mailto:Leslye.fitterman3@cms.hhs.gov?subject=WEB%20EMAIL%20-%20CAG-00422N>

1-410-786-1802

Lead Medical Officer(s)

Lori Paserchia, MD



## Actions Taken

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**Rollins, James (CMS/OCSQ)**

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Wednesday, July 21, 2010 5:00 PM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Provenge TA SOW

Elise:

Please call me about the SOW with BCBS on the "safety and efficacy of Provenge". Thanks –

Received a very nice thank you note from David!

Leslye  
Phone - 410-786-1806  
Email - [Leslye.Fitterman3@cms.hhs.gov](mailto:Leslye.Fitterman3@cms.hhs.gov)

## Rollins, James (CMS/OCSQ)

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**Sent:** Wednesday, July 21, 2010 5:13 PM  
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**Subject:** Re: autologous cellular immunotherapy treatment of prostate cancer

Louis sent a response to Erin on Monday evening. There was no follow up email from Erin so I think she was satisfied.

Sent from my iPhone

On Jul 21, 2010, at 5:08 PM, "Rollins, James (CMS/OCSQ)" <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)> wrote:

Let's get together tomorrow to craft a response to these questions. Jarollins

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**Lead Analyst(s)**

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CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effectiveness of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010.

Instructions on submitting public comments can be found at [http://www.cms.hhs.gov/InfoExchange/02\\_publiccomments.asp](http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp). You can also submit a public comment by clicking on the highlighted word **comment** in the top bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**

||

**Rollins, James (CMS/OCSQ)**

---

**From:** Kouzoukas, Demetrios [dkouzoukas@cov.com]  
**Sent:** Thursday, July 22, 2010 2:01 PM  
**To:** Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** follow-up and background  
**Attachments:** Cancer Experts Threatened A...pdf

James, Leslye, and Elaine:

Here is the article I referenced in my conversations with James and Leslye. If you are open to the procedure I discussed with Leslye -- whereby a commenter could request that their identity not be released, I would be pleased to propose language that such commenters could use and on which basis CMS would then oblige the request.

Thank you very much for your consideration.

-- Demetrios

Demetrios L. Kouzoukas  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401  
<http://www.cov.com/dkouzoukas/dkouzoukas@cov.com>  
Tel: 202.662.5057  
Assistant: Dee Perkins (202.662.6003, [dperkins@cov.com](mailto:dperkins@cov.com))  
Fax: 202.778.5057  
download vcard: <http://www.cov.com/biographies/vcard.aspx?Attorney=13540>

*This message is from a law firm and may contain information that is confidential or legally privileged. If you are not the intended recipient, please immediately advise the sender by reply e-mail that this message has been inadvertently transmitted to you and delete this e-mail from your system. Thank you for your cooperation.*

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 1:52 PM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

We will take their comments seriously even if anonymous

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 1:50 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Demetrius Kouzoukas

Louis, got a phone call from a lawyer (Demetrius Kouzoukas), who has been in contact with a number of providers who would like to make comments on provenge. But because of certain "death threats" that they have received in the past on this product as well as safety concerns, they would prefer not to communicate via our web posting comment mechanism, but would like for us to consider some other way in which they can communicate with us. Demitrius knows that they can comment anonymously, but they are concerned that if they do, then their comments might not be taken seriously and might be looked upon with suspect. They want to be a credible source and would like to convey their concerns about provenge. In closing they want to know what can CMS do to accommodate them without compromising their safety. They said that they would be unwilling to communicate with us unless they get that assurance. Demetrius says he has published articles documenting providers receiving threats after expressing their concerns about products. He will forward these to us. Jarollins

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**Sent:** Thursday, July 22, 2010 2:13 PM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

I'm following up with OGC. In the meantime they can submit anonymously. We have already received some anonymous comments.

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 1:54 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
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**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 2:23 PM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

Is Demetrius willing to submit the comments on behalf of his clients?

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**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 1:54 PM  
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## Rollins, James (CMS/OCSQ)

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 2:27 PM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

I just got the back story from OGC, sit tight

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 2:26 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

Based on our conversation, he would prefer for the commenters to speak for themselves. I have his number and we can discuss alternatives to the web comment process. He said that he will work on behalf of them. Jarollins

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 2:23 PM  
**To:** Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Demetrius Kouzoukas

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**Rollins, James (CMS/OCSQ)**

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Thursday, July 22, 2010 3:17 PM  
**To:** Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); 'Aronson, Naomi'  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge  
**Attachments:** Provenge.doc

Jim and Naomi,

(b)(5) - Predecisional



Thanks,  
Elise

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 8:29 AM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge

The proposal looks fine. What about the budget? Jarollins

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Tuesday, June 22, 2010 9:55 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** provenge

Jim,

Attached is the proposal from BCBSA TEC on Provenge.

Please let me know if you approve this, or if you have any questions or comments. If possible, please send a reply by COB today, we are trying to set up all the paperwork quickly.

Thanks,  
Elise

**Rollins, James (CMS/OCSQ)**

---

**From:** Aronson, Naomi [Naomi.Aronson@bcbsa.com]  
**Sent:** Thursday, July 22, 2010 3:55 PM  
**To:** Berliner, Elise (AHRQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
**Subject:** Re: provenge

Point well taken. May I suggest (b)(5) - Predecisional

(b)(5) -

Naomi Aronson, PhD  
Executive Director  
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Blue Cross Blue Shield Association  
312.297.5530  
[naomi.aronson@bcbsa.com](mailto:naomi.aronson@bcbsa.com)

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**From:** Berliner, Elise (AHRQ) <[Elise.Berliner@ahrq.hhs.gov](mailto:Elise.Berliner@ahrq.hhs.gov)>  
**To:** Rollins, James (CMS/OCSQ) <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)>; Fitterman, Leslye (CMS/OCSQ) <[Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov)>; Aronson, Naomi  
**Cc:** Wittenberg, Kim (AHRQ/COE) <[Kim.Wittenberg@AHRQ.hhs.gov](mailto:Kim.Wittenberg@AHRQ.hhs.gov)>  
**Sent:** Thu Jul 22 14:17:27 2010  
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Jim and Naomi,

(b)(5) - Predecisional

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**Cc:** Wittenberg, Kim (AHRQ/COE)  
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Thanks,  
Elise

## Rollins, James (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 4:02 PM  
**To:** Meister, Mike (HHS/OGC); Burns, Julie (HHS/OGC); Fisher, Barbara (HHS/OGC); Mantoan, Patricia (HHS/OGC); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** Provenge Public Comments

Dear All,

Following up on the issue of anonymous public comments and allegations of death threats to physicians/commenters who are critical of Provenge, I think we should set up a meeting or telecon with relevant Federal participants, which may include FDA and DOJ, to coordinate how we will respond to the allegations, especially if the commenters were to allege scientific misconduct or fraud re: the materials submitted to FDA. So I'd like to get a sense of who should be included from OGC, and whether you have FDA or DOJ contacts who should be included.

We do accept anonymous comments, and I note that some of the names clearly appear to be made up anyway.

So far the comments are largely "my (father/grandfather/husband) (has/had) prostate cancer and Medicare should pay for it..." A few say we should not cover. Some say we should cover but ask us to clearly define the appropriate population and maybe require CED. Some commenters are verbally sniping at each other and alleging that other commenters conflict of interest. Here are two, the first anonymous the second had a name which I redacted.

There is major trial design flaw in trials.FDA/CMS need to investigate further before anyreimbursement. Placebo patients receivedsignificantly less tcells than Provenge armpatients (pbo only received 1/3 cells back). Thisdifference could have led to effect, but becauseof harm in pbo arm.Full analysis here:<http://mfi.re/?zdiewnyttqg4vnz> Provenge Analysis Apologies for anon. Very sorry for patients andappreciate there is very vocal support, which hasbecome very threatening to some researchersththerefore staying anon. Even if this is redacted,do examine the trial design analysis to see themassive flaw

Dear CMS Reviewers,Unfortunately, during the last few years, skepticism about Provenge efficacy and calls for a new thorough review have all been unjustly labelled as disguised attempts of financial entities set to profit from Dendreon's demise. However, you as well as the American public ought to appreciate that there is a large community of physicians and scientists who once were and still remain unconvinced of Provenge efficacy and are committed to saving our fragile cancer patients from receiving an expensive and medically futile treatment. Sadly, there are of course those who do not want us to speak. We have been driven into silence and anonymity because we do value our own life as we value that of our cancer patients: the last few oncology experts who publicly expressed doubts on Provenge were forced out of the scientific debate by murder threats. The FDA approved Provenge under extreme duress, asphyxiating lobbying and congressional pressure. This outside interference was able to crack the system and enable Provenge to escape without receiving appropriate scrutiny. Yet, we appreciate that it would be unfair to ask you to reject the national coverage of Provenge based on the failures of another agency. Then, we simply encourage you to perform full and detailed diligence on Provenge efficacy before offering it to patients at the national expense. We encourage you to consult multiple experts, scrutinize every available data set, employ every alternative perspective outside of the box. Above all, we encourage you to conduct a fair and independent review, unswayed by lobbying efforts and political pressure. Free scientific dialogue and rigorous review are not the killers of hope and miracles, although they are being denounced as such. We encourage you to promote and embrace free dialogue: it is essential for the enunciation of truth. Respectfully,

Louis B. Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Mailstop C1-09-06  
7500 Security Blvd  
Baltimore MD 21244  
(410) 786-4512  
(410) 786-9286 (FAX)  
[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)

## Rollins, James (CMS/OCSQ)

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 4:03 PM  
**To:** Aronson, Naomi; Berliner, Elise (AHRQ); Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
**Subject:** RE: provenge

(b)(5) - Predecisional

---

**From:** Aronson, Naomi [<mailto:Naomi.Aronson@bcbsa.com>]  
**Sent:** Thursday, July 22, 2010 3:55 PM  
**To:** Berliner, Elise (AHRQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
**Subject:** Re: provenge

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**To:** Rollins, James (CMS/OCSQ) <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)>; Fitterman, Leslye (CMS/OCSQ) <[Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov)>; Aronson, Naomi  
**Cc:** Wittenberg, Kim (AHRQ/COE) <[Kim.Wittenberg@AHRQ.hhs.gov](mailto:Kim.Wittenberg@AHRQ.hhs.gov)>  
**Sent:** Thu Jul 22 14:17:27 2010  
**Subject:** RE: provenge

Jim and Naomi,

(b)(5) - Predecisional

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**Cc:** Wittenberg, Kim (AHRQ/COE)  
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**From:** Aronson, Naomi [Naomi.Aronson@bcbsa.com]  
**Sent:** Thursday, July 22, 2010 4:06 PM  
**To:** Rollins, James (CMS/OCSQ); Berliner, Elise (AHRQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
**Subject:** Re: provenge

(b)(5) - Predecisional

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Executive Director  
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312.297.5530  
[naomi.aronson@bcbsa.com](mailto:naomi.aronson@bcbsa.com)

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**From:** Rollins, James (CMS/OCSQ) <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)>  
**To:** Aronson, Naomi; Berliner, Elise (AHRQ) <[Elise.Berliner@ahrq.hhs.gov](mailto:Elise.Berliner@ahrq.hhs.gov)>; Fitterman, Leslye (CMS/OCSQ) <[Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov)>  
**Cc:** Wittenberg, Kim (AHRQ/COE) <[Kim.Wittenberg@AHRQ.hhs.gov](mailto:Kim.Wittenberg@AHRQ.hhs.gov)>; Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
**Sent:** Thu Jul 22 14:57:32 2010  
**Subject:** RE: provenge

(b)(5) - Predecisional

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**From:** Aronson, Naomi [<mailto:Naomi.Aronson@bcbsa.com>]  
**Sent:** Thursday, July 22, 2010 3:55 PM  
**To:** Berliner, Elise (AHRQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); Mark, David; Flaherty, Sharon; Sarsany, Lisa; Ziegler, Kathleen  
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**Rollins, James (CMS/OCSQ)**

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 22, 2010 4:20 PM  
**To:** clockett@dendreon.com  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Meeting with Dendreon at CMS

Dear Mr. Lockett:

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We looking forward to meeting with you on August 3<sup>rd</sup>.

Regards, Leslye

Leslye Fitterman, PhD.  
Centers for Medicare and Medicaid Services  
Office of Clinical Standards and Quality  
Coverage and Analysis Group  
7500 Security Boulevard  
C1-09-06  
Fax - 410-786-9286  
Phone - 410-786-1806  
Email - [Leslye.Fitterman3@cms.hhs.gov](mailto:Leslye.Fitterman3@cms.hhs.gov)

**Rollins, James (CMS/OCSQ)**

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**Sent:** Thursday, July 22, 2010 4:25 PM  
**To:** 'Aronson, Naomi'; Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE); 'Mark, David'; 'Flaherty, Sharon'; 'Sarsany, Lisa'; 'Ziegler, Kathleen'  
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CMS team,

let us know which you prefer.

(b)(5) - Predecisional

Elise

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**Sent:** Thursday, July 22, 2010 10:16 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: Meeting with Dendreon at CMS

Why do they need clarification? Where is comparative effectiveness coming into play?

We need to maintain an arms length relationship with them. We do not owe them any specific questions. They can present their evidence and we will listen and our questions will depend on their presentation.

-----Original Message-----

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thu 7/22/2010 4:19 PM  
**To:** [clockett@dendreon.com](mailto:clockett@dendreon.com)  
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Regards, Leslye

Leslye Fitterman, PhD.

Centers for Medicare and Medicaid Services

Office of Clinical Standards and Quality

Coverage and Analysis Group

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C1-09-06

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**From:** Berliner, Elise (AHRQ) <[Elise.Berliner@ahrq.hhs.gov](mailto:Elise.Berliner@ahrq.hhs.gov)>

**To:** Rollins, James (CMS/OCSQ) <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)>; Fitterman, Leslye (CMS/OCSQ) <[Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov)>; Aronson, Naomi

**Cc:** Wittenberg, Kim (AHRQ/COE) <[Kim.Wittenberg@AHRQ.hhs.gov](mailto:Kim.Wittenberg@AHRQ.hhs.gov)>

**Sent:** Thu Jul 22 14:17:27 2010

**Subject:** RE: provenge



Jim and Naomi,

(b)(5) - Predecisional

(b)(5) - Predecisional

Thanks,

Elise

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Thursday, June 24, 2010 8:29 AM  
**To:** Berliner, Elise (AHRQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** RE: provenge

The proposal looks fine. What about the budget? Jarollins

---

**From:** Berliner, Elise (AHRQ)  
**Sent:** Tuesday, June 22, 2010 9:55 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Wittenberg, Kim (AHRQ/COE)  
**Subject:** provenge

Jim,

Attached is the proposal from BCBSA TEC on Provenge.

Please let me know if you approve this, or if you have any questions or comments. If possible, please send a reply by COB today, we are trying to set up all the paperwork quickly.

Thanks,

Elise

## Rollins, James (CMS/OCSQ)

---

**From:** Kouzoukas, Demetrios [dkouzoukas@cov.com]  
**Sent:** Friday, July 23, 2010 4:29 PM  
**To:** Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** RE: follow-up and background

Is there any more information, or perhaps draft language, I can provide to help you consider how best to proceed at this point?

-- Demetrios

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---

oukas, Demetrios  
ay, July 22, 2010 2:01 PM  
[Rollins2@CMS.hhs.gov](mailto:Rollins2@CMS.hhs.gov); [Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov); [Elaine.Dolina@cms.hhs.gov](mailto:Elaine.Dolina@cms.hhs.gov)  
follow-up and background

James, Leslye, and Elaine:

Here is the article I referenced in my conversations with James and Leslye. If you are open to the procedure I discussed with Leslye -- whereby a commenter could request that their identity not be released, I would be pleased to propose language that such commenters could use and on which basis CMS would then oblige the request.

Thank you very much for your consideration.

<< File: Cancer Experts Threatened A...pdf >>

-- Demetrios

Demetrios L. Kouzoukas  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401  
<http://www.cov.com/dkouzoukas/dkouzoukas@cov.com>  
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Fax: 202.778.5057  
download vcard: <http://www.cov.com/biographies/vcard.aspx?Attorney=13540>

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## Rollins, James (CMS/OCSQ)

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, July 23, 2010 5:35 PM  
**To:** Kouzoukas, Demetrios  
**Cc:** Rollins, James (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** Re: follow-up and background

We anticipate a respond by the end of next week before the comment period ends. We have confirmed that all anonymous comments are considered as credible.

Sent from my iPhone

On Jul 23, 2010, at 4:29 PM, "Kouzoukas, Demetrios" <[dkouzoukas@cov.com](mailto:dkouzoukas@cov.com)> wrote:

Is there any more information, or perhaps draft language, I can provide to help you consider how best to proceed at this point?

-- Demetrios

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---

**From:** Kouzoukas, Demetrios  
**Sent:** Thursday, July 22, 2010 2:01 PM  
**To:** [James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov); [Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov); [Elaine.Dolina@cms.hhs.gov](mailto:Elaine.Dolina@cms.hhs.gov)  
**Subject:** follow-up and background

James, Leslye, and Elaine:

Here is the article I referenced in my conversations with James and Leslye. If you are open to the procedure I discussed with Leslye -- whereby a commenter could request that their identity not be released, I would be pleased to propose language that such commenters could use and on which basis CMS would then oblige the request.

Thank you very much for your consideration.

<< File: Cancer Experts Threatened A...pdf >>

-- Demetrios

Demetrios L. Kouzoukas  
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1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401  
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## Rollins, James (CMS/OCSQ)

---

**From:** Kouzoukas, Demetrios [dkouzoukas@cov.com]  
**Sent:** Monday, July 26, 2010 9:08 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** RE: follow-up and background

Thank you very much. Your prompt attention and further inquiry is most helpful and appreciated. Unfortunately, if we are to have a realistic chance at getting these comments in, the commenters would need to hear back by end of day tomorrow. Is that feasible?

In the interests of expediting matters, I offer the following potential language for commenters to use:

"I am concerned about the disclosure of my identity in making these comments, and therefore I am providing the information in these comments on the condition that my identity (including name, email address, IP address, employer, any other affiliation) is considered "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" in a "system of records" and therefore protected from release under the Privacy Act of 1974 (section (b)) and the Freedom of Information Act (exemption (b)(6))."

-- Demetrios

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---

**From:** Fitterman, Leslye (CMS/OCSQ) [mailto:Leslye.Fitterman3@CMS.hhs.gov]  
**Sent:** Friday, July 23, 2010 2:35 PM  
**To:** Kouzoukas, Demetrios  
**Cc:** James.Rollins2@CMS.hhs.gov; Elaine.Dolina@cms.hhs.gov  
**Subject:** Re: follow-up and background

We anticipate a respond by the end of next week before the comment period ends. We have confirmed that all anonymous comments are considered as credible.

Sent from my iPhone

On Jul 23, 2010, at 4:29 PM, "Kouzoukas, Demetrios" <[dkouzoukas@cov.com](mailto:dkouzoukas@cov.com)> wrote:

Is there any more information, or perhaps draft language, I can provide to help you consider how best to proceed at this point?

-- Demetrios

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*sender by reply e-mail that this message has been inadvertently transmitted to you and delete this e-mail from your system. Thank you for your cooperation.*

---

**From:** Kouzoukas, Demetrios  
**Sent:** Thursday, July 22, 2010 2:01 PM  
**To:** [James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov); [Leslye.Fitterman3@CMS.hhs.gov](mailto:Leslye.Fitterman3@CMS.hhs.gov); [Elaine.Dolina@cms.hhs.gov](mailto:Elaine.Dolina@cms.hhs.gov)  
**Subject:** follow-up and background

James, Leslye, and Elaine:

Here is the article I referenced in my conversations with James and Leslye. If you are open to the procedure I discussed with Leslye -- whereby a commenter could request that their identity not be released, I would be pleased to propose language that such commenters could use and on which basis CMS would then oblige the request.

Thank you very much for your consideration.

<< File: Cancer Experts Threatened A...pdf >>

-- Demetrios

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Fax: 202.778.5057  
download vcard: <http://www.cov.com/biographies/vcard.aspx?Attorney=13540>

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**Rollins, James (CMS/OCSQ)**

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Tuesday, July 27, 2010 1:06 PM  
**To:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** FW: cber provenge reviews

I just put these 2 on the G drive

---

**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Tuesday, July 27, 2010 9:36 AM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Subject:** cber provenge reviews

FYI. It doesn't appear that this review is in our G drive folder

<http://fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm214540.pdf>

I tried to access it but the FDA website is still down

There is also a statistical review that we'll have to eventually get our hands on:

<http://fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm214543.pdf>

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115



**Rollins, James (CMS/OCSQ)**

---

**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Tuesday, July 27, 2010 2:32 PM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** RE: email to Demetrios

I'm ok with this.

Tamara Syrek Jensen  
Deputy Director  
Coverage and Analysis Group  
Office of Clinical Standards and Quality, CMS  
7500 Security Blvd.  
Baltimore, MD 21244  
(410) 786-3529  
[tamara.syrekjensen@cms.hhs.gov](mailto:tamara.syrekjensen@cms.hhs.gov)

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Tuesday, July 27, 2010 10:03 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** email to Demetrios

Tamara, here is the wording of the email that I want to send to Demetrios. Edit as needed. Jarollins

Demetrios, thank you for your comments. I have reviewed the wording of the document that you sent us and feel that it is not necessary. In order to more effectively serve the Medicare population, we need credible information to help us make our decisions. As noted in the previous correspondence, CMS takes all statements from commenters seriously, whether or not they are given with consent or anonymously. Also CMS cannot guarantee that names of commenters will not be released to the public. I hope that this information will help you in your efforts. Jarollins

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, July 28, 2010 11:23 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)  
**Attachments:** CMS Letter July 28 2010.pdf; 1froh\_oa-Final 2010-07-02.pdf; Small JCO 07-01-06.pdf; Higano-IntegratedProvenge-Cancer2009.pdf; NCCN.pdf

-----Original Message-----

**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

**Re:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

On behalf of Dendreon Corporation (Dendreon), I am submitting the following comments on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.[1] Dendreon is the manufacturer of PROVENGE® (sipuleucel-T), an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE is the first in a new class of biological products designed to induce a tumor-specific immune response. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug

Administration (FDA) approved PROVENGE on April 29, 2010 under a biologic license application (BLA, license number 1749). Bringing PROVENGE to market has been a 15-year journey that has involved more than a thousand courageous patients, 15 clinical trials, and nearly one billion dollars of funding of research and development.

Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology.[4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P=0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A[5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate  $\geq 15\%$ , were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common ( $\geq 2\%$ ) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

We believe that if CMS does decide to move forward with this NCA, it should conclude the process quickly, without a TA or a MedCAC meeting. We believe that a TA is not needed because none of the conditions listed in the guidance document regarding factors CMS considers in commissioning a TA exist. In particular, there are no "significant differences in opinion among experts," as shown by the fact that soon after PROVENGE was approved by the FDA, the National Comprehensive Cancer Network (NCCN) listed PROVENGE in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>T</sup>) for Prostate Cancer (version 2.2010) and NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>T</sup>) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T,"[10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

2 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

3 Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.

4 Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.

5 Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.

6 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6) <[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)> .

7 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

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- 14 NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

#### Attachments

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**Rollins, James (CMS/OCSQ)**

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**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 6:58 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

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Elaine

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**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

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**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

On behalf of Dendreon Corporation (Dendreon), I am submitting the following comments on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.[1] Dendreon is the manufacturer of PROVENGE® (sipuleucel-T), an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE is the first in a new class of biological products designed to induce a tumor-specific immune response. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) approved PROVENGE on April 29, 2010 under a biologic license application (BLA, license number 1749). Bringing PROVENGE to market has been a 15-year journey that has involved more than a thousand courageous patients, 15 clinical trials, and nearly one billion dollars of funding of research and development.

Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology. [4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P=0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A [5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate  $\geq 15\%$ , were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common ( $\geq 2\%$ ) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

We believe that if CMS does decide to move forward with this NCA, it should conclude the process quickly, without a TA or a MedCAC meeting. We believe that a TA is not needed because none of the conditions listed in the guidance document regarding factors CMS considers in commissioning a TA exist. In particular, there are no "significant differences in opinion among experts," as shown by the fact that soon after PROVENGE was approved by the FDA, the National Comprehensive Cancer Network (NCCN) listed PROVENGE in the NCCN Clinical Practice Guidelines in Oncology (NCCN GuidelinesT) for Prostate Cancer (version 2.2010) and

NCCN Drugs & Biologics Compendium (NCCN CompendiumT) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T," [10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

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**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 7:16 AM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

The default would be all of it unless parts are off topic or have phi. The team can make a rec.

Sent from my Blackberry

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**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thu Jul 29 06:58:09 2010  
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July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

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Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology. [4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P=0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A [5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate  $\geq$  15%, were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common ( $\geq$  2%) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their

battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

We believe that if CMS does decide to move forward with this NCA, it should conclude the process quickly, without a TA or a MedCAC meeting. We believe that a TA is not needed because none of the conditions listed in the guidance document regarding factors CMS considers in commissioning a TA exist. In particular, there are no "significant differences in opinion among experts," as shown by the fact that soon after PROVENGE was approved by the FDA, the National Comprehensive Cancer Network (NCCN) listed PROVENGE in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>T</sup>) for Prostate Cancer (version 2.2010) and NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>T</sup>) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T," [10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly

reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

2 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

3 Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.

4 Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.

5 Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.

6 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
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7 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
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8 NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.

9 NCCN Categories of Evidence and Consensus,  
[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)  
<[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)> .

10 Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.

11 SSA § 1861(t)(2)(A)-(B).

12 SSA § 1861(t)(2)(B)(ii).

13 Medicare Benefit Policy Manual, ch. 15, § 50.4.5.

14 NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

## Attachments

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[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.



- [2] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
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- [3] Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.
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- [10] Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.
- [11] SSA § 1861(t)(2)(A)-(B).
- [12] SSA § 1861(t)(2)(B)(ii).
- [13] Medicare Benefit Policy Manual, ch. 15, § 50.4.5.
- [14] NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

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**Rollins, James (CMS/OCSQ)**

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**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 7:51 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

I went ahead and entered the comment.

[https://www.cms.gov/mcd/publiccomment\\_popup.asp?comment\\_id=21547](https://www.cms.gov/mcd/publiccomment_popup.asp?comment_id=21547)

We can worry about the attachments later. They might be difficult to make 508 compliant.

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, July 28, 2010 11:23 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

-----Original Message-----

**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

**Re:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

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NCCN Drugs & Biologics Compendium (NCCN CompendiumT) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T," [10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

2 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

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10 Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.

11 SSA § 1861(t)(2)(A)-(B).

12 SSA § 1861(t)(2)(B)(ii).

13 Medicare Benefit Policy Manual, ch. 15, § 50.4.5.

14 NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

#### Attachments

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**Rollins, James (CMS/OCSQ)**

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 8:30 AM  
**To:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Attachments:** IMPACT NEJM manuscript 2010.pdf

Please find the pivotal study published in the NEJM today. I received it from Dendreon. It has been saved on the G drive.

**Rollins, James (CMS/OCSQ)**

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**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 8:30 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

The IMPACT publication in the NEJM has been sent to you and saved on the G drive. I have forwarded this to Elaine to be posted.

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, July 28, 2010 11:23 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

-----Original Message-----

**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N).

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

**Re:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

On behalf of Dendreon Corporation (Dendreon), I am submitting the following comments on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.[1] Dendreon is the manufacturer of PROVENGE® (sipuleucel-T), an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE is the first in a new class of biological products designed to induce a tumor-specific immune response. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) approved PROVENGE on April 29, 2010 under a biologic license application (BLA, license number 1749). Bringing PROVENGE to market has been a 15-year journey that has involved more than a thousand courageous patients, 15 clinical trials, and nearly one billion dollars of funding of research and development.

Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology. [4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P=0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A [5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate  $\geq 15\%$ , were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common ( $\geq 2\%$ ) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

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Mark Frohlich, Chief Medical Officer of Dendreon

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[6] 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)  
<[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)> .

[7] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

[8] NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.

[9] NCCN Categories of Evidence and Consensus,  
[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)  
<[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)> .

[10] Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.

[11] SSA § 1861(t)(2)(A)-(B).

[12] SSA § 1861(t)(2)(B)(ii).

[13] Medicare Benefit Policy Manual, ch. 15, § 50.4.5.

[14] NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

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**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 8:30 AM  
**To:** Dolina, Elaine L. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Please add all attachments since they are published literature and one was published today.  
Thanks!

-----Original Message-----

**From:** Dolina, Elaine L. (CMS/OCSQ)  
**Sent:** Thursday, July 29, 2010 6:58 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** RE: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Would you like me to add this comment to the database? If so, which attachments (if any) should I include?

Elaine

-----Original Message-----

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, July 28, 2010 11:23 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ)  
**Subject:** FW: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

-----Original Message-----

**From:** Larson, Tricia [mailto:tlarson@Dendreon.com]  
**Sent:** Wed 7/28/2010 10:25 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Bishop, Hans; Frohlich, Mark; Lockett, Chris  
**Subject:** NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

July 28, 2010

Louis Jacques, MD

Director, Coverage and Analysis Group

Centers for Medicare & Medicaid Services

Mail Stop S3-02-01

7500 Security Blvd.

Baltimore, MD 21244

Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

On behalf of Dendreon Corporation (Dendreon), I am submitting the following comments on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.[1] Dendreon is the manufacturer of PROVENGE® (sipuleucel-T), an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE is the first in a new class of biological products designed to induce a tumor-specific immune response. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) approved PROVENGE on April 29, 2010 under a biologic license application (BLA, license number 1749). Bringing PROVENGE to market has been a 15-year journey that has involved more than a thousand courageous patients, 15 clinical trials, and nearly one billion dollars of funding of research and development.

Dendreon appreciates the numerous opportunities we have had to meet with the Centers for Medicare and Medicaid Services (CMS) to discuss PROVENGE both pre- and post- FDA approval. We believe that the agency should be very familiar with PROVENGE's clinical benefits and manufacturing process as a result of these meetings and all of the additional information we have provided in other various forms. Specifically, in just the past few months, Dendreon applied for a Healthcare Common Procedure Coding System (HCPCS) code and for pass-through biological status under the hospital outpatient prospective payment system (OPPS). Each application requires substantial clinical and product information that further demonstrates the appropriateness and reasonableness of immediate Medicare coverage. As we describe in further detail below, we are now enhancing the breadth and depth of evidence of PROVENGE's effectiveness in the Medicare population by including a recently published study in the New England Journal of Medicine. Based upon the overwhelming clinical evidence showing a significant improvement in overall survival in this patient population, the "gold standard" of all endpoints in oncology clinical trials, we ask CMS to reconsider whether a NCA is necessary. We make this request based on the fact that CMS's initiation of this process was highly unusual. Since the current NCA process was implemented after the Medicare Modernization Act of 2003 (MMA), this is the first time CMS has internally initiated a NCA for an approved use of an innovative new cancer biological. The evidence we have submitted demonstrates that consistent with other drugs and biologicals CMS currently covers, PROVENGE clearly is reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Dendreon believes that upon further review, CMS should conclude that the NCA can be closed at this time, without the need for further evaluation, a technology assessment (TA), or a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting.

Under CMS's Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, CMS identifies several circumstances in which CMS could internally initiate a NCA for a new technology. Although we do not know the precise reason CMS opened this NCA, we think the agency may have initiated it based on a belief that "significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology." [2] As stated above, we believe that any uncertainty about the health benefits, patient selection, and appropriate provision of PROVENGE can be addressed without further analysis by CMS. FDA's review of PROVENGE was comprehensive and rigorous. The agency reviewed data from 4 randomized trials involving over 900 patients. The pivotal registration study was conducted under a Special Protocol Assessment agreement with the FDA and demonstrated a statistically significant survival benefit. Similar results were seen in a previous smaller randomized trial.

In addition to the data relied upon by the FDA, the attached article, published in the New England Journal of Medicine on July 29, 2010, presents the results of the double-blind, placebo-controlled phase III trial for PROVENGE, as well as summarizes the findings from 2 earlier phase III trials. The article concludes that the "use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer." [3]

As described in the New England Journal of Medicine article, sipuleucel-T has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer. In the randomized double-blind, placebo-controlled, multicenter phase III "IMPACT" trial, we randomly assigned 512 patients with median age of 71, in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of 3 infusions.

The primary endpoint of this study was overall survival, the most meaningful clinical outcome for patients, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase. In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio (HR), 0.78; 95% confidence interval (CI), 0.61 to 0.98;  $P = 0.03$ ). There was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (HR, 0.77; 95% CI, 0.61 to 0.97;  $P = 0.02$ ) and after adjustment for use of docetaxel after the study therapy (HR, 0.78; 95% CI, 0.62 to 0.98;  $P = 0.03$ ).

Importantly, the results of the IMPACT trial confirmed the results of the earlier D9901 study, published in the attached article in the Journal of Clinical Oncology. [4] Specifically, in this study there was a relative reduction of 41% in the risk of death in the sipuleucel-T group compared with the placebo group (HR, 0.586; 95% CI, 0.388 to 0.884;  $P = 0.010$ ). There was a 4.5 month improvement in median survival (25.9 months in the sipuleucel-T group vs. 21.4 months in the placebo group). In this study, 34% of the men were alive at the 3 year follow-up compared to 11% in the placebo group. An integrated survival analysis completed with these results together with the results from the D9902A [5] trial and IMPACT demonstrated a p-value of  $<0.001$ , suggesting a less than 1 in 1000 chance that the results would have been observed by chance alone.

Additionally, PROVENGE has a favorable side effect profile. The most common adverse events (AEs), reported in patients in the sipuleucel-T group at a rate ? 15%, were chills, fatigue, fever, back pain, nausea, joint ache, and headache. The majority of AEs in trials were grades 1 or 2. The most common (? 2%) Grade 3-5 adverse events reported in the sipuleucel-T group were back pain and chills. The percentage of patients in each arm experiencing serious AEs (SAEs) was comparable, including the percentage with cerebral vascular accidents (CVAs), of which none were attributed to sipuleucel-T. Safety concerns raised earlier by the FDA about the incidence of CVAs are addressed by a Risk Management Plan submitted as part of the amendment to the BLA and a post-marketing registry study.

In conclusion, multiple randomized trials have shown that PROVENGE prolonged survival among men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This strong clinical evidence led to FDA approval and should serve as the foundation for coverage by CMS. There is a current unmet need for the treatment of men with metastatic castrate resistant prostate cancer who have yet become symptomatic enough to receive traditional chemotherapy manipulation. PROVENGE provides a new, innovative, safe, and proven opportunity for such patients to extend their lives with minimal daily interruptions.

The evidence provided to CMS and contained in the New England Journal of Medicine article, demonstrates that PROVENGE is reasonable and necessary for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and that the NCA is not warranted. More important, it creates an unnecessary additional hurdle for patients to navigate as they seek treatment for this deadly disease. Now that CMS has adequately gathered "comments and additional information or evidence of studies" about the policy under consideration,[6] the agency need not invest additional time and resources into evaluating coverage of PROVENGE. This is particularly true as the primary endpoint of the IMPACT trial was overall survival, and the median age of patients enrolled was 71 years, with 75% of the patients being 65 years of age or older and eligible for Medicare. The subgroup analysis of patients 65 years of age or older in the integrated dataset for the 3 randomized trials in metastatic castrate resistant prostate cancer demonstrated consistency of the PROVENGE treatment effect. The median survival was 23.4 months in the PROVENGE group and 17.1 months in the placebo group. PROVENGE clearly shows effectiveness in the Medicare population and improves health outcomes in patients with prostate cancer. Accordingly, we request that CMS close this NCA and instead allow its local contractors to cover PROVENGE, applying the same coverage criteria as they apply to any other new cancer drug or biological. We believe that CMS should rely on its local contractors and physicians, through its local processes to determine appropriate use. CMS should not stand in the way of the adoption of new technologies and perhaps a new standard of care; rather, it should partner with its local contractors and physicians to educate Medicare beneficiaries on the clinical benefits and appropriate use of PROVENGE.

To the extent that CMS initiated this NCA based on concerns about "health inequalities" and "local variation" and a desire to ensure that this "substantial clinical advance . . . diffuses more rapidly to all patients for whom it is indicated,"[7] this uniformity and diffusion already is occurring. Although we expressed concerns during our most recent meeting with you about the variations in coverage of PROVENGE between contractors, these variations have subsided. Currently most Medicare contractors have published guidelines or verbally indicated they are/will cover PROVENGE as a biological product for its on-label indication, and Medicare beneficiaries across the country have access to PROVENGE in their

battle against metastatic castrate resistant prostate cancer. Again, this reinforces why the NCA is not necessary at this time.

We believe that if CMS does decide to move forward with this NCA, it should conclude the process quickly, without a TA or a MedCAC meeting. We believe that a TA is not needed because none of the conditions listed in the guidance document regarding factors CMS considers in commissioning a TA exist. In particular, there are no "significant differences in opinion among experts," as shown by the fact that soon after PROVENGE was approved by the FDA, the National Comprehensive Cancer Network (NCCN) listed PROVENGE in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>T</sup>) for Prostate Cancer (version 2.2010) and NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>T</sup>) as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer.[8] A category 1 recommendation means that "the recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus." [9] NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. Its experts are world renowned, and its Prostate Cancer Panel includes 28 members from the best cancer hospitals across the country. NCCN's rapid inclusion of PROVENGE in its Guidelines and Compendium with a category 1 recommendation shows the high level of consensus that exists regarding PROVENGE's clinical data as well as PROVENGE's role in the treatment regimen for prostate cancer.

Furthermore, although the description of the TA on the Agency for Healthcare Research and Quality (AHRQ) website recently was changed from "The Efficacy and Safety of Sipuleucel T" to "The Outcomes of Sipuleucel T," [10] we continue to be concerned that the scope of the assessment duplicates the review already conducted by the FDA. For the same reasons, we believe that a meeting of the MedCAC is not needed to assess the data on PROVENGE, all of which already has been reviewed by CMS.

If CMS proceeds with the NCA, we believe the agency should issue a proposed decision as soon as possible covering PROVENGE under the same standards as apply to any other drug or biological used in an anticancer chemotherapeutic regimen. Under the Social Security Act (SSA), any FDA-approved use of a drug or biological in an anticancer chemotherapeutic drug regimen is a "medically accepted indication" that is included in the definition of "drugs and biologicals" that may be covered by Medicare.[11] The use of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer is approved by the FDA and thus is a "medically accepted indication" used in an anticancer chemotherapeutic drug regimen that should be covered by Medicare. In addition, other uses of FDA-approved drugs used in anticancer chemotherapeutic drug regimens are "medically accepted indications" if the use is supported by authoritative compendia recognized by the Secretary of Health and Human Services.[12] The NCCN Drugs and Biologics Compendium is one of these compendia,[13] and it supports use of PROVENGE for "asymptomatic or minimally symptomatic patients with performance status 0-1 and a life expectancy of greater than 6 months and no visceral disease." [14] By virtue of this listing in the NCCN Compendium, PROVENGE would satisfy the criteria for coverage even if it had not been approved for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer; therefore, it undoubtedly should be covered for its FDA-approved use.

Thank you for your thoughtful consideration of our comments. We remind you that the patients we serve have late-stage cancer and few, if any, appealing treatment options available to them, with only chemotherapy as an FDA-approved alternative. Not only is PROVENGE clearly

reasonable and necessary for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, but it provides an unambiguous survival benefit and real hope for patients battling their disease. At Dendreon, so many of us have been affected by cancer, which is why we have dedicated our lives to transforming the way cancer is treated. The patients PROVENGE treats are our fathers, our husbands, our brothers and sons, our teachers and physicians, our veterans and our friends. We urge you not to deny them access to PROVENGE and recognize that survival is more than just surviving: it allows cancer patients the freedom to live. We appreciate the opportunity to submit these comments and would be pleased to meet with the agency again to address any questions you may have.

Sincerely,

Hans Bishop, Chief Operating Officer of Dendreon

Mark Frohlich, Chief Medical Officer of Dendreon

[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

2 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).



3 Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.

4 Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.

5 Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.

6 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)  
<[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)> .

7 Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006, [http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).

8 NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.

9 NCCN Categories of Evidence and Consensus, [http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)  
<[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)> .

10 Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.

11 SSA § 1861(t)(2)(A)-(B).

12 SSA § 1861(t)(2)(B)(ii).

13 Medicare Benefit Policy Manual, ch. 15, § 50.4.5.

14 NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

## Attachments

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[1] NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010, <http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247>.

- [2] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).
- [3] Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010;363:411-22.
- [4] Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol 2006; 24:3089-94.
- [5] Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer 2009;115:3670-9.
- [6] 68 Fed. Reg. 55634, 55639; see also Guidance Document on Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
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<[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6)> .
- [7] Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006,  
[http://www.cms.gov/mcd/ncpc\\_view\\_document.asp?id=6](http://www.cms.gov/mcd/ncpc_view_document.asp?id=6).
- [8] NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v.2.2010, May 12, 2010.
- [9] NCCN Categories of Evidence and Consensus,  
[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)  
<[http://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.asp](http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp)> .
- [10] Technology Assessments in Progress, <http://www.ahrq.gov/clinic/techix.htm#progress>.
- [11] SSA § 1861(t)(2)(A)-(B).
- [12] SSA § 1861(t)(2)(B)(ii).
- [13] Medicare Benefit Policy Manual, ch. 15, § 50.4.5.
- [14] NCCN Drugs & Biologics Compendium, "Sipuleucel-T," current as of July 26, 2010.

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## Rollins, James (CMS/OCSQ)

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 7:40 AM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Re: Meeting with Dendreon at CMS

I will respond to him and cc the team  
Sent from my Blackberry

---

**From:** Lockett, Chris <[clockett@Dendreon.com](mailto:clockett@Dendreon.com)>  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Thu Jul 29 23:42:14 2010  
**Subject:** RE: Meeting with Dendreon at CMS

Leslye,

When we confirmed our meeting last week you informed us that you would provide us with your questions in advance. Having these questions will allow us to prepare the most relevant slide presentation for your analysis. You also stated that the NCA was initiated to determine the "effectiveness" of Provenge (see Below). We are still struggling to understand the rational CMS has used to initiate the NCA and we were hoping your clarification of "effectiveness" would provide us some of that understanding. Dendreon wants to provide CMS with any additional evidence that the agency needs for this analysis, at this point we are still unclear as to exactly what evidence the agency is seeking. Any further guidance would be greatly appreciated.

Regards,

Chris

---

**From:** Fitterman, Leslye (CMS/OCSQ) [<mailto:Leslye.Fitterman3@CMS.hhs.gov>]  
**Sent:** Thursday, July 22, 2010 4:20 PM  
**To:** Lockett, Chris  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Meeting with Dendreon at CMS

Dear Mr. Lockett:

We have scheduled a meeting with you and your colleagues at our office in Baltimore, MD for August 3, 2010 11:00 am to 12 noon. I will follow-up with you early next week when we have composed questions. I will also clarify what I mean by "effectiveness" and "comparative effectiveness".

We looking forward to meeting with you on August 3<sup>rd</sup>.

Regards, Leslye

Leslye Fitterman, PhD.  
Centers for Medicare and Medicaid Services  
Office of Clinical Standards and Quality  
Coverage and Analysis Group  
7500 Security Boulevard  
C1-09-06  
Fax - 410-786-9286  
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**Rollins, James (CMS/OCSQ)**

---

**From:** Wittenberg, Kim (AHRQ/COE)  
**Sent:** Thursday, July 29, 2010 11:08 AM  
**To:** Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** Provenge MedCAC

Good morning,

Do we have a confirmed date for the Provenge MedCAC? Thank you in advance for this information.

Sincerely,  
Kim

Kim Marie Wittenberg, MA

Agency for Healthcare Research and Quality

Center for Outcomes and Evidence

540 Gaither Road, Room 6018

Rockville, MD 20850

Ph: 301-427-1488

Fax: 301-427-1639

E-mail: [Kim.Wittenberg@ahrq.hhs.gov](mailto:Kim.Wittenberg@ahrq.hhs.gov)

**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 9:13 AM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Provenge News

**Provenge Study May Not Reveal How It Extends Patients' Lives.**

The [NPR](#) (7/29, Knox) "Shots" blog reported that this week's New England Journal of Medicine includes "the study that led to FDA approval" of Provenge [sipuleucel-T] to treat prostate cancer, but "it's clear that experts are still scratching their heads about just how Provenge works." NPR added, "The primary mystery is how Provenge extends life, since it doesn't shrink prostate tumors, as far as anyone can tell. 'Prolongation of survival without a measurable antitumor effect is surprising,' writes Dr. Dan Longo of the National Institute on Aging in a NEJM editorial." Still, "study shows that patients who got Provenge were indeed more likely to mount immune-cell responses to a prostate cancer antigen in the test tube. But oddly, the patients who had these activated immune cells didn't survive any longer than those who didn't."

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## Rollins, James (CMS/OCSQ)

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 11:27 AM  
**To:** Lockett, Chris; Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Meeting with Dendreon at CMS

Chris,

We'd like to focus our discussion at the upcoming meeting on the following topics.

- The criteria used in the trials to identify subjects with "asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer." More specifically, how were symptoms assessed, did the symptoms have to be secondary to prostate CA or prior or current CA treatment, and what cutoffs were applied to differentiate these men from more symptomatic subjects?
- How do the characteristics of the actual enrolled study population compare to the affected Medicare beneficiary population, in light of the apparent disparate impact of prostate CA on particular populations? As the unclear biologic mechanism of action of Provenge is still being debated/discussed in the press, is there any reason to believe that Provenge would be more or less effective in the impacted populations?
- I recall that there was discussion of a Provenge registry. We'd like to hear more about its design, the included data elements, and the plans for downstream analysis.

In addition, as we discuss the above we may have more questions on the evidence you present.

Louis

---

**From:** Lockett, Chris [<mailto:clockett@Dendreon.com>]  
**Sent:** Thursday, July 29, 2010 11:42 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Meeting with Dendreon at CMS

Leslye,

When we confirmed our meeting last week you informed us that you would provide us with your questions in advance.

Having these questions will allow us to prepare the most relevant slide presentation for your analysis. You also stated that the NCA was initiated to determine the "effectiveness" of Provenge (see Below). We are still struggling to understand the rationale CMS has used to initiate the NCA and we were hoping your clarification of "effectiveness" would provide us some of that understanding. Dendreon wants to provide CMS with any additional evidence that the agency needs for this analysis, at this point we are still unclear as to exactly what evidence the agency is seeking. Any further guidance would be greatly appreciated.

Regards,

Chris

## Rollins, James (CMS/OCSQ)

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 2:59 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** FW: Meeting with Dendreon at CMS

Just FYI

---

**From:** Lockett, Chris [<mailto:clockett@Dendreon.com>]  
**Sent:** Friday, July 30, 2010 2:57 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Subject:** RE: Meeting with Dendreon at CMS

Dr Jacques,

Thank you for this guidance, we will prepare accordingly. I will send you our attendee list for the meeting by Monday morning. We look forward to meeting with your team next Tuesday at 11am.

Regards,

Chris

---

**From:** Jacques, Louis B. (CMS/OCSQ) [<mailto:Louis.Jacques@cms.hhs.gov>]  
**Sent:** Friday, July 30, 2010 11:27 AM  
**To:** Lockett, Chris; Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Meeting with Dendreon at CMS

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Louis



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**From:** Lockett, Chris [mailto:clockett@Dendreon.com]

**Sent:** Thursday, July 29, 2010 11:42 PM

**To:** Fitterman, Leslye (CMS/OCSQ)

**Cc:** Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

**Subject:** RE: Meeting with Dendreon at CMS

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Regards,

Chris

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**Rollins, James (CMS/OCSQ)**

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, July 30, 2010 3:56 PM  
**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 073010 lbj.doc  
**Attachments:** Provenge MEDCAC questions 073010 lbj.doc

We need to get closer to this model. There is room to integrate your questions, which were good. Let's discuss next week.

## **Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, August 02, 2010 11:44 AM  
**To:** Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080210 lbj.doc  
**Attachments:** Provenge MEDCAC questions 080210 lbj.doc

Revised (see added questions) to bring in the team's question ideas. Let's discuss.

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, August 03, 2010 9:06 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** Dendreon

With Sebelius here today, pls make sure Leslye is out in time to get Dendreon at security. Thanks.

---

**From:** Rollins, James (CMS/OCSQ)  
**Sent:** Tuesday, August 03, 2010 8:08 AM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** Ellis, Maria A. (CMS/OCSQ)  
**Subject:** FW: Web Posting

Louis, here is the January MEDCAC minutes and transcripts to be posted. Jarollins

---

**From:** Ellis, Maria A. (CMS/OCSQ)  
**Sent:** Tuesday, March 16, 2010 11:01 AM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** Roche, Jeffrey (CMS/OCSQ); Eggleston, Lisa J. (CMS/OCSQ); Miller, Susan (CMS/OCSQ)  
**Subject:** Web Posting

*Good Morning!*

*Please find attached the signed meeting minutes and transcript from the January 27<sup>th</sup> MEDCAC meeting on Pharmacogenomic for clearance/approval for web posting. Please let me know if I can be of further assistance.*

*Maria A. Ellis*

*Health Insurance Specialist  
Division of Operations and Information Management  
Coverage and Analysis Group, OCSQ  
(410) 786-0309*

*Maria.Ellis@cms.hhs.gov*

## **Rollins, James (CMS/OCSQ)**

---

**From:** Pencek, Eileen (CMS/OCSQ)  
**Sent:** Tuesday, August 03, 2010 10:11 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions 080210 lbj.doc

I like this format, and I think these questions are good.

The vast majority of comments from the general public (and many treating physicians) are using Taxotere as the only comparator. Used on-label, Provenge and Taxotere with associated health outcomes such as overall survival, avoidance of adverse effects of anticancer therapy, and control of symptoms would not be compared. (b)(5) - Predecisional

(b)(5) - Predecisional

Eileen

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, August 02, 2010 11:44 AM  
**To:** Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080210 lbj.doc

Revised (see added questions) to bring in the team's question ideas. Let's discuss.

## **Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, August 03, 2010 10:18 AM  
**To:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions 080210 lbj.doc


Question 5b gets to the symptomatic folks. The MEDCAC chair and co chair always have suggestions regarding the questions when we share a few mos before the meeting.

---

**From:** Pencek, Eileen (CMS/OCSQ)  
**Sent:** Tuesday, August 03, 2010 10:11 AM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions 080210 lbj.doc

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(b)(5) - Predecisional



Eileen

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, August 02, 2010 11:44 AM  
**To:** Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080210 lbj.doc

Revised (see added questions) to bring in the team's question ideas. Let's discuss.

**Rollins, James (CMS/OCSQ)**

---

**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 1:22 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions  
**Attachments:** Provenge MEDCAC questions 080210 lbj LP rev.doc

Hi. Please see the attachment for potential revisions to the questions based on our meeting today.

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115

**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 1:24 PM  
**To:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Cc:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions

Thanks-

---

**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 1:22 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions

Hi. Please see the attachment for potential revisions to the questions based on our meeting today.

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115



**Rollins, James (CMS/OCSQ)**

---

**From:** Pencek, Eileen (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 3:54 PM  
**To:** PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Rollins, James (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions

Lori,  
I think it looks good. The only comment (b)(5) - Predecisional  
(b)(5) - Predecisional  
Eileen

---

**From:** PASERCHIA, LORI A. (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 1:22 PM  
**To:** Fitterman, Leslye (CMS/OCSQ)  
**Cc:** Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions

Hi. Please see the attachment for potential revisions to the questions based on our meeting today.

Lori A. Paserchia, MD  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
[Lori.Paserchia@cms.hhs.gov](mailto:Lori.Paserchia@cms.hhs.gov)  
410.786.2115

**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Wednesday, August 04, 2010 5:09 PM  
**To:** Rollins, James (CMS/OCSQ)  
**Subject:** Re: provege inquest

Agree

Sent from my iPhone

On Aug 4, 2010, at 5:02 PM, "Rollins, James (CMS/OCSQ)" <[James.Rollins2@CMS.hhs.gov](mailto:James.Rollins2@CMS.hhs.gov)> wrote:

> Got a letter from representative Dana Rohrabacher that CMS carefully  
> consider the inquires related to a national coverage for provege.

(b)(5) - Predecisional

> Jarollins

**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, August 06, 2010 1:52 PM  
**To:** Rollins, James (CMS/OCSQ)  
**Cc:** PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080610 team.doc  
**Attachments:** Provenge MEDCAC questions 080610 team.doc

Revised as discussed.

**Rollins, James (CMS/OCSQ)**

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Friday, August 06, 2010 3:28 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Ellis, Maria A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080610 team lbj.doc  
**Attachments:** Provenge MEDCAC questions 080610 team lbj.doc

Looks ready for Cliff and Saty next week if possible. Redline attached as FYI. (b)(5) - Predecisional  
(b)(5) - Predecisional

How are we doing on the website and FR notices?

## Rollins, James (CMS/OCSQ)

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Friday, August 06, 2010 3:36 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Ellis, Maria A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions 080610 team lbj.doc

Louis:

I agree with your changes and have saved this version on the G drive.

I will talk with Maria next week to establish the timeline to select MEDCAC attendees and invited guests and preparation and submission of the FR notice. Am I correct in assuming that Cliff and Saty will want to review and weigh in on the attendees?

Leslye

---

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**Sent:** Friday, August 06, 2010 3:28 PM  
**To:** Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Ellis, Maria A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
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How are we doing on the website and FR notices?

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**To:** Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Cc:** Ellis, Maria A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Provenge MEDCAC questions 080610 team lbj.doc

The panel selection is a CAG process. I would like to get their input on the overall flow of the meeting, i.e. which questions will be specifically addressed by the TA, which are likely to be addressed by guest speakers, like the minimally symptomatic criteria. Also do they think some draft questions are missing the point, or missing entirely? That may lead us to choose guest panelists to address any expertise gaps if any. It's always been a good hour well spent with them.

---

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**Sent:** Friday, August 06, 2010 3:36 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
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**Cc:** Ellis, Maria A. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080610 team lbj.doc

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(b)(5) - Predecisional

How are we doing on the website and FR notices?

**Rollins, James (CMS/OCSQ)**

---

**From:** Fitterman, Leslye (CMS/OCSQ)  
**Sent:** Monday, August 09, 2010 1:30 PM  
**To:** PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)  
**Subject:** Provenge MEDCAC questions 080910 team lbj lf.doc  
**Attachments:** Provenge MEDCAC questions 080910 team lbj lf.doc

Please see changes I made to question 7 and will verify with the FDA review documents.