Judicial Watch

Interim Response #2

FOIA Request #111520107025

Provenge Related Records

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Tuesday, September 14, 2010 8:40 AM
To: clockett@dendreon.com
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: Request from Dendreon to present at the 11/17 MEDCAC

Dear Chris:

Interested parties (including manufacturers) may request presentation time by submitting an email along with their PowerPoint presentation to MEDCACPresentations@cms.hhs.gov by the deadline which will be stated in the Federal Register Notice to be posted at the end of the month. The allotted time for any individual presenter will be determined by the number of requests. Manufacturers do not have special status in the MEDCAC presentation process.

If Dendreon wishes to submit written comments before the meeting we will make them available to the MEDCAC panelists. The MEDCAC questions will be posted by the end of September on the same day the Federal Register Notice is published. Both documents may be found on the CMS CAG website on the date the Federal Register notice is published.

Best 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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 3:29 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Specter Kerry provenge lkf 091310 lbj rev.doc

Thank you. Do you have any revisions on the Summary Statement requested by OA?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 3:24 PM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Specter Kerry provenge lkf 091310 lbj rev.doc

Revised to include language from previous replies.(b)(5) - Predecisional
(b)(5) - Predecisional

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 4:11 PM
To: Ashby, Lori M. (CMS/OCSQ)
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)
Subject: Spector Kerry letter re PROVENGE
Attachments: Specter Kerry provenge 091310 lbj rev.doc; SUM-ADMIN Specter Kerry 091310 lbj.doc

Lori:

Attached please find the response letter and summary statement as finalized by Louis.

Leslye

(Do not type date)

The Honorable Arlen Specter and the Honorable John Kerry
United States Senate
Washington, DC 20510

Dear Senators Specter and Kerry:

Thank you for your letter to the Administrator regarding the recently opened national coverage analysis (NCA), 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 the NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with our published guidance document "Factors CMS Considers in Opening a National Coverage Determination," and with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes. Both documents support the use of NCDs to promote greater consistency in coverage across local contractors. The guidance document is available on the CMS website at https://www4.cms.gov/mcd/ncpc_view_document.asp?id=6. We are also convening a public meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on November 17, 2010 to consider the currently available evidence on this topic. 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.

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,

SUMMARY STATEMENT – ADMINISTRATOR'S CORRESPONDENCE

NAME OF CORRESPONDENTS:
Senator Arlen Specter and Senator John Kerry

SUBJECT/ISSUES RAISED BY CORRESPONDENTS:

- The correspondents want to know why CMS opened a national coverage analysis (NCA) for autologous cellular immunotherapy treatment therapy for prostate cancer for a new treatment that has FDA approval (i.e., one indication) for marketing.
- Correspondent claims erroneously that CMS has previously only used NCDs to review off label uses of anticancer drugs.

MAJOR POINTS IN THE RESPONSE:

- CMS opened the NCD process in response to variations in local coverage, other substantive questions about PROVENGE, and inquiries from Congress..
- The NCA is part of the national coverage determination process (NCD) as stated in section 1862 (l) of the Social Security Act. This provision also guides CMS to consider developing national policy when there is local variation in coverage.
- The guidance document entitled, "Factors CMS Considers in Opening an NCD" states that one reason to open an NCD is to address variation in coverage by local contractors that may lead to the detriment of beneficiaries.

POLICY OPTIONS:

- The completion of the NCD process may result in national coverage or noncoverage for on label or off label indications with or without specific additional conditions that could include Coverage with Evidence Development.
- We cannot speculate on the policy outcome at this early point in the process.

CLEARANCE COMMENTS:

- (b)(5) - Predecisional

CONTACT PERSONS:
James Rollins
Leslye Fitterman

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 2:56 PM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ)
Subject: Inquiry from Senators Specter and Keryy
Attachments: cms-senators-spector-kerry.gif; SUM-ADMIN Specter Kerry lkf 091310.doc; Specter Kerry provenge lkf 091310 lbj.doc

Louis:

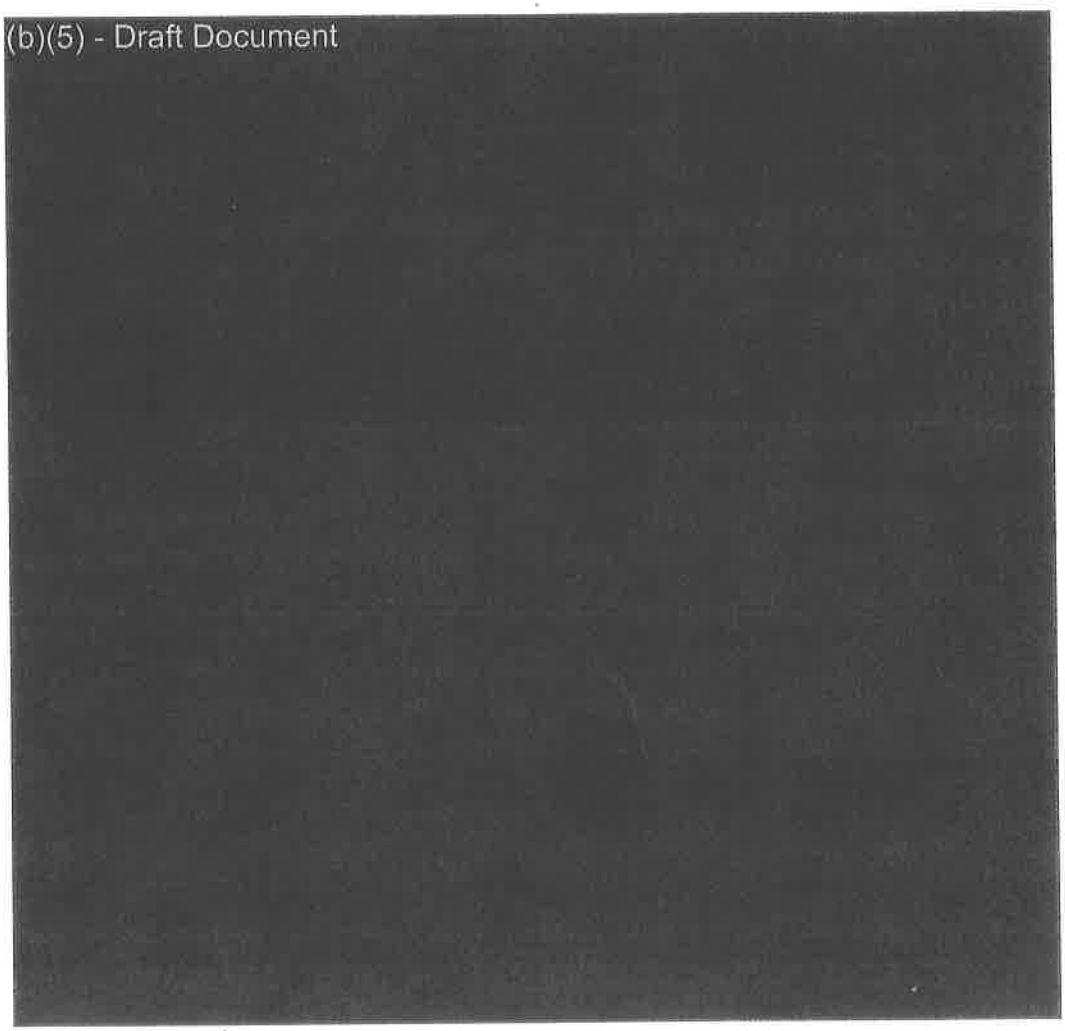
Attached please find the letter sent to Dr. Berwick, a draft response and a draft summary statement to address the inquiry received from Senators Specter and Kerry. Jim has reviewed these and I have incorporated his changes.

Thanks,

Leslye

SUMMARY STATEMENT – ADMINISTRATOR'S CORRESPONDENCE

NAME OF CORRESPONDENTS:
Senator Arlen Specter and Senator John Kerry



Comment [f1]: Not sure what is called for here

CONTACT PERSONS:
James Rollins
Leslye Fitterman

United States Senate

WASHINGTON, DC 20510

August 20, 2010

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
Mailstop 314G
Washington, DC 20201

Dear Administrator Berwick:

We are writing you regarding a National Coverage Analysis that the Centers for Medicare and Medicaid Services (CMS) issued on June 30, 2010, for autologous cellular immunotherapy treatment for prostate cancer. We are informed that this action was taken based on internal concerns regarding a new FDA-approved treatment regimen.

Only three times in the past has CMS issued a National Coverage Assessment on a new treatment for cancer, each time focusing on the need to restrict potential off-label usage of such drugs. These assessments have not focused on whether or not to cover appropriate on-label use of such a therapy as this latest review appears to be.

There is great concern from the prostate cancer community that this assessment could limit access to appropriate care for Medicare beneficiaries with prostate cancer. We would appreciate an explanation as to why CMS decided to proceed with a National Coverage Assessment for on-label use of an FDA-approved cancer treatment. We look forward to your timely response.

Sincerely,

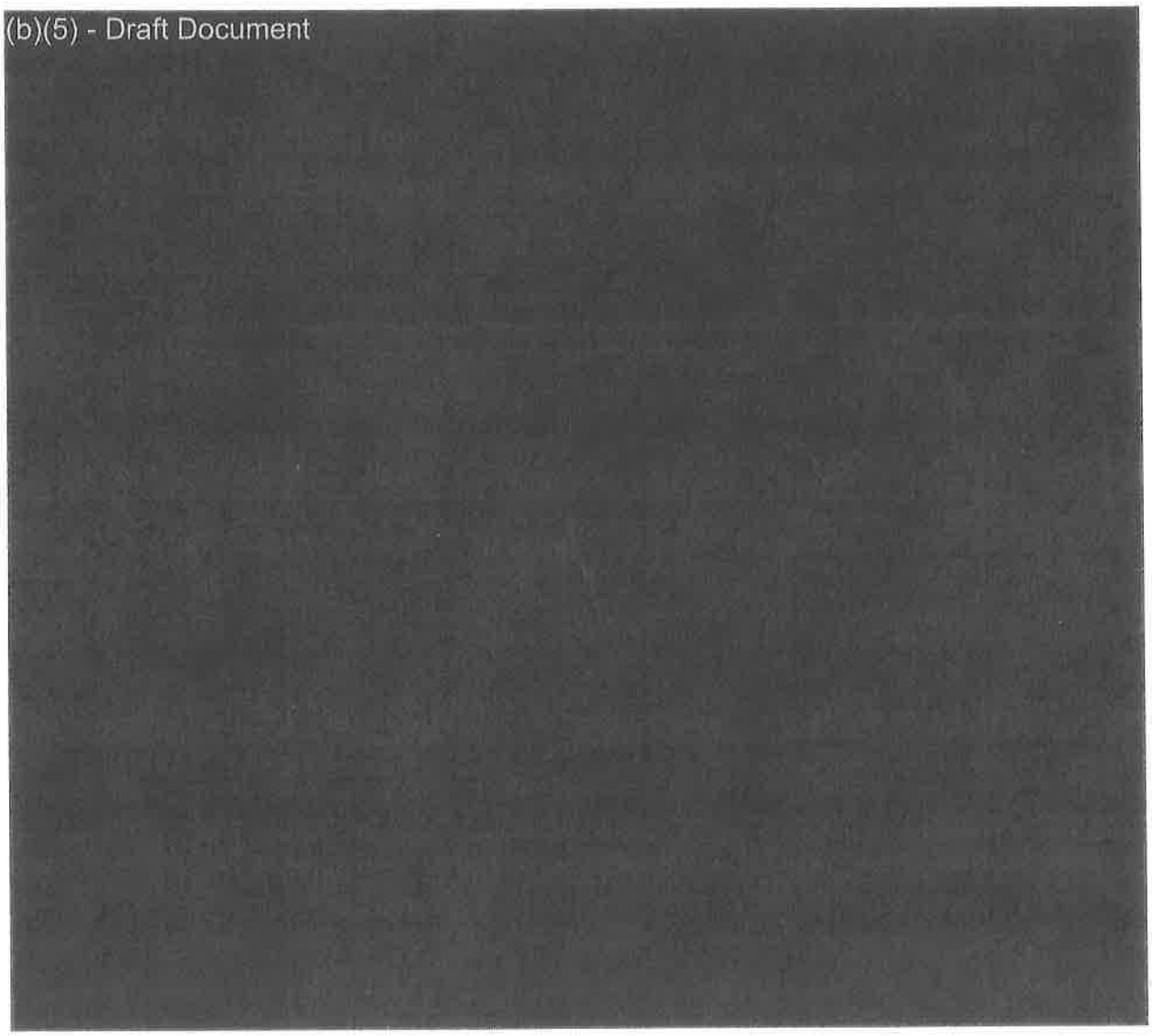
Arlen Specter

John Kerry

(Do not type date)

The Honorable Arlen Specter and the Honorable John Kerry
United States Senate
Washington, DC 20510

Dear Senators Specter and Kerry:



Sincerely,

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:49 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Therefore, do I say "no" to Dendreon?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:45 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

GAPPnet was not the product in the same sense as Provenge. The underlying topic for the May 2009 MEDCAC was desirable characteristics of evidence on genetic screening tests. So it looks like we do not have an actual case of a manufacturer speaking at a meeting where coverage of its own product was the topic.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Thank you!

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:00 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

So that means that Dendreon will not be given the opportunity to give a presentation. But I am sure that there will be representatives in the audience to give a 5 minute public comment. Jarollins

---

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:58 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

They are not an invited speaker. They can do what other manufacturers have done in the past and use the usual process.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:49 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Therefore, do I say "no" to Dendreon?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:45 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

GAPPnet was not the product in the same sense as Provenge. The underlying topic for the May 2009 MEDCAC was desirable characteristics of evidence on genetic screening tests. So it looks like we do not have an actual case of a manufacturer speaking at a meeting where coverage of its own product was the topic.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the

committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Thank you!

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM

To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:05 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I think that we are all in agreement. Jarollins

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:03 PM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

We need to be precise. Dendreon has the opportunity to give a presentation, just like the rest of the public. They do not have special invited presentation status. I told Amgen before the March 2010 MEDCAC that they did not have special status as the manufacturer. We are being consistent.

From: Rollins, James (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:00 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

So that means that Dendreon will not be given the opportunity to give a presentation. But I am sure that there will be representatives in the audience to give a 5 minute public comment. Jarollins

---

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:58 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

They are not an invited speaker. They can do what other manufacturers have done in the past and use the usual process.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:49 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Therefore, do I say "no" to Dendreon?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:45 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

GAPPnet was not the product in the same sense as Provenge. The underlying topic for the May 2009 MEDCAC was desirable characteristics of evidence on genetic screening tests. So it looks like we do not have an actual case of a manufacturer speaking at a meeting where coverage of its own product was the topic.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Thank you!

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:05 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I will relay the official position of CAG.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:03 PM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

We need to be precise. Dendreon has the opportunity to give a presentation, just like the rest of the public. They do not have special invited presentation status. I told Amgen before the March 2010 MEDCAC that they did not have special status as the manufacturer. We are being consistent.

From: Rollins, James (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:00 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

So that means that Dendreon will not be given the opportunity to give a presentation. But I am sure that there will be representatives in the audience to give a 5 minute public comment. Jarollins

---

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:58 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

They are not an invited speaker. They can do what other manufacturers have done in the past and use the usual process.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:49 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Therefore, do I say "no" to Dendreon?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:45 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

GAPPnet was not the product in the same sense as Provenge. The underlying topic for the May 2009 MEDCAC was desirable characteristics of evidence on genetic screening tests. So it looks like we do not have an actual case of a manufacturer speaking at a meeting where coverage of its own product was the topic.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:11 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Why don't you and Jim call Chris Lockett at 301-832-5340? He discussed this with me on 9/1 and 9/3. I will be glad to do the call with you.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:07 PM
To: Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Please let Jim and me take a look at it before sending to Dendreon, thanks.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:05 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I will relay the official position of CAG.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:03 PM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

We need to be precise. Dendreon has the opportunity to give a presentation, just like the rest of the public. They do not have special invited presentation status. I told Amgen before the March 2010 MEDCAC that they did not have special status as the manufacturer. We are being consistent.

From: Rollins, James (CMS/OCSQ)
Sent: Monday, September 13, 2010 12:00 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

So that means that Dendreon will not be given the opportunity to give a presentation. But I am sure that there will be representatives in the audience to give a 5 minute public comment. Jarollins

---

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:58 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

They are not an invited speaker. They can do what other manufacturers have done in the past and use the usual process.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:49 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Therefore, do I say "no" to Dendreon?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:45 AM
To: Fitterman, Leslye (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

GAPPnet was not the product in the same sense as Provenge. The underlying topic for the May 2009 MEDCAC was desirable characteristics of evidence on genetic screening tests. So it looks like we do not have an actual case of a manufacturer speaking at a meeting where coverage of its own product was the topic.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Thank you!

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 11:07 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

Louis and Tamara:

This is a follow-up to our discussion several weeks ago regarding Dendreon's request for a 20 – 30 minute presentation to the MEDCAC on Nov 17th. You wanted to know if at any prior MEDCACs the sponsor was allowed to present. I believe that the case identified by Michele, Steve Teutcsh presentation on GAPPnet and his role as an voting member of the committee at the May 6, 2009 meeting, may represent a precedent for allowing Dendreon to present. In addition, Dendreon will not be sitting on the committee at all.

Please let me know your thoughts on next steps with Dendreon.

Leslye

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:59 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

He was also a member of Genomic Applications in Practice and Prevention Network (GAPPNet™): A National Collaboration for Realizing the Promise of Genomics in Health Care and Disease Prevention.

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:23 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

It was on the May 6, 2009 Screening for Genetic Testing, Steven Teutsch, MD, MPH, was a voting panel member and a guest speaker.

Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:06 AM
To: Atkinson, Michelle L. (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

Thank you!

From: Atkinson, Michelle L. (CMS/OCSQ)
Sent: Monday, September 13, 2010 10:03 AM
To: Fitterman, Leslye (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: MEDCAC Presentations

I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

Thanks
Michelle

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, September 13, 2010 7:28 AM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: FW: MEDCAC Presentations

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
Subject: MEDCAC Presentations

Maria & Michele:

The PROVENGE Team has spoken with Louis and Tamara regarding the request from Dendreon to have a 20 minute time slot to present their product at the MEDCAC scheduled for November 17, 2010. CAG management would like to know if this has been permitted at a prior MEDCAC and if so can you provide examples.

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Goodman, Cliff
Sent: Friday, September 03, 2010 7:18 PM
To: (b)(6) @gmail.com
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: Re: November 17th MEDCAC Questions - re: "burden"

Yes, I still concur on that.

From: Saty Satya-Murti (b)(6) gmail.com>
To: Goodman, Cliff
Cc: Jacques, Louis B. (CMS/OCSQ) <Louis.Jacques@cms.hhs.gov>; Syrek Jensen, Tamara S. (CMS/OCSQ) <tamara.syrekjensen@cms.hhs.gov>; PASERCHIA, LORI A. (CMS/OCSQ) <Lori.Paserchia@cms.hhs.gov>; Fitterman, Leslye (CMS/OCSQ) <Leslye.Fitterman3@cms.hhs.gov>; Pencek, Eileen (CMS/OCSQ) <Eileen.Pencek@cms.hhs.gov>; Rollins, James (CMS/OCSQ) <James.Rollins2@cms.hhs.gov>; Ellis, Maria A. (CMS/OCSQ) <Maria.Ellis@cms.hhs.gov>
Sent: Fri Sep 03 19:11:56 2010
Subject: Re: November 17th MEDCAC Questions - re: "burden"

Cliff and Louis:

I am at ease with these questions. My only suggestion, (b)(5) - Predecisional
(b)(5) - Predecisional

Saty.

On Fri, Sep 3, 2010 at 8:33 AM, Goodman, Cliff <clifford.goodman@lewin.com> wrote:

(b)(5) - Predecisional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Friday, September 03, 2010 11:23 AM
To: Goodman, Cliff
Cc: (b)(6) gmail.com; Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: November 17th MEDCAC Questions - re: "burden"

Cliff,

(b)(5) - Predecisional

Louis

(b)(5) - Predecisional

From: Goodman, Cliff
Sent: Tuesday, August 31, 2010 11:45 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: (b)(6) gmail.com
Subject: FW: November 17th MEDCAC Questions - re: "burden"

(b)(5) - Predecisional

(b)(5) - Predecisional

(b)(5) - Predecisional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Ellis, Maria A. (CMS/OCSQ) [mailto:Maria.Ellis@cms.hhs.gov]
Sent: Tuesday, August 31, 2010 11:29 AM
To: Goodman, Cliff; (b)(6) @gmail.com
Subject: November 17th MEDCAC Questions

Good Morning!

Attached are the revised questions for the November 17th MEDCAC. If you agree with the changes, please let me know via email response so that they can be posted. 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

********** IMPORTANT - PLEASE READ **********

This e-mail, including attachments, may include confidential and/or proprietary information, and may be used only by the person or entity to which it is addressed. If the reader of this e-mail is not the intended recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this e-mail in error, please notify the sender by replying to this message and delete this e-mail immediately.

Jacques, Louis B. (CMS/OCSQ)

From: Saty Satya-Murti(b)(6) @gmail.com]
Sent: Friday, September 03, 2010 7:12 PM
To: Goodman, Cliff
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: Re: November 17th MEDCAC Questions - re: "burden"

Cliff and Louis:

I am at ease with these questions. My only suggestion, (b)(5) - Predecisional
(b)(5) - Predecisional

Saty.

On Fri, Sep 3, 2010 at 8:33 AM, Goodman, Cliff <clifford.goodman@lewin.com> wrote:

(b)(5) - Predecisional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Friday, September 03, 2010 11:23 AM
To: Goodman, Cliff
Cc: (b)(6) @gmail.com; Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)
Subject: RE: November 17th MEDCAC Questions - re: "burden"

Cliff,

(b)(5) - Predecisional

Louis

(b)(5) - Predecisional

From: Goodman, Cliff
Sent: Tuesday, August 31, 2010 11:45 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: (b)(6) @gmail.com
Subject: FW: November 17th MEDCAC Questions - re: "burden"

(b)(5) - Predecisional

(b)(5) - Predecisional

(b)(5) - Predecisional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Ellis, Maria A. (CMS/OCSQ) [mailto:Maria.Ellis@cms.hhs.gov]
Sent: Tuesday, August 31, 2010 11:29 AM
To: Goodman, Cliff; (b)(6) @gmail.com
Subject: November 17th MEDCAC Questions

Good Morning!

Attached are the revised questions for the November 17th MEDCAC. If you agree with the changes, please let me know via email response so that they can be posted. 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

Jacques, Louis B. (CMS/OCSQ)

From: Brocato-Simons, Patricia M. (CMS/OCSQ)
Sent: Wednesday, September 01, 2010 11:05 AM
To: Hake, Cynthia S. (CMS/CMM); Eggleston, Felicia Y. (CMS/CMM); Fagan, Ann B. (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Brooks, Gaysha M. (CMS/CMM); Motsiopoulos, Diana S. (CMS/CMM)
Cc: Graves, Patricia A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Belle, Wanda M. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: RE: There is a HCPCS "C" code for Provenge, currently published

Cindy, et. al: Following up to verify if we're creating a physician office code for the January update relative to the Provenge NCD. FYI - Both a MEDCAC and technology assessment are planned as part of our analysis, with the proposed decision released on or around 3/30/11, along with the proposed CR, followed by a final decision on or around 6/30/11. Thanks. Patti

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Wednesday, August 04, 2010 11:36 AM
To: Brocato-Simons, Patricia M. (CMS/OCSQ); Belle, Wanda M. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Cc: Graves, Patricia A. (CMS/OCSQ)
Subject: FW: There is a HCPCS "C" code for Provenge, currently published

FYI

From: Hake, Cynthia S. (CMS/CMM)
Sent: Wednesday, August 04, 2010 11:33 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: There is a HCPCS "C" code for Provenge, currently published

Established by HAPG – outside the workgroup process – for use in HOPPS. As you can see by John's note below, we will likely establish a code in January for use is doctor's office.

From: Warren, John F. (CMS/CMM)
Sent: Wednesday, August 04, 2010 8:14 AM
To: Hake, Cynthia S. (CMS/CMM)
Subject: RE: FYI - Provenge

Yes, C9273. We don't see a need to code just yet so maybe January for the physician office.

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

From: Hake, Cynthia S. (CMS/CMM)
Sent: Tuesday, August 03, 2010 5:29 PM
To: Warren, John F. (CMS/CMM)
Subject: RE: FYI - Provenge

Do you happen to know if there is a "C" code out there for Provenge now? OR are we looking at January for a J code? Would ask Marjorie about the C code, but she's vacating.

From: Warren, John F. (CMS/CMM)
Sent: Tuesday, August 03, 2010 3:40 PM
To: Hake, Cynthia S. (CMS/CMM)
Subject: RE: FYI - Provenge

Paying for it as a drug. OCSQ is doing an NCD.

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

From: Hake, Cynthia S. (CMS/CMM)
Sent: Tuesday, August 03, 2010 2:41 PM
To: Warren, John F. (CMS/CMM)
Subject: FW: FYI - Provenge

Hi John –
I've missed a couple of workgroup meetings while on a detail, but heard that you formulated a position on this. Can you tell me in a nutshell?
Please and thanks!
Cindy

From: Bonnell, Claudia [mailto:Claudia.Bonnell@bcbsa.com]
Sent: Tuesday, August 03, 2010 8:55 AM
To: Hake, Cynthia S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Gilbreath, Cheryl (CMS/CMM)
Subject: FYI - Provenge

You probably already know about this – but in case you don't....

Dendreon's $93,000 Cancer Drug Price Must Be Paid by U.S., Doctors Say

By Tom Randall - Aug 2, 2010

Dendreon Inc.'s $93,000 price tag for its Provenge prostate cancer treatment must be covered under the rules of the U.S. Medicare health plan, according to a letter submitted by the American Society of Clinical Oncology.

The Centers for Medicare & Medicaid Services, the government agency that determines which treatments will be reimbursed, is required by the Social Security Act to pay for all cancer drugs approved by U.S. regulators, the cancer society said in a public letter submitted to the agency.

Provenge won marketing rights in the U.S. in April, becoming the first drug designed to train the body's immune system to fight cancer. Medicare, the government's health plan for the elderly and disabled, routinely pays for medicines once they've been approved regardless of price. The agency initiated a yearlong internal review on June 30 to determine whether Provenge should be an exception.

"We are concerned that CMS may have plans to examine the issue of whether to cover this therapy for its FDA-approved indications," the Alexandria, Virginia-based cancer society said in a letter posted on a CMS website for public comments. "This would be both counter-productive and ill-advised."

Dendreon rose 93 cents, or 2.9 percent, to $33.84 at 4 p.m. New York time in Nasdaq Stock Market composite trading. The stock has declined 33 percent since the drug was approved on April 29.

28,000 Doctors

The American Society of Clinical Oncology represents 28,000 cancer doctors and medical practitioners. The group holds the world's biggest annual meeting devoted to cancer drug research.

Treatment with Provenge costs about $93,000 for three doses administered over the course of a month. The medicine helped patients live about 4.1 months longer than those given a placebo, according to tests used to gain approval.

Before the review was announced, Don McLeod, an agency spokesman, said Provenge would almost certainly be covered by Medicare. He declined to comment today on the review.

The agency doesn't typically make formal determinations on cancer drugs. Instead, it pays claims through the local contractors who administer payments.

"Under any scenario, we urge CMS to provide clear public statements regarding Medicare's current policies governing the coverage of this therapy," ASCO said in the comments to Medicare. "Ambiguity and uncertainty regarding coverage policies can act as an unacceptable barrier to medically necessary care."

To contact the reporter on this story: Tom Randall in New York at trandall6@bloomberg.net.

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, August 30, 2010 8:40 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ)
Subject: PROVENGE MedCAC & AUA

Louis:
Lori and I talked with the representatives from AUA on Friday afternoon. There suggestion for a presenter of "late stage prostate cancer 101" (e.g., how assess symptoms related to cancer, treatment options, etc.) was David F. Penson, M.D., who was an investigator in the IMPACT trial. We suggested that they find someone who is a thought leader that was not associated with any of the PROVENGE trials. They will send us a list of other experts to present early this week.
In addition, we asked about Dr. Patrick Walsh (JHH) for another role in the MedCAC and were assured that he is a renowned thought leader.

Leslye

Jacques, Louis B. (CMS/OCSQ)

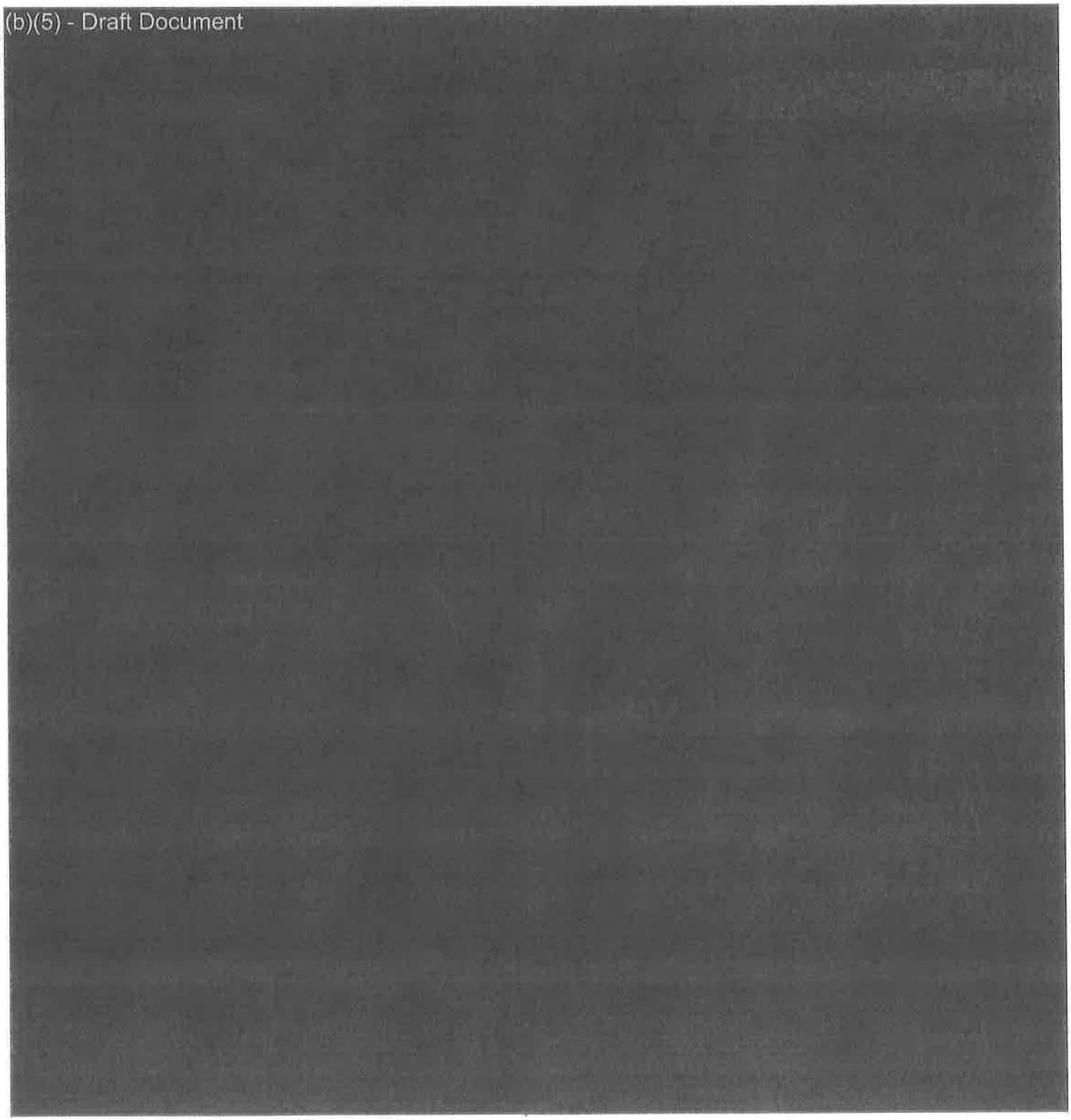
From: Fitterman, Leslye (CMS/OCSQ)
Sent: Tuesday, August 31, 2010 9:55 AM
To: Rollins, James (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Subject: Provenge MEDCAC Questions v2 082410 doc revision 3.doc
Attachments: Provenge MEDCAC Questions v2 082410 doc revision 3.doc

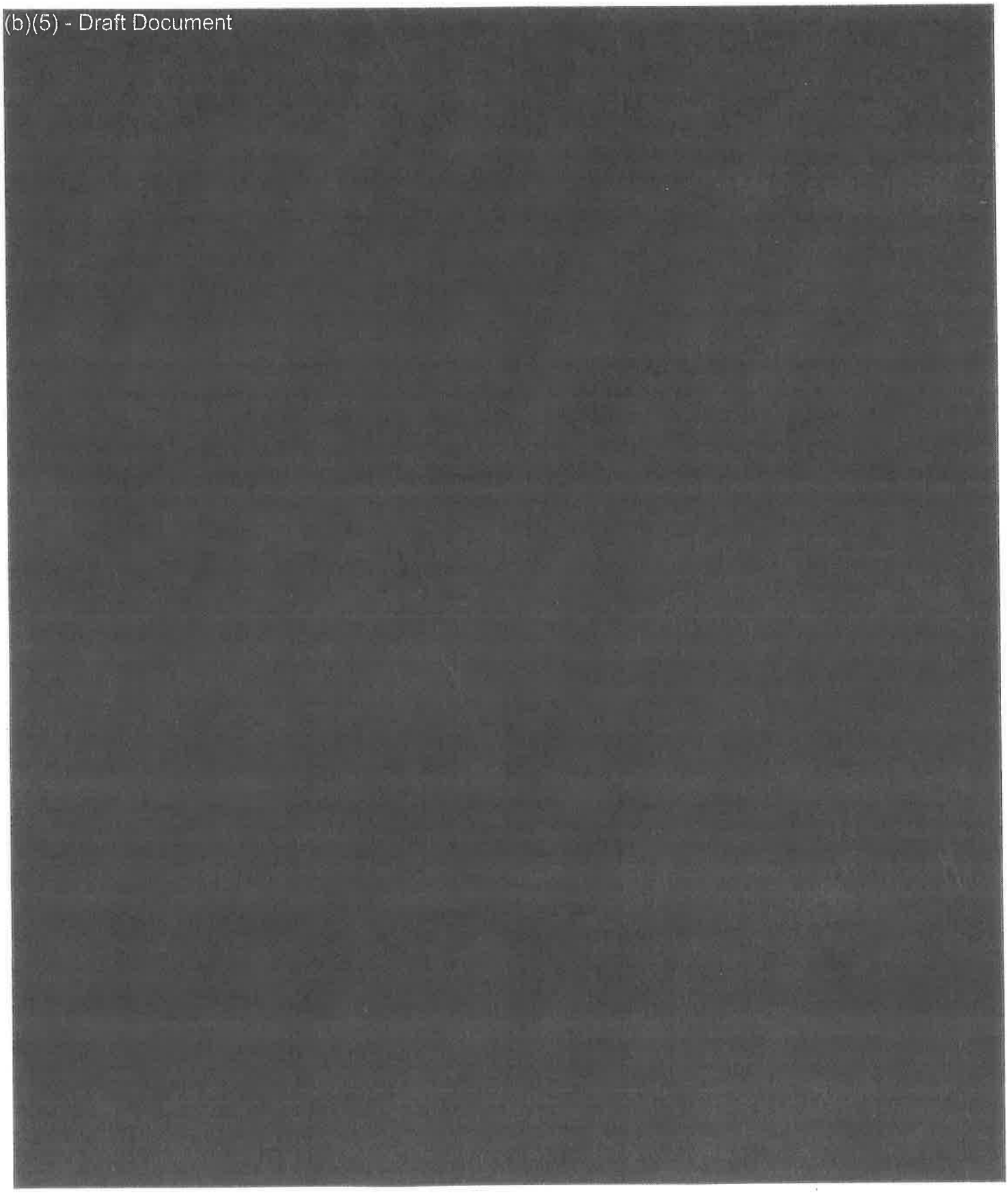
Jim:

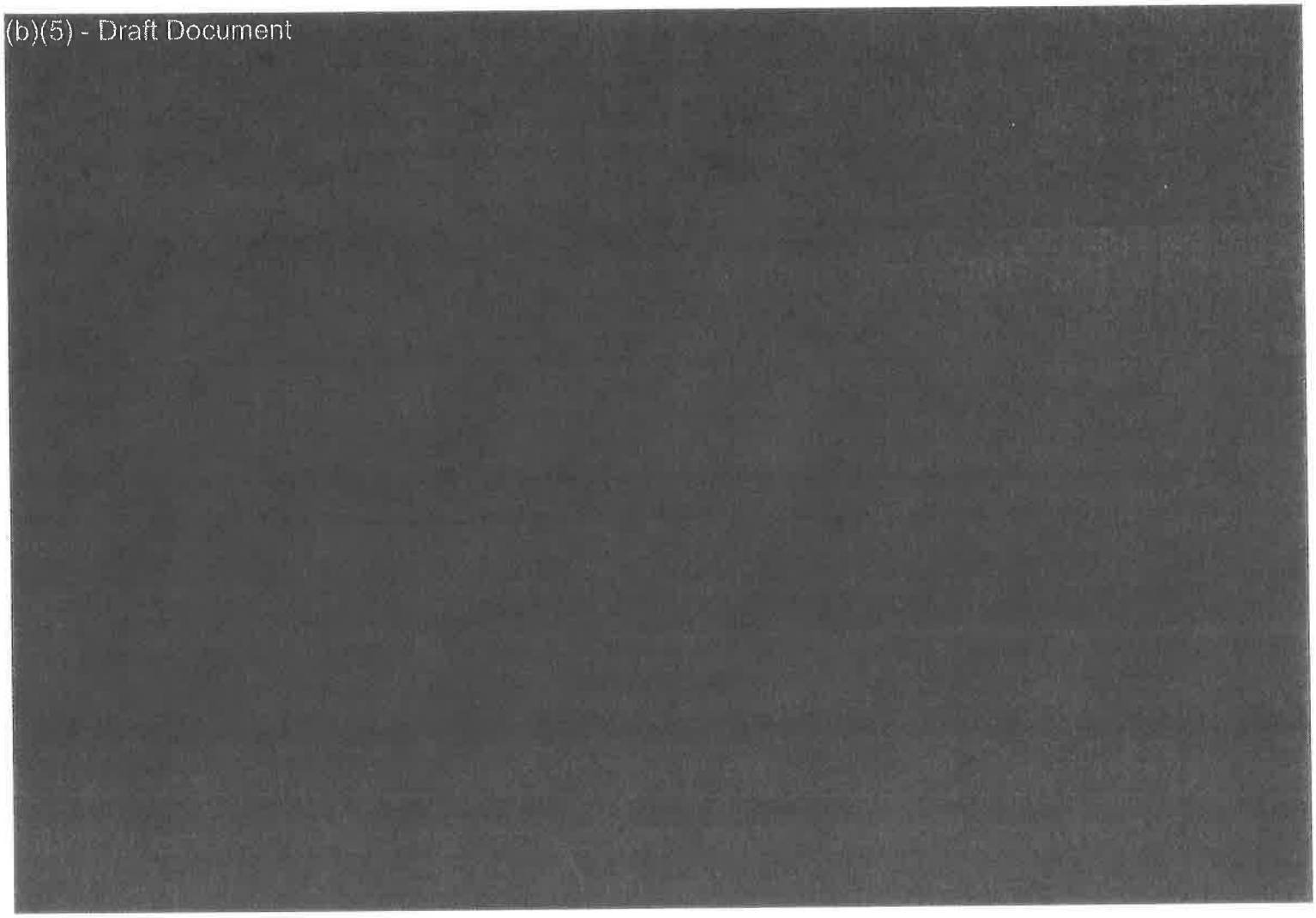
Attached please find the MedCAC questions as revised with the input of Saty and Cliff. Are they ready for Maria to send to Saty and Cliff for their review of this version.

Leslye

MEDCAC –November 17, 2010
DRAFT QUESTIONS
Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer




(b)(5) - Draft Document


(b)(5) - Draft Document

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Tuesday, August 31, 2010 10:47 AM
To: Fitterman, Leslye (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge MEDCAC Questions v2 082410 doc revision 3.doc

Yes, lets forward them to Maria for her to send them to Saty and Cliff for a final review. Jarollins

---

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Tuesday, August 31, 2010 9:55 AM
To: Rollins, James (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Subject: Provenge MEDCAC Questions v2 082410 doc revision 3.doc

Jim:

Attached please find the MedCAC questions as revised with the input of Saty and Cliff. Are they ready for Maria to send to Saty and Cliff for their review of this version.

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Monday, August 16, 2010 3:33 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Fitterman, Leslye (CMS/OCSQ)
Subject: FW: Brownback provenge lkf 081610.doc
Attachments: Brownback provenge lkf 081610.doc

Louis, here is the response to a request from a constituent of Senator Brownback. We have the incoming information. Jarollins

---

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, August 16, 2010 2:17 PM
To: Rollins, James (CMS/OCSQ)
Subject: Brownback provenge lkf 081610.doc

Jim:

Attached is the draft response to Senator Brownback. It includes portions from the responses edited by Louis sent to Senator Webb and Representative Rohrabacher to address the specific issues in this inquiry.

Leslye

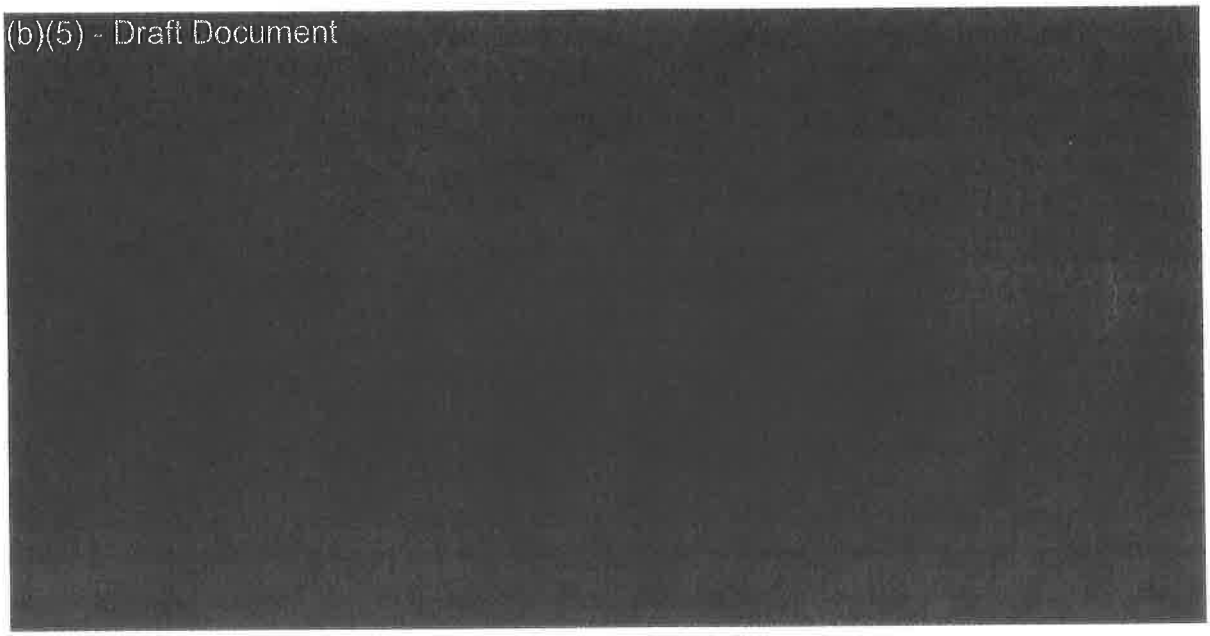
+

(Do not type date)

The Honorable Sam Brownback
United States Senate
11111 West 95th, Suite 245
Overland Park, KS 66214
Attention to: Shawn Cowing
(b)(6)

Dear Senator Brownback:

(b)(5) - Draft Document



Sincerely,

Jacques, Louis B. (CMS/OCSQ)

From: Stieber, Joan (CMS/OL)
Sent: Monday, August 09, 2010 4:45 PM
To: Jacques, Louis B. (CMS/OCSQ); 'FITTERMAN, LESLYE K. (CMS/OCSQ)'; PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Saklas, Ariadne (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Subject: FW: NCA Question

Louis, Leslye, Lori – OL received an inquiry seeking more information on *"what spurred CMS to open a NCA [on Provenge]"*.

Is there anything more you'd be willing to share about this, apart from what's already said on the coverage website? – e.g., the Tracking Sheet says: *"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®."*

thanks – Joan in OL

From: Saklas, Ariadne (CMS/OL)
Sent: Monday, August 09, 2010 11:47 AM
To: Stieber, Joan (CMS/OL)
Cc: Pettijohn, Juneous A. (CMS/OL)
Subject: FW: NCA Question

Dear Joan:

I think I might have heard you mention something about this at stand-up. Are you able to speak to me and the staffer from Rep. Inslee's office about PROVENGE? Thanks!

Sincerely,

Ariadne Saklas
Health Insurance Specialist
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, D.C. 20201
(202) 690-8606
(202) 690-8168 Fax
ariadne.saklas@cms.hhs.gov

From: Pettijohn, Juneous A. (CMS/OL)
Sent: Friday, August 06, 2010 4:08 PM
To: Saklas, Ariadne (CMS/OL)
Subject: FW: NCA Question

Check with Joan on this issue. Most likely she wants a conference call on this.

Thanks.

From: Eidman, Megan [mailto:Megan.Eidman@mail.house.gov]
Sent: Friday, August 06, 2010 11:20 AM

To: Pettijohn, Juneous A. (CMS/OL)
Subject: NCA Question

Hi Juneous,

On June 30th, CMS opened a NCA to determine if Medicare would cover PROVENGE, a prostate cancer treatment. PROVENGE, was approved by the FDA in April 2010 for the treatment of minimally symptomatic metastatic prostate cancer. I am curious to know what spurred CMS to open a NCA, is there someone at CMS that I can speak to about this?

Many thanks in advance for your help.

Best,
Megan

Megan Eidman
Legislative Assistant
Congressman Jay Inslee
403 Cannon HOB
Washington, D.C. 20515
202-225-6311
202-226-1606 (fax)
www.house.gov/inslee
megan.eidman@mail.house.gov

Jacques, Louis B. (CMS/OCSQ)

From: Stieber, Joan (CMS/OL)
Sent: Monday, August 09, 2010 4:58 PM
To: Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Cc: Saklas, Ariadne (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Subject: RE: NCA Question

Thanks Louis. Are you saying you have a FOIA request seeking an explanation of why you opened the NCA?

And if so, does that preclude our sharing any information on it with this Congressional inquirer (Rep. Inslee, D-WA)? Or would those be 2 separate matters?

Also, is the fact that we have received a FOIA request disclosable?

thanks -- Joan

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, August 09, 2010 4:50 PM
To: Stieber, Joan (CMS/OL); 'Leslye.Fitterman@cms.hhs.gov'; PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Saklas, Ariadne (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Subject: Re: NCA Question

We have a foia
Sent from my Blackberry

From: Stieber, Joan (CMS/OL)
To: Jacques, Louis B. (CMS/OCSQ); 'FITTERMAN, LESLYE K. (CMS/OCSQ)'; PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Saklas, Ariadne (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Sent: Mon Aug 09 16:44:31 2010
Subject: FW: NCA Question

Louis, Leslye, Lori – OL received an inquiry seeking more information on *"what spurred CMS to open a NCA [on Provenge]"*.

Is there anything more you'd be willing to share about this, apart from what's already said on the coverage website? – e.g., the Tracking Sheet says: *"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®."*

thanks – Joan in OL

From: Saklas, Ariadne (CMS/OL)
Sent: Monday, August 09, 2010 11:47 AM
To: Stieber, Joan (CMS/OL)
Cc: Pettijohn, Juneous A. (CMS/OL)
Subject: FW: NCA Question

Dear Joan:

I think I might have heard you mention something about this at stand-up. Are you able to speak to me and the staffer from Rep. Inslee's office about PROVENGE? Thanks!

Sincerely,

Ariadne Saklas
Health Insurance Specialist
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, D.C. 20201
(202) 690-8606
(202) 690-8168 Fax
ariadne.saklas@cms.hhs.gov

From: Pettijohn, Juneous A. (CMS/OL)
Sent: Friday, August 06, 2010 4:08 PM
To: Saklas, Ariadne (CMS/OL)
Subject: FW: NCA Question

Check with Joan on this issue. Most likely she wants a conference call on this.

Thanks.

From: Eidman, Megan [mailto:Megan.Eidman@mail.house.gov]
Sent: Friday, August 06, 2010 11:20 AM
To: Pettijohn, Juneous A. (CMS/OL)
Subject: NCA Question

Hi Juneous,

On June 30th, CMS opened a NCA to determine if Medicare would cover PROVENGE, a prostate cancer treatment. PROVENGE, was approved by the FDA in April 2010 for the treatment of minimally symptomatic metastatic prostate cancer. I am curious to know what spurred CMS to open a NCA, is there someone at CMS that I can speak to about this?

Many thanks in advance for your help.

Best,
Megan

Megan Eidman
Legislative Assistant
Congressman Jay Inslee
403 Cannon HOB
Washington, D.C. 20515
202-225-6311
202-226-1606 (fax)
www.house.gov/inslee
megan.eidman@mail.house.gov

Dendreon rose 93 cents, or 2.9 percent, to $33.84 at 4 p.m. New York time in Nasdaq Stock Market composite trading. The stock has declined 33 percent since the drug was approved on April 29.

28,000 Doctors

The American Society of Clinical Oncology represents 28,000 cancer doctors and medical practitioners. The group holds the world's biggest annual meeting devoted to cancer drug research.

Treatment with Provenge costs about $93,000 for three doses administered over the course of a month. The medicine helped patients live about 4.1 months longer than those given a placebo, according to tests used to gain approval.

Before the review was announced, Don McLeod, an agency spokesman, said Provenge would almost certainly be covered by Medicare. He declined to comment today on the review.

The agency doesn't typically make formal determinations on cancer drugs. Instead, it pays claims through the local contractors who administer payments.

"Under any scenario, we urge CMS to provide clear public statements regarding Medicare's current policies governing the coverage of this therapy," ASCO said in the comments to Medicare. "Ambiguity and uncertainty regarding coverage policies can act as an unacceptable barrier to medically necessary care."

To contact the reporter on this story: Tom Randall in New York at trandall6@bloomberg.net.

Jacques, Louis B. (CMS/OCSQ)

From: Hake, Cynthia S. (CMS/CMM)
Sent: Tuesday, August 03, 2010 5:28 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: FYI - Provenge

See string. This may or may not be of interest to you. Appears as though we will be establishing a code. At any rate, it seems that you guys might be able to glean important information about mortality, etc.. if there is a separate coded for Provenge, since you have the NCD going on. Is that an accurate statement?

From: Warren, John F. (CMS/CMM)
Sent: Tuesday, August 03, 2010 3:40 PM
To: Hake, Cynthia S. (CMS/CMM)
Subject: RE: FYI - Provenge

Paying for it as a drug. OCSQ is doing an NCD.

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

---

From: Hake, Cynthia S. (CMS/CMM)
Sent: Tuesday, August 03, 2010 2:41 PM
To: Warren, John F. (CMS/CMM)
Subject: FW: FYI - Provenge

Hi John –
I've missed a couple of workgroup meetings while on a detail, but heard that you formulated a position on this. Can you tell me in a nutshell?
Please and thanks!
Cindy

From: Bonnell, Claudia [mailto:Claudia.Bonnell@bcbsa.com]
Sent: Tuesday, August 03, 2010 8:55 AM
To: Hake, Cynthia S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Gilbreath, Cheryl (CMS/CMM)
Subject: FYI - Provenge

You probably already know about this – but in case you don't....

Dendreon's $93,000 Cancer Drug Price Must Be Paid by U.S., Doctors Say

By Tom Randall - Aug 2, 2010

Dendreon Inc.'s $93,000 price tag for its Provenge prostate cancer treatment must be covered under the rules of the U.S. Medicare health plan, according to a letter submitted by the American Society of Clinical Oncology.

The Centers for Medicare & Medicaid Services, the government agency that determines which treatments will be reimbursed, is required by the Social Security Act to pay for all cancer drugs approved by U.S. regulators, the cancer society said in a public letter submitted to the agency.

Provenge won marketing rights in the U.S. in April, becoming the first drug designed to train the body's immune system to fight cancer. Medicare, the government's health plan for the elderly and disabled, routinely pays for medicines once they've been approved regardless of price. The agency initiated a yearlong internal review on June 30 to determine whether Provenge should be an exception.

"We are concerned that CMS may have plans to examine the issue of whether to cover this therapy for its FDA-approved indications," the Alexandria, Virginia-based cancer society said in a letter posted on a CMS website for public comments. "This would be both counter-productive and ill-advised."

Dendreon rose 93 cents, or 2.9 percent, to $33.84 at 4 p.m. New York time in Nasdaq Stock Market composite trading. The stock has declined 33 percent since the drug was approved on April 29.

28,000 Doctors

The American Society of Clinical Oncology represents 28,000 cancer doctors and medical practitioners. The group holds the world's biggest annual meeting devoted to cancer drug research.

Treatment with Provenge costs about $93,000 for three doses administered over the course of a month. The medicine helped patients live about 4.1 months longer than those given a placebo, according to tests used to gain approval.

Before the review was announced, Don McLeod, an agency spokesman, said Provenge would almost certainly be covered by Medicare. He declined to comment today on the review.

The agency doesn't typically make formal determinations on cancer drugs. Instead, it pays claims through the local contractors who administer payments.

"Under any scenario, we urge CMS to provide clear public statements regarding Medicare's current policies governing the coverage of this therapy," ASCO said in the comments to Medicare. "Ambiguity and uncertainty regarding coverage policies can act as an unacceptable barrier to medically necessary care."

To contact the reporter on this story: Tom Randall in New York at trandall6@bloomberg.net.

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Tuesday, August 03, 2010 9:57 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Dendreon

Will do. Jarollins

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 27th 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

Jacques, Louis B. (CMS/OCSQ)

From: Lockett, Chris [clockett@Dendreon.com]
Sent: Monday, August 02, 2010 10:47 AM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: Meeting Attendees

Dr. Jacques,

Here is out list attendees for our meeting tomorrow;

Mark Frohlich, MD
Dendreon Corporation
SVP, Clinical Affairs & Chief Medical Officer

Celestia S. Higano, MD
Professor of Medicine
University of Washington

Chris Lockett
Sr. Director Government Affairs
Dendreon Corporation

Beth Roberts
Partner
Hogan Lovells

Regards,

Chris

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Sunday, August 01, 2010 11:24 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: Fwd: Sipuleucel-T Review Unethical

FYI

Sent from my iPhone

Begin forwarded message:

> **From:** "Brad Loncar" <(b)(6)
> **Date:** August 1, 2010 7:05:56 AM EDT
> **To:** Leslye.fitterman3@cms.hhs.gov
> **Subject: Sipuleucel-T Review Unethical**
>
> On page 14 of the U.S. Food and Drug Administration's Summary Basis of Regulatory Approval of sipuleucel-T, the agency states that "Because D9902B provides substantial evidence of improved survival, a second study would be neither **ethical** nor feasible."
>
> In other words, the FDA is saying that substantial scientific evidence confirms that this therapy works and to investigate it further and add delay to cancer patients receiving it would be **unethical**.
>
> Yet this is exactly what you are doing. On behalf of the tens of thousands of men who are suffering from this debilitating disease, I strongly recommend that your agency drop its NCA of sipuleucel-T, or at the very least publicly clarify what the aims and scope of your NCA is.
>
> Through your lack of transparency about what is going on here, you are adding a de facto 2nd regulatory hurdle to usage of a FDA approved drug. Which is very alarming for these men and medicine in general because it (1) creates an unnecessary barrier for men to receive this life-prolonging therapy and (2) hurts innovation in this country by raising the bar of risk the scientific community will face when deciding whether to attempt new discoveries.
> Please reconsider and/or clarify to the public what you are doing.
>
> Sincerely,
> Brad Loncar

Jacques, Louis B. (CMS/OCSQ)

Subject:	Meeting with Dendreon
Location:	N3-06-11
Start:	Tue 08/03/2010 11:00 AM
End:	Tue 08/03/2010 12:00 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Not yet responded
Organizer:	Fitterman, Leslye (CMS/OCSQ)
Required Attendees:	Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); HAKIM, ROSEMARIE B. (CMS/OCSQ); Debnam, Theresa T. (CMS/OCSQ)

Please see LOCATION

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 23, 2010 11:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: Odd comment

After discussing with Pat we did not post this one.

From: Dolina, Elaine L. (CMS/OCSQ)
Sent: Monday, July 19, 2010 2:26 PM
To: Fitterman, Leslye (CMS/OCSQ)
Cc: Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ)
Subject: Odd comment

Leslye-

This is a really weird comment and I'm not sure what to do with it. Any opinions are appreciated.

First Name	Dr. Joe
Last Name	Mengala
Title	Director of Experimental and Therapeutic Studies
Organization	Jacsobeer Manufacturing, Inc.
Email	(b)(6)
Comment	First, I have to tell you that I have to use my real name since I am fearful for my life and that of my friends and family. For years I worked for a company that made a chemotherapy agent that sounds like Jacksobeer. It was used to treat the poor men that had advanced prostate cancer. It was expensive as hell and the company made tons of money selling it, but the side effects were horrible. More horrible than some of the experiments I used to do back in the old days before CMS was even a glimmer in the "progressives" eye. Many men offered the jacksobeer concoction refused it altogether, preferring a painful death to a Godawful, feeling REALLY-sh*tty-all-the-time death. The chemo agent kept a few of the treated men alive for a few months but the complications were frequent and expensive, since most of the complications required admission to the hospital and horrific medical bills. Of course, those bills were mostly paid by Medicare and Medicaid, so nobody cared. Except for the few taxpayer''s s

left who pay the Medicare tax and see the huge increase in Medicaid spending. Thank your God that Obama is going to raise taxes so that the few taxpayers left can still foot the bill.

Anyway, jacksobeer generated hundreds of millions of dollars in PROFIT for the maker of the poison. Then, a new therapy came along. You know it as Provenge, but my boss referred to it as "that crap from those bastards at Dendreon."

FDA studies done over 5 years showed "that crap" was more effective in improving survival of advanced PCa AND the side effects were far fewer.

Top level conferences were held in the old Reichstag conference room and they decided that jacksobeer might not make much as much money any more.
When I spoke up on behalf of "that crap" Provenge, some guys with funny "SS" marks on their arms roughly ushered me out and took away my party membership card.
I was shown some pictures of what looked like a big outdoor barbeque pit and told to keep quiet.

But, I met Pope John Paul II one time and he heard my act of contrition and gave me a rosary that he had personally blessed with water from the Jordan.

I realize that by revealing this story, my life is in danger, but Jesus said that laying down one''s life for another is the greatest good. So I do not fear being a martyr for the poor men who are dying of Pca and seek "that crap" form Dendreon.

Please consider all the merits of Provenge and the decide if YOU would rather have jacksobeer or PV if YOU got prostate cancer.

J. Mengala MD/PHD/VDRL/STD/AWOL

Jacques, Louis B. (CMS/OCSQ)

From: PASERCHIA, LORI A. (CMS/OCSQ)
Sent: Friday, July 23, 2010 9:53 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge Public Comments

Celia Witten from CBER/FDA is the logical choice to invite. We can ask her if anyone else from FDA should attend.

Lori A. Paserchia, MD
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Lori.Paserchia@cms.hhs.gov
410.786.2115

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 tosome researcherstherefore staying anon. Even if this is redacted,do examine the trial design analysis tosee 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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 23, 2010 7:35 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge Public Comments

Please include Pat since her division is responsible for comments.

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 researchersthereforestaying 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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 23, 2010 7:52 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Meeting with Dendreon at CMS

Will schedule a meeting today if possible.

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Friday, July 23, 2010 7:46 AM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Meeting with Dendreon at CMS

(b)(5) - Predecisional

Sent from my Blackberry

----- Original Message -----
From: Rollins, James (CMS/OCSQ)
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Sent: Fri Jul 23 06:58:22 2010
Subject: RE: Meeting with Dendreon at CMS

In this situation, comparative effectiveness might mean, when considering the options for prostate cancer treatment, how would provenge compare to other treatment forms. I'm sure there are no studies looking at this, but this might be a way of we would look at adding a new treatment option to our armamentarium for the treatment of the condition. But our function in the meeting is to basically observe and listen to their comments. Jarollins

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
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

(b)(5) - Predecisional

-----Original Message-----
From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thu 7/22/2010 4:19 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:

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 3rd.

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

Jacques, Louis B. (CMS/OCSQ)

From: Rollins, James (CMS/OCSQ)
Sent: Friday, July 23, 2010 6:58 AM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: RE: Meeting with Dendreon at CMS

In this situation, comparative effectiveness might mean, when considering the options for prostate cancer treatment, how would provenge compare to other treatment forms. I'm sure there are no studies looking at this, but this might be a way of we would look at adding a new treatment option to our armamentarium for the treatment of the condition. But our function in the meeting is to basically observe and listen to their comments. Jarollins

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
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

(b)(5) - Predecisional

[redacted]

-----Original Message-----
From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thu 7/22/2010 4:19 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:

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 3rd.

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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, July 22, 2010 3:19 PM
To: Pencek, Eileen (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: provenge
Attachments: Provenge.doc

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

Jim and Naomi,

(b)(5) - Predecisional

[redacted]

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

Jacques, Louis B. (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
Attachments: image001.gif

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?
(2) For those who aren't covering it, what is the basis for not covering it?
(3) With regard to NCDs, how often are they self-initiated, i.e., how many do we open ourselves versus receiving a request to open one?
(4) Have we opened any other NCDs on other cancer drugs? If so, how many were opened at the agency's direction versus upon request?
(5) Have we commissioned the external TA mentioned below? Have they met yet?
(6) Has the MEDCAC held a meeting on this yet? If not, when is it expected to meet?
(7) What is the next step in the process? What is the expected timeline for this process?

Thanks for your help on this.

Erin M. Clapton
Director
Medicare Part A & Part B Analysis Group
CMS Office of Legislation

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 reagarding 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) [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."
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
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. 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: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, July 19, 2010 8:06 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: Re: autologous cellular immunotherapy treatment of prostate cancer

I will draft the responses and send it to you for editing.

Leslye

Sent from my iPhone

On Jul 19, 2010, at 7:55 PM, "Jacques, Louis B. (CMS/OCSQ)" <Louis.Jacques@cms.hhs.gov> wrote:

> 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(l)) 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)

Cc: Leung, Isabella (CMS/OL); Stieber, Joan (CMS/OL)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer

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?

(2) For those who aren't covering it, what is the basis for not covering it?

(3) With regard to NCDs, how often are they self-initiated, i.e., how many do we open ourselves versus receiving a request to open one?

(4) Have we opened any other NCDs on other cancer drugs? If so, how many were opened at the agency's direction versus upon request?

(5) Have we commissioned the external TA mentioned below? Have they met yet?

(6) Has the MEDCAC held a meeting on this yet? If not, when is it expected to meet?

(7) What is the next step in the process? What is the expected timeline for this process?

Thanks for your help on this.

Erin M. Clapton

Director

Medicare Part A & Part B Analysis Group

CMS Office of Legislation

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 reagarding 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) <http://www.cms.gov/mcd/public_comment.asp?nca_id=247&basketitem=>

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?subject=WEB%20EMAIL%20-%20CAG-00422N>
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.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.

<image001.gif>

Jacques, Louis B. (CMS/OCSQ)

From: Chadwick, Alpheus K. (CMS/OL)
Sent: Monday, July 12, 2010 2:35 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer
Attachments: image001.gif

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?

-Al

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 reagarding 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) [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."
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
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. 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.**

(1 inch margins all around)

(Do not type date)

(b)(5) - Draft Document

Formatted: Highlight

Formatted: Highlight

Jacques, Louis B. (CMS/OCSQ)

From: Hake, Cynthia S. (CMS/CMM)
Sent: Tuesday, August 03, 2010 5:49 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: FYI - Provenge

HAPG had to first establish that this treatment would be considered a drug. Evidently, they have done so. However even when separate payment is appropriate (if a product meets the requirements for separate payment under Section 1847A of the Act), a unique and separate code does not necessarily have to follow – although it typically does – to facilitate separate payment.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, August 03, 2010 5:42 PM
To: Hake, Cynthia S. (CMS/CMM)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: Re: FYI - Provenge

Yes. A sep code would help. Don't drugs automatically get J codes?

On Aug 3, 2010, at 17:28, "Hake, Cynthia S. (CMS/CMM)" <Cynthia.Hake@cms.hhs.gov> wrote:

> See string. This may or may not be of interest to you. Appears as though we will be establishing a code. At any rate, it seems that you guys might be able to glean important information about mortality, etc.. if there is a separate coded for Provenge, since you have the NCD going on. Is that an accurate statement?
>
> ---
>
> **From:** Warren, John F. (CMS/CMM)
> **Sent:** Tuesday, August 03, 2010 3:40 PM
> **To:** Hake, Cynthia S. (CMS/CMM)
> **Subject:** RE: FYI - Provenge
>
> Paying for it as a drug. OCSQ is doing an NCD.
>
> **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**
>
> ---
>
> **From:** Hake, Cynthia S. (CMS/CMM)
> **Sent:** Tuesday, August 03, 2010 2:41 PM
> **To:** Warren, John F. (CMS/CMM)
> **Subject:** FW: FYI - Provenge

Hi John –

I've missed a couple of workgroup meetings while on a detail, but heard that you formulated a position on this. Can you tell me in a nutshell?

Please and thanks!

Cindy

From: Bonnell, Claudia [mailto:Claudia.Bonnell@bcbsa.com]
Sent: Tuesday, August 03, 2010 8:55 AM
To: Hake, Cynthia S. (CMS/CMM); Baldo, Marjorie D. (CMS/CMM); Gilbreath, Cheryl (CMS/CMM)
Subject: FYI - Provenge

You probably already know about this – but in case you don't....

Dendreon's $93,000 Cancer Drug Price Must Be Paid by U.S., Doctors Say

By Tom Randall - Aug 2, 2010

Dendreon Inc.'s $93,000 price tag for its Provenge prostate cancer treatment must be covered under the rules of the U.S. Medicare health plan, according to a letter submitted by the American Society of Clinical Oncology.

The Centers for Medicare & Medicaid Services, the government agency that determines which treatments will be reimbursed, is required by the Social Security Act to pay for all cancer drugs approved by U.S. regulators, the cancer society said in a public letter submitted to the agency.

Provenge won marketing rights in the U.S. in April, becoming the first drug designed to train the body's immune system to fight cancer. Medicare, the government's health plan for the elderly and disabled, routinely pays for medicines once they've been approved regardless of price. The agency initiated a yearlong internal review on June 30 to determine whether Provenge should be an exception.

"We are concerned that CMS may have plans to examine the issue of whether to cover this therapy for its FDA-approved indications," the Alexandria, Virginia-based cancer society said in a letter posted on a CMS website for public comments. "This would be both counter-productive and ill-advised."

(b)(5) - Draft Document

[redacted]

(2 lines)

Sincerely, *(Tab in 6 times to align correctly)*

(4 lines)

(type name of signer)

(2 lines)

Enclosure

http://secureservices001.palmettogba.com/palmetto/providers.nsf/docsCat/Providers~Jurisdiction%201%20Part%20B~Articles~Drugs%20and%20Biologicals~Drugs%20Biologicals%20Provenge?open

http://www.cms.gov/mcd/viewtrackingsheet.asp?id=247

cc:
Mary Smith, ASPE
Jerry Seinfeld, ACF
Bob Bensen, NIH

(If there is a "cc" list, do the following: click **"Insert," "Break," "Page Break," and "OK."** *Type the list on the next [or* ***last]*** *page.)*

Jacques, Louis B. (CMS/OCSQ)

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

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 table 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: 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 table 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: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:57 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

I attached it to the my email.

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 table 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: 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 table 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: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:59 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: response to Jim Webb
Attachments: Provenge letter to Webb.docx; Webb, Jim 062920104043[1].pdf

Second attachment is the incoming.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thursday, July 08, 2010 5:05 PM
To: Rinker, Karen A. (CMS/OCSQ)
Subject: FW: response to Jim Webb

Karen:

The pdf is the correspondence from Senator Webb.

Thanks for your assistance.

Leslye

From: Ashby, Lori M. (CMS/OCSQ)
Sent: Thursday, July 08, 2010 11:03 AM
To: Rollins, James (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: FW: response to Jim Webb

Jim:

Thanks for your quick response, but we're going to need a bit more detail in the draft response than what you sent yesterday (first attachment), and it should be in the correct format. Here's the link to the Agency's correspondence guidelines which contain information on what a Congressional response should look like and general information about what it should contain: http://cmsnet.cms.hhs.gov/hpages/ocos/correspondence/01tc.asp

Also, as Louis and JoAnna indicated in yesterday's Division Director meeting, Leslye probably has some good examples that can serve as a template for responding to this letter.

The second attachment is an electronic version of what is in the folder I handed to you yesterday. I asked BOS to send an e-version since Leslye is working off-site for awhile.

Please let me know if you have any additional questions. Thanks!

From: Rollins, James (CMS/OCSQ)
Sent: Wednesday, July 07, 2010 2:02 PM
To: Ashby, Lori M. (CMS/OCSQ)
Subject: response to Jim Webb

How does this sound? Modify as needed based on Louis' comment. Jarollins

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 09, 2010 3:05 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: response to Jim Webb
Attachments: Provenge letter to Webb.docx; Webb, Jim 062920104043[1].pdf

PLEASE NOTE THAT THE PHYSICIAN WHO CONTACTED SENATOR WEBB IS AN INVESTIGATOR FOR DENDREON ON PROVENGE

From: Ashby, Lori M. (CMS/OCSQ)
Sent: Thursday, July 08, 2010 11:03 AM
To: Rollins, James (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: FW: response to Jim Webb

Jim:

Thanks for your quick response, but we're going to need a bit more detail in the draft response than what you sent yesterday (first attachment), and it should be in the correct format. Here's the link to the Agency's correspondence guidelines which contain information on what a Congressional response should look like and general information about what it should contain: http://cmsnet.cms.hhs.gov/hpages/ocos/correspondence/01tc.asp

Also, as Louis and JoAnna indicated in yesterday's Division Director meeting, Leslye probably has some good examples that can serve as a template for responding to this letter.

The second attachment is an electronic version of what is in the folder I handed to you yesterday. I asked BOS to send an e-version since Leslye is working off-site for awhile.

Please let me know if you have any additional questions. Thanks!

From: Rollins, James (CMS/OCSQ)
Sent: Wednesday, July 07, 2010 2:02 PM
To: Ashby, Lori M. (CMS/OCSQ)
Subject: response to Jim Webb

How does this sound? Modify as needed based on Louis' comment. Jarollins

Jacques, Louis B. (CMS/OCSQ)

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
Attachments: Palmetto GBA - Jurisdiction 1 Part B - Drugs & Biologicals Provenge.mht

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 table 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: 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 table 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: 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
Attachments: 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

PROVENGE® National Coverage Analysis (NCA)

Questions and Answers

Internal Document Only

1. **Q: Why was this NCA opened?**

   A: This NCA was opened because prostate cancer is primarily a disease of older men, who comprise a large component of the Medicare population. Therefore, any treatment for prostate cancer will have a large impact on the Medicare program. We believe a nationally consistent policy for this therapy is warranted.

2. **Q: Are any local contractors covering PROVENGE®?**

   A: Currently the local Medicare contractors have the authority to make decisions on this therapy.

3. **Q: What is the NCD process?**

   A: Please see the information available on the website - http://www.cms.gov/DeterminationProcess/01_Overview.asp#TopOfPage

4. **Q: Was this NCA opened because PROVENGE® is the first product using a new technology platform?**

   A: No. Please see the answer to question 1.

5. **Q: Was the cost of this therapy a factor in opening the NCA?**

   A: Please see answer to question 1.

6. **Q: Has Medicare ever opened an NCA on a specific drug before?**

   A: Yes. The Agency did an NCA on abarelix for the treatment of prostate cancer and on Charite lumbar artificial disc for lumbar artificial disc replacement. However, the current NCA was opened on autologous cellular immunotherapy treatment of metastatic prostate cancer. This analysis may consider other treatments in this category of products and is not limited to Provenge.

   Q: Who made inquiries that prompted opening this NCA?

   A: Examples of entities that made inquiries on this treatment include patients, advocates, providers and local Medicare contractors.

7. **Q: Why is CMS opening an NCA on an FDA approved treatment?**

A: CMS and the FDA have different missions. FDA determines whether a drug, biologic, device etc. is safe and effective for the general population. CMS determines whether the drug, biologic, device, etc. is reasonable and necessary, that is, does it improve health outcomes, for the Medicare population.

Q: What is assessed to determine if the treatment is "reasonable and necessary"?

A: When making national coverage determinations, CMS determines whether relevant clinical evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

Please see Appendix A, which is included in every national coverage determination, for more information. For example, in the following decision memo at http://www.cms.gov/mcd/viewdraftdecisionmemo.asp?id=237

8. **Q: NCCN has included PROVENGE® in its guidelines for the treatment of prostate cancer. Why is CMS opening this NCA?**

A: We are aware that NCCN has included coverage for PROVENGE® in its guidelines. We will take this guideline, as well as other guidelines, under consideration as we review all relevant clinical evidence during our analysis. We encourage the public to share any available clinical evidence with CMS by submitting it during the 30-day comment period.

Jacques, Louis B. (CMS/OCSQ)

From: Griffith, Ellen B. (CMS/OEA)
Sent: Tuesday, July 06, 2010 2:53 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: question from Ed at Pharmalot

Louis – Don is out today. Do you want to talk with Ed Silverman? And if so, when would be a good time for you.

Ellen

From: Ed Silverman [mailto:pharmalot@gmail.com]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharmalot

Hi Ellen,

My name is Ed Silverman and I run the Pharmalot site, where I've covered the Provenge prostate cancer vaccine. I would like to speak with Louis Jacques because I'm curious to know more about the informal inquiries that prompted the coverage review. For instance, were these inquiries made by individuals or insurers? What constitutes an informal inquiry? Does this mean that formal inquiries aren't needed to spark a coverage review?

I'd be grateful if you could help facilitate this.

Thanks,
Ed S
editor
Pharmalot
ed@pharmalot.com
973-493-7851

Jacques, Louis B. (CMS/OCSQ)

From: Griffith, Ellen B. (CMS/OEA)
Sent: Tuesday, July 06, 2010 2:59 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: question from Ed at Pharmalot

Thanks,

Ellen

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, July 06, 2010 2:58 PM
To: Griffith, Ellen B. (CMS/OEA)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: Re: question from Ed at Pharmalot

There's nothing to say really. We just heard over the course of several months that people had questions about what it is, eg vaccine, immunotherapy, drug and how local contractors would cover or not. There's no "secret" requestor. Ill FW you my response to OL.
Sent from my Blackberry

From: Griffith, Ellen B. (CMS/OEA)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Tue Jul 06 14:53:08 2010
Subject: FW: question from Ed at Pharmalot

Louis – Don is out today. Do you want to talk with Ed Silverman? And if so, when would be a good time for you.

Ellen

From: Ed Silverman [mailto:pharmalot@gmail.com]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharmalot

Hi Ellen,

My name is Ed Silverman and I run the Pharmalot site, where I've covered the Provenge prostate cancer vaccine. I would like to speak with Louis Jacques because I'm curious to know more about the informal inquiries that prompted the coverage review. For instance, were these inquiries made by individuals or insurers? What constitutes an informal inquiry? Does this mean that formal inquiries aren't needed to spark a coverage review?

I'd be grateful if you could help facilitate this.

Thanks,
Ed S
editor
Pharmalot
ed@pharmalot.com
973-493-7851

Jacques, Louis B. (CMS/OCSQ)

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
Attachments: image001.gif

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 reagarding 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) [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."
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
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. 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: Fitterman, Leslye (CMS/OCSQ)
Sent: Tuesday, July 06, 2010 3:05 PM
To: Jacques, Louis B. (CMS/OCSQ); Griffith, Ellen B. (CMS/OEA)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: question from Ed at Pharmalot

Peter in the Press Office is willing to take the calls and re-direct them if necessary. I spoke with him this morning.

Leslye

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, July 06, 2010 2:58 PM
To: Griffith, Ellen B. (CMS/OEA)

Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: Re: question from Ed at Pharmalot

There's nothing to say really. We just heard over the course of several months that people had questions about what it is, eg vaccine, immunotherapy, drug and how local contractors would cover or not. There's no "secret" requestor. Ill FW you my response to OL.
Sent from my Blackberry

From: Griffith, Ellen B. (CMS/OEA)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Tue Jul 06 14:53:08 2010
Subject: FW: question from Ed at Pharmalot

Louis – Don is out today. Do you want to talk with Ed Silverman? And if so, when would be a good time for you.

Ellen

From: Ed Silverman [mailto:pharmalot@gmail.com]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharmalot

Hi Ellen,

My name is Ed Silverman and I run the Pharmalot site, where I've covered the Provenge prostate cancer vaccine. I would like to speak with Louis Jacques because I'm curious to know more about the informal inquiries that prompted the coverage review. For instance, were these inquiries made by individuals or insurers? What constitutes an informal inquiry? Does this mean that formal inquiries aren't needed to spark a coverage review?

I'd be grateful if you could help facilitate this.

Thanks,
Ed S

editor
Pharmalot
ed@pharmalot.com
973-493-7851

Jacques, Louis B. (CMS/OCSQ)

From: Griffith, Ellen B. (CMS/OEA)
Sent: Tuesday, July 06, 2010 3:26 PM
To: 'Ed Silverman'
Subject: RE: question from Ed at Pharmalot

This NCA was opened because prostate cancer is primarily a disease of older men, who comprise a large component of the Medicare population. Therefore, any treatment for prostate cancer will have a large impact on the Medicare program. We believe a nationally consistent policy for this therapy is warranted.

Incidentally, the NCA was opened on autologous cellular immunotherapy treatment of metastatic prostate cancer. Therefore, this analysis may consider other treatments in this category of products and is not limited to Provenge.

I hope this is helpful.

Ellen

From: Ed Silverman [mailto:pharmalot@gmail.com]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharmalot

Hi Ellen,

My name is Ed Silverman and I run the Pharmalot site, where I've covered the Provenge prostate cancer vaccine. I would like to speak with Louis Jacques because I'm curious to know more about the informal inquiries that prompted the coverage review. For instance, were these inquiries made by individuals or insurers? What constitutes an informal inquiry? Does this mean that formal inquiries aren't needed to spark a coverage review?

I'd be grateful if you could help facilitate this.

Thanks,
Ed S
editor
Pharmalot
ed@pharmalot.com
973-493-7851

Jacques, Louis B. (CMS/OCSQ)

From: Martino, Maria (CMS/OL)
Sent: Tuesday, July 06, 2010 4:28 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer
Attachments: image001.gif

Thanks! The staffer was wondering if there was anything public that he could give to the prostate cancer groups aside from the information below—but looks like there is not.

Maria

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, July 06, 2010 4:17 PM
To: Martino, Maria (CMS/OL)
Cc: Ashby, Lori M. (CMS/OCSQ); Griffith, Ellen B. (CMS/OEA); Ashkenaz, Peter (CMS/OEABS)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer

Peter Ashkenaz in OEA has QAs on Provenge. We published the official tracking sheet notice last Wednesday on the web which was pasted at the bottom. It's not as detailed, as my reply to you was for an internal audience.

From: Martino, Maria (CMS/OL)
Sent: Tuesday, July 06, 2010 4:14 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer

Hey Louis—is what you generally said below in an official document somewhere? Do we publish a notice or something when we announce that we are doing an NCD?

Thanks,
Maria

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 reagarding 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

Jacques, Louis B. (CMS/OCSQ)

From: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 12:26 PM
To: Fitterman, Leslye (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Subject: Re: autologous cellular immunotherapy treatment of prostate cancer

Let's discuss how to handle these later today. How about 2:30.

Sent from BlackBerry

----- Original Message -----
From: Fitterman, Leslye (CMS/OCSQ)
To: Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ)
Sent: Thu Jul 01 10:48:09 2010
Subject: FW: autologous cellular immunotherapy treatment of prostate cancer

Proposed answer. We did not receive a formal request to open the NCA so there is not a party to identify. RESPONSIBILITY TO IDENTIFY INFORMAL INQUIRIES?

-----Original Message-----
From: Bill Wuepper [mailto:(b)(6) .net]
Sent: Thursday, July 01, 2010 10:00 AM
To: Fitterman, Leslye (CMS/OCSQ)
Subject: autologous cellular immunotherapy treatment of prostate cancer

Dear Dr. Fitterman,

You should recognize the following as coming from CMS:

" 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®."

I see that you have opened this under "internally requested by CMS". However from the very first line, it does not look like an accurate statement. I am requesting the name(s) of the party (or
parties) that made the initial request.

If you feel that you cannot answer this request, would you provide me with the name and contact email of the Freedom of Information Act liason at CMS.

Thank you,
William Wuepper
(b)(6) .net

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 1:40 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Dendreon: Medicare reviewing Provenge coverage

Call me when your free.

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.

Jacques, Louis B. (CMS/OCSQ)

From: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 1:48 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer

ON MY WAY

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

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 1:47 PM
To: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: autologous cellular immunotherapy treatment of prostate cancer

On phone w Dendreon
Sent from my Blackberry

----- Original Message -----
From: Syrek Jensen, Tamara S. (CMS/OCSQ)
To: Fitterman, Leslye (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 12:26:09 2010
Subject: Re: autologous cellular immunotherapy treatment of prostate cancer

Let's discuss how to handle these later today. How about 2:30.

Sent from BlackBerry

----- Original Message -----
From: Fitterman, Leslye (CMS/OCSQ)
To: Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ)
Sent: Thu Jul 01 10:48:09 2010
Subject: FW: autologous cellular immunotherapy treatment of prostate cancer

Proposed answer. We did not receive a formal request to open the NCA so there is not a party to identify. RESPONSIBILITY TO IDENTIFY INFORMAL INQUIRIES?

-----Original Message-----
From: Bill Wuepper [mailto:(b)(6) .net]
Sent: Thursday, July 01, 2010 10:00 AM
To: Fitterman, Leslye (CMS/OCSQ)
Subject: autologous cellular immunotherapy treatment of prostate cancer

Dear Dr. Fitterman,

You should recognize the following as coming from CMS:

" 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®."

I see that you have opened this under "internally requested by CMS". However from the very first line, it does not look like an accurate statement. I am requesting the name(s) of the party (or
parties) that made the initial request.

If you feel that you cannot answer this request, would you provide me with the name and contact email of the Freedom of Information Act liason at CMS.

Thank you,
William Wuepper
(b)(6) .net

Jacques, Louis B. (CMS/OCSQ)

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.

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Monday, July 05, 2010 1:50 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

Everybody saw Provenge opened. Proud of you. Let me know how I can help or get help as needed.

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Sunday, July 04, 2010 8:04 PM
To: Bernice.Hecker@noridian.com
Subject: Re:

Jay me. Did ya see we opened NCD on provenge. Ok to continue local case by case either way.
Sent from my Blackberry

From: Bernice Hecker <Bernice.Hecker@noridian.com>
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Sun Jul 04 22:40:25 2010
Subject: RE:

Going to meeting on lumbar fusion in Madison. Saw her name on list but had never heard of her. Is this pronounced Jim-E?

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Sunday, July 04, 2010 7:02 PM
To: Bernice.Hecker@noridian.com
Subject: Re:

She's Marcel's replacement as DMSS director. Has been in coverage about 5 yrs. Why?
Sent from my Blackberry

From: Bernice Hecker <Bernice.Hecker@noridian.com>
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Sun Jul 04 20:41:45 2010
Subject:

Louis, who's this?
Jyme H. Schafer, MD, MPH; Medical Officer, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare and Medicaid

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

Jacques, Louis B. (CMS/OCSQ)

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
Attachments: image001.gif

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

I got the e-mail below on Friday afternoon reagarding 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) [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."
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
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. 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: 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
Attachments: image001.png

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

Subcommittee on Health

202.225.4021

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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 8:34 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: AP questions on Provenge coverage analysis

Ok, thanks

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 8:10 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: Re: AP questions on Provenge coverage analysis

Ill call u when I get in
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Sent: Thu Jul 01 08:08:49 2010
Subject: RE: AP questions on Provenge coverage analysis

Ok, who volunteers to help me out since I don't know this as well as some other stuff? I have a number of calls about this tracking sheet and I am not very smart.

Thanks. Peter

-----Original Message-----
From: Seaman, Marley [mailto:MSeaman@ap.org]
Sent: Thursday, July 01, 2010 7:26 AM
To: CMS OEABox
Subject: AP questions on Provenge coverage analysis

Good morning Peter,
I was reading Dendreon Corp.'s press release from last night about CMS calling for a "national coverage analysis" of Provenge, their cancer drug, and I was hoping to get some information from you about what that analysis entails. It sounds like a period for comment while CMS decides whether it's going to cover a drug. Is that about right? Please let me know if there are some details I am missing. I'd also like to know how long this analysis might take, how often CMS chooses to do it, and in what situations it's done. Thank you for your time.

-Marley Seaman
AP Health Writer
(212) 621-1947

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 8:35 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: Provenge Question - Investment Community
Attachments: image001.gif

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 7th 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

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 8:54 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: 3 news stories: Dendreon shares pummeled as Medicare studies coverage

k

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 8:54 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: 3 news stories: Dendreon shares pummeled as Medicare studies coverage

Call u at 9
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Cc: Khalid, Aryana C. (CMS/OA)
Sent: Thu Jul 01 08:46:08 2010
Subject: 3 news stories: Dendreon shares pummeled as Medicare studies coverage

Dendreon shares pummeled as Medicare studies coverage By Seattle Times business staff Shares of Seattle biotechnology company Dendreon were slammed in after-hours trading Wednesday after Medicare regulators said they were opening an inquiry on whether to pay for the pioneering prostate-cancer immunotherapy.
Dendreon shares fell $5.64, or 17.5 percent, to $26.69 in after-hours trading on Nasdaq after losing $1.26 during regular trading.
That left the stock at less than half its peak above $55 in the days immediately after the Food and Drug Administration approved the treatment, Provenge, on April 29.
The federal Centers for Medicare and Medicaid Services (CMS), which determines what treatments Medicare covers, said Wednesday it will study "whether or not autologous cellular immunotherapy is reasonable and necessary."
That report is due in March, according to the agency's website.
Dendreon said late Wednesday the inquiry doesn't change existing coverage. Pending conclusion of the CMS study, the company said in a statement, "Medicare beneficiaries are still able to access Provenge and private payers can also still cover Provenge."
The treatment costs $93,000 per patient. In clinical studies, it boosted median survival time by four months, from 22 months in the placebo group to 26 months in the Provenge group.
Investors and analysts were surprised by the CMS announcement, and were trying to get a clearer picture from Dendreon management late Wednesday, said David Miller, CEO of Biotech Stock Research in Seattle.
"This is not something any of us is familiar with," he said. "CMS routinely approves any drug approved by the FDA, certainly with oncology drugs."
Miller, a longtime bull on Dendreon and its drug, said CMS, like the FDA, is prohibited from considering price when it decides whether to approve a drug.
"All they're doing is judging whether the drug is useful for the patient, and it clearly is" in the case of Provenge, he said.
Given the data Dendreon provided for the FDA review, Miller said, "I can't imagine there's any situation where CMS review would be different."
Because almost all prostate-cancer patients are over 65 and covered by Medicare, "it'll be the single largest insurer for Provenge," he said.

Medicare to Weigh Coverage for Dendreon Drug By GEORGE STAHL / Wall Street Journal The U.S. government said Wednesday it would analyze whether covering the costs of Dendreon Corp.'s expensive immunotherapy treatment for prostate cancer is "reasonable and necessary." Dendreon's shares plunged in late trading.

The announcement was the latest hurdle in Dendreon's push to get its Provenge treatment used. If the Centers for Medicare and Medicaid Services covers Provenge, that would increase the number of patients eligible and likely force private insurers to do the same. A denial by CMS could severely stifle the product's growth.

The Provenge question is also seen as a test of President Barack Obama's health-care reform bill. The government's costs from the treatment could rise significantly when the 32 million currently uninsured Americans are expected to join the nation's health-care system in 2014.

The Centers for Medicare and Medicaid Services said Wednesday that it expects to complete its assessment by this time next year, with the public comment period lasting until July 30 and a proposed decision memo due March 30. It's unclear what CMS's investigation means for the drug's sales in the short term.

Dendreon shares, which fell 3.8% during the regular session on the Nasdaq Stock Market, fell an additional 23% in after-hours trading to $24.95. Dendreon officials weren't available for comment.

Provenge, seen as the first in a new class of cancer-fighting drugs, is designed to use a patient's own cells to stimulate the body's immune system to fight the cancer. However, because of its complexity, a normal three-infusion course of treatment is expected to cost $93,000, making it difficult to afford without insurance support.

When the Food and Drug Administration approved Provenge in April, Dendreon defended the treatment's price. Chief Operating Officer Hans Bishop said then that based on supporting clinical data, the price tag equated to about $23,000 per added month of survival for a patient, which compared "very favorably to many other widely used oncology products in similar advanced disease settings."

Prostate cancer is the second most common type of cancer among men in the U.S., behind skin cancer, and usually occurs in older men. In 2009, an estimated 192,000 new cases of prostate cancer were diagnosed and about 27,000 men died from the disease, according to the National Cancer Institute.

Dendreon had a tough time getting Provenge on the market. In 2007, the FDA rejected Provenge despite a unanimous vote from an expert panel in favor of the treatment. At the time, FDA said the two clinical studies submitted didn't meet study goals of reducing so-called time to progression, or the advancement, of cancer.

The rejection caused Dendreon's stock to plunge and provoked an uproar among some patients and investors.

In 2009, Dendreon submitted additional data from a trial of 512 patients that showed an increase in overall survival of 4.1 months among those receiving Provenge. The median survival for patients receiving Provenge treatments was 25.8 months, compared with 21.7 months for those who didn't receive the treatment.

Write to George Stahl at george.stahl@dowjones.com

UPDATE 3-Medicare looking at Dendreon cancer vaccine Wed, Jun 30 2010

* Medicare weighs nationwide coverage policy for Provenge
* Dendreon shares drop 23 percent on news
* Proposed decision expected by March 30 (Adds company comment) By Lisa Richwine/Reuters

WASHINGTON, June 30 (Reuters) - The U.S. Medicare program said on Wednesday it was evaluating data on Dendreon Corp's (DNDN.O: Quote, Profile, Research, Stock Buzz) prostate cancer therapy to decide whether to cover the product for seniors nationwide.

Shares of the company fell 23 percent to $25 on the news after closing at $32.33 on Nasdaq.

The Centers for Medicare & Medicaid Services (CMS) said it had opened a national coverage analysis after receiving inquiries following the approval of Dendreon's Provenge therapy in April.

Nationwide Medicare coverage could help make the product successful, while a denial could sharply hit sales.
The agency said it will determine if the treatment is "reasonable and necessary" for patients in Medicare, the federal health program that covers 45 million elderly and disabled Americans.
Provenge costs a total of $93,000 for the full treatment of three infusions. The generic name is sipuleucel-T.
CMS said Medicare was commissioning an external assessment of Provenge and would bring the issue to an outside advisory committee this year.
Dendreon said the announcement did not restrict local Medicare contractors from covering Provenge.
"Therefore, Medicare beneficiaries are still able to access Provenge and private payers can also still cover Provenge," the company said in a statement.
Dendreon also said it "welcomes the opportunity to continue our discussions with CMS about how Provenge will be provided to Medicare beneficiaries, particularly given the survival benefit and safety profile."
CMS said a proposed decision was expected by March 30, 2011, with a final ruling in June 2011.
The product is the first vaccine approved to treat a type of cancer. Unlike traditional vaccines that prevent a disease, Provenge treats prostate cancer by stimulating the body's immune system to attack malignant cells.
The Food and Drug Administration cleared Provenge for advanced prostate cancer after a study showed men treated with the vaccine lived an average of 4.1 months longer compared with a placebo.
The vaccine is produced by taking cells from a patient's tumor and incorporating them into a vaccine that is injected back into the patient.
CMS posted the Provenge notice here (Editing by Gary Hill)

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:10 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Anderson, Kelly (CMS/OCSQ)
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.

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:16 AM
To: Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:26 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:23 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:31 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

I'm on a call, when are you free?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:30 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thu Jul 01 11:26:02 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:23 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:32 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Medicare coverage determination

Are you at your desk for the next half hour?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:32 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

Variable. Gone at 330
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:30:46 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

I'm on a call, when are you free?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:30 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thu Jul 01 11:26:02 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:23 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:36 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: FW: DNDN MEDCAC

And more

From: 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
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
www.twitter.com/ReutersDChealth

thomsonreuters.com

Jacques, Louis B. (CMS/OCSQ)

From: PASERCHIA, LORI A. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:40 AM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ)
Subject: FW: nyt article on provenge (AP source)

Lori A. Paserchia, MD
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Lori.Paserchia@cms.hhs.gov
410.786.2115

From: SCHAFER, JYME H. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:05 AM
To: PASERCHIA, LORI A. (CMS/OCSQ)
Subject: nyt provenge

http://www.nytimes.com/aponline/2010/07/01/business/AP-US-Dendreon-Medicare.html?_r=1&hp=&adxnnl=1&adxnnlx=1277996468-5qpvrVI1lz%20dRWe9puKYKA&pagewanted=print

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:42 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Medicare coverage determination

So when?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:41 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

No
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:32:20 2010
Subject: RE: Medicare coverage determination

Are you at your desk for the next half hour?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:32 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

Variable. Gone at 330
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:30:46 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

I'm on a call, when are you free?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:30 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

2nd sentence last para is problem
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)

To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thu Jul 01 11:26:02 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:23 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:55 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Medicare coverage determination

Ok, you get to talk to Reuters then

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:50 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

12;40
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:42:10 2010
Subject: RE: Medicare coverage determination

So when?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:41 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

No
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:32:20 2010
Subject: RE: Medicare coverage determination

Are you at your desk for the next half hour?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:32 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

Variable. Gone at 330
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Thu Jul 01 11:30:46 2010

Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

I'm on a call, when are you free?

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:30 AM
To: Ashkenaz, Peter (CMS/OEABS)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
Sent from my Blackberry

----- Original Message -----
From: Ashkenaz, Peter (CMS/OEABS)
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thu Jul 01 11:26:02 2010
Subject: RE: Medicare coverage determination

(b)(5) - Predecisional

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 11:23 AM
To: Ashkenaz, Peter (CMS/OEABS); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Medicare coverage determination

(b)(5) - Predecisional
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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 11:55 AM
To: Jacques, Louis B. (CMS/OCSQ)
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:

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: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 12:03 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: FW: DNDN MEDCAC

You available after 130?

From: 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>
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]
Sent: Thursday, July 01, 2010 11:34 AM
To: Ashkenaz, Peter (CMS/OEABS)
Cc: 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
www.twitter.com/ReutersDChealth

This email was sent to you by Thomson Reuters, the global news and information company.
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: Dolina, Elaine L. (CMS/OCSQ)
Sent: Thursday, July 01, 2010 7:19 AM
To: Jacques, Louis B. (CMS/OCSQ); 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); Manlove, John (CMS/OCSQ); Wagner, Dennis C. (CMS/OCSQ)
Subject: RE: Provenge DRAFT track sheet 062110 lbj.doc

FYI,

Since this tracking sheet was posted late yesterday afternoon, we've received 50+ comments. Should be a biggie.

Elaine

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Ashkenaz, Peter (CMS/OEABS)
Sent: Thursday, July 01, 2010 8:09 AM
To: Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: AP questions on Provenge coverage analysis

Ok, who volunteers to help me out since I don't know this as well as some other stuff? I have a number of calls about this tracking sheet and I am not very smart.

Thanks. Peter

-----Original Message-----
From: Seaman, Marley [mailto:MSeaman@ap.org]
Sent: Thursday, July 01, 2010 7:26 AM
To: CMS OEABox
Subject: AP questions on Provenge coverage analysis

Good morning Peter,
I was reading Dendreon Corp.'s press release from last night about CMS calling for a "national coverage analysis" of Provenge, their cancer drug, and I was hoping to get some information from you about what that analysis entails. It sounds like a period for comment while CMS decides whether it's going to cover a drug. Is that about right? Please let me know if there are some details I am missing. I'd also like to know how long this analysis might take, how often CMS chooses to do it, and in what situations it's done. Thank you for your time.

-Marley Seaman
AP Health Writer
(212) 621-1947

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, June 28, 2010 12:02 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: Provenge DRAFT track sheet 062110 lbj.doc
Attachments: Provenge DRAFT track sheet 062110 lbj.doc

Louis:

Why is the PDM due in 6 months and the final in 9 months if we are having a MedCAC in November?

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, June 28, 2010 12:13 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge DRAFT track sheet 062110 lbj.doc
Attachments: Provenge DRAFT track sheet 062810 lbj lf.doc

Here is the updated tracking sheet.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 28, 2010 12:06 PM
To: Fitterman, Leslye (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Dolina, Elaine L. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge DRAFT track sheet 062110 lbj.doc

You're right. Sometimes we hold off on announcing the MEDCAC, but I agree we may as well be upfront about it. We have commissioned the TA so we get the extra time for that anyway. We should add a line saying that. Please edit the version I sent to Barry and then send to me. Thanks.

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, June 28, 2010 12:02 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: Provenge DRAFT track sheet 062110 lbj.doc

Louis:

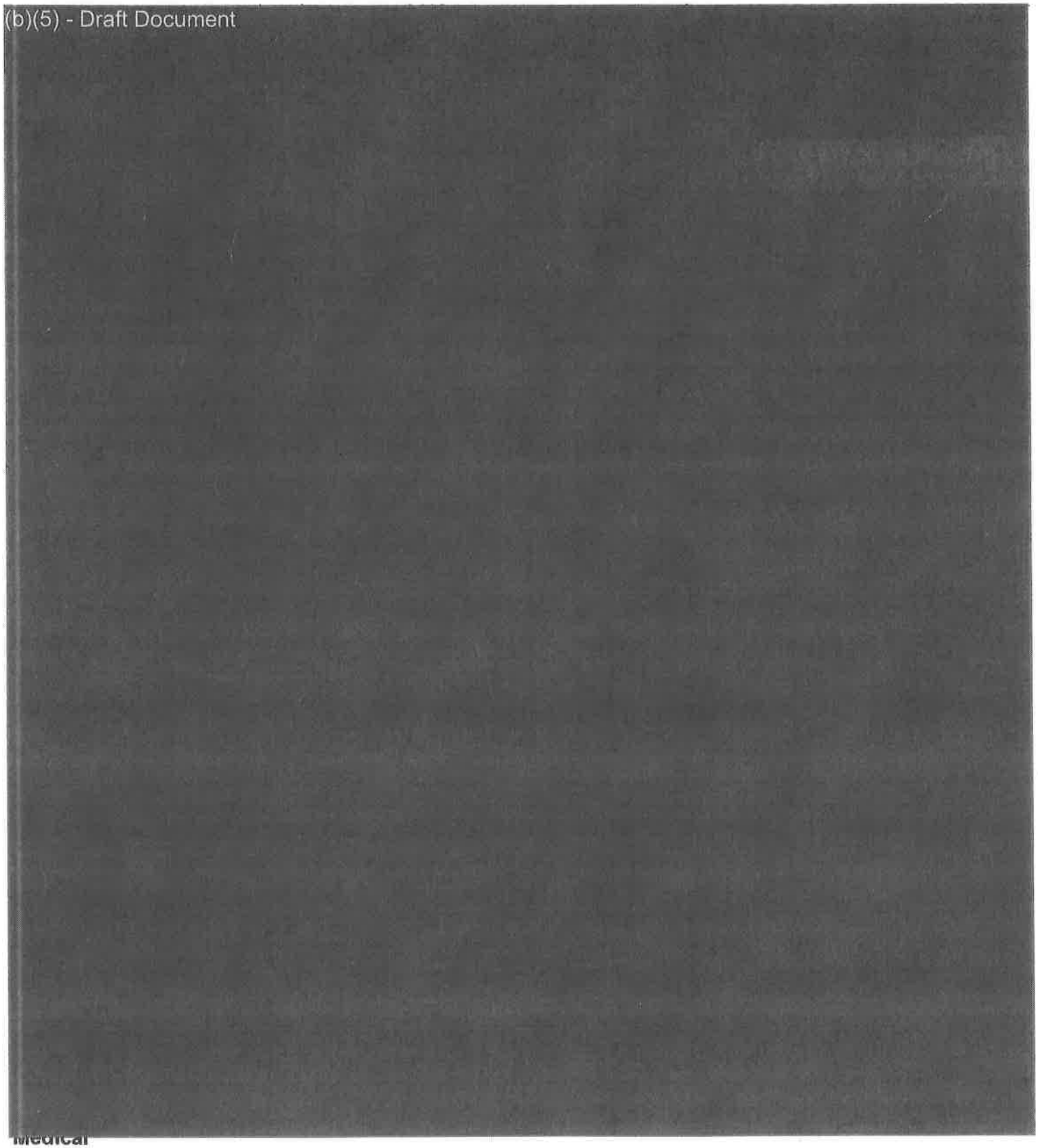
Why is the PDM due in 6 months and the final in 9 months if we are having a MedCAC in November?

Leslye

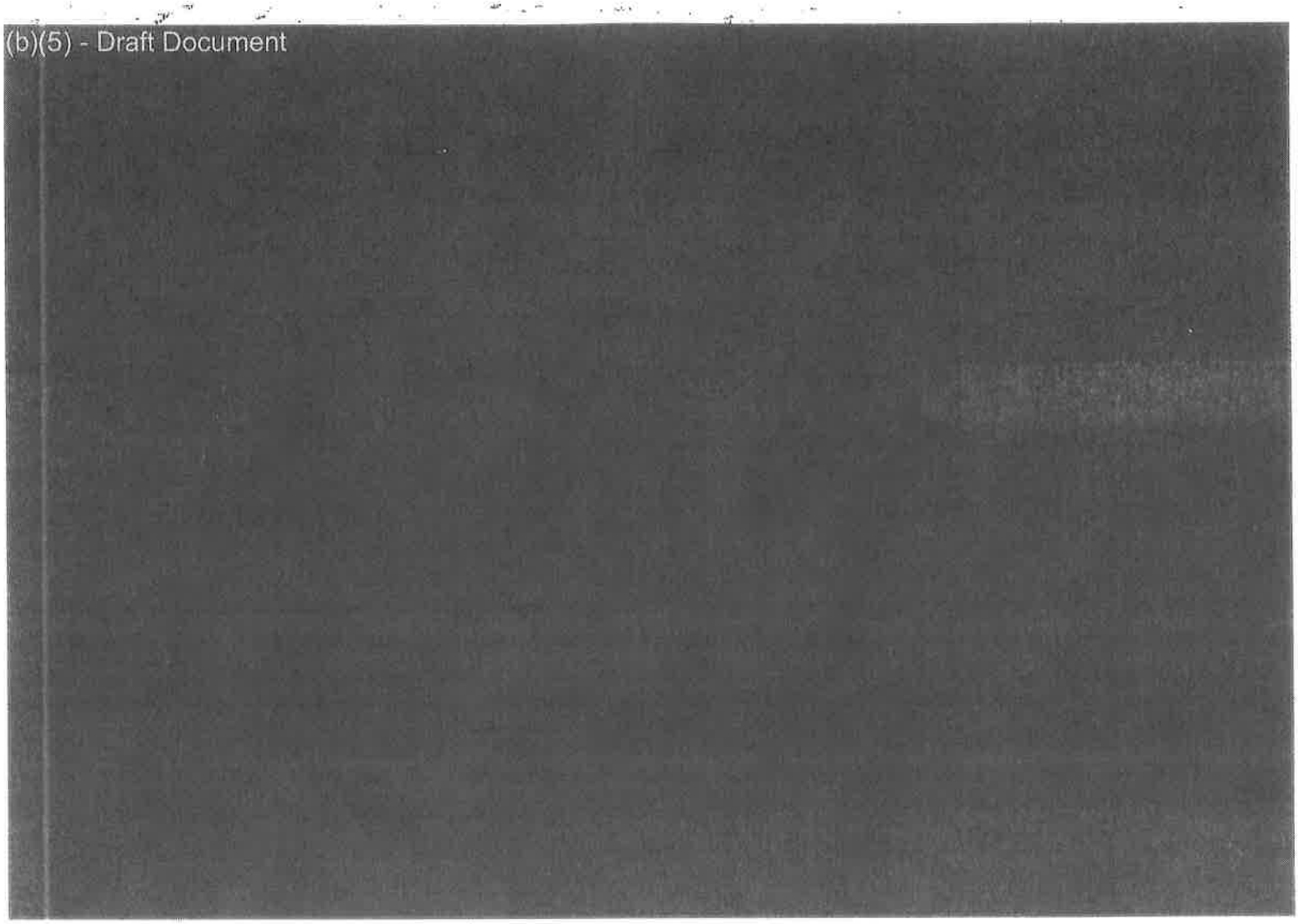
Tracking Sheet

(Use Mouse Click for Calendar)

Tracking # CAG-00422N

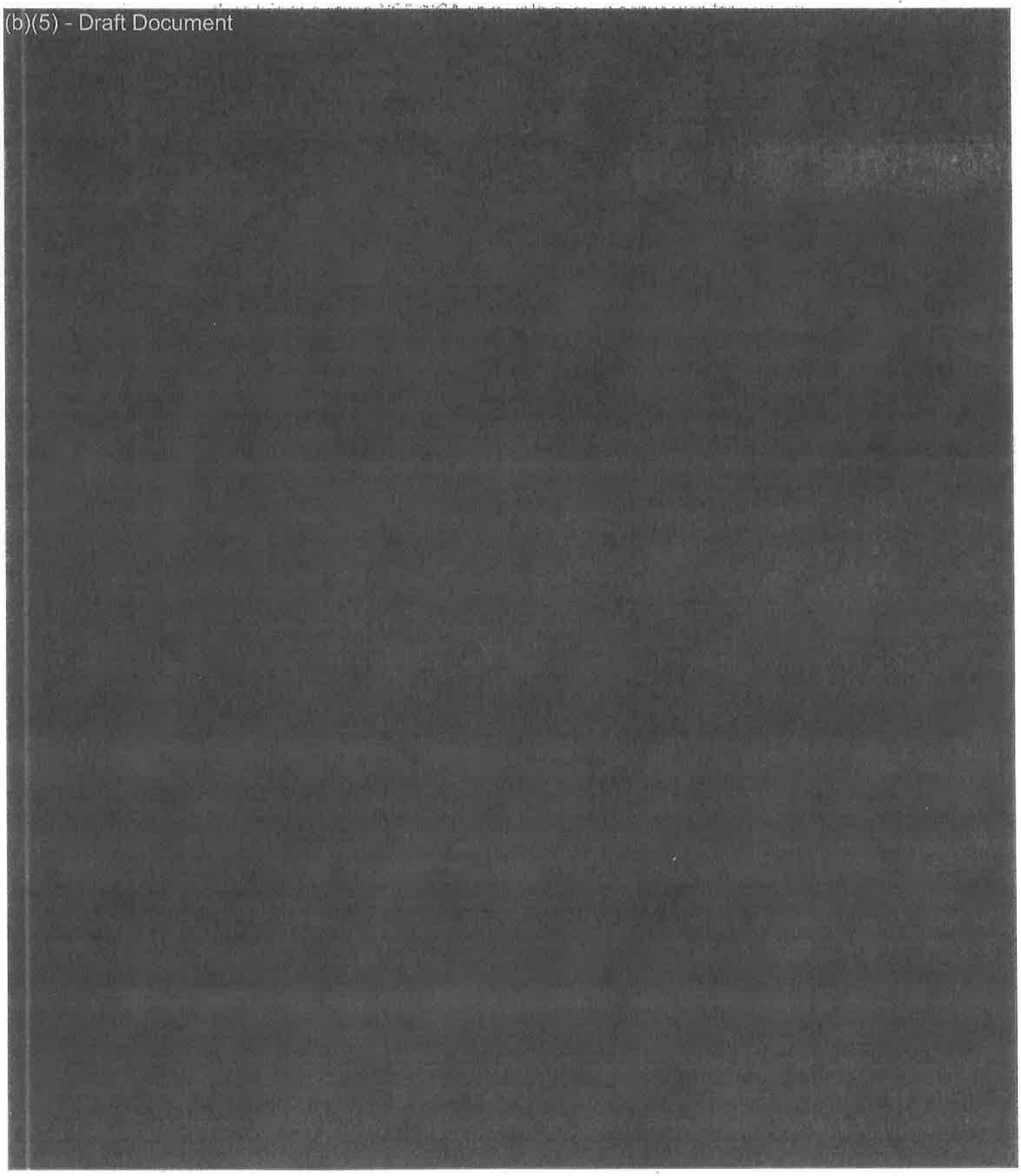


Medical Officer(s)

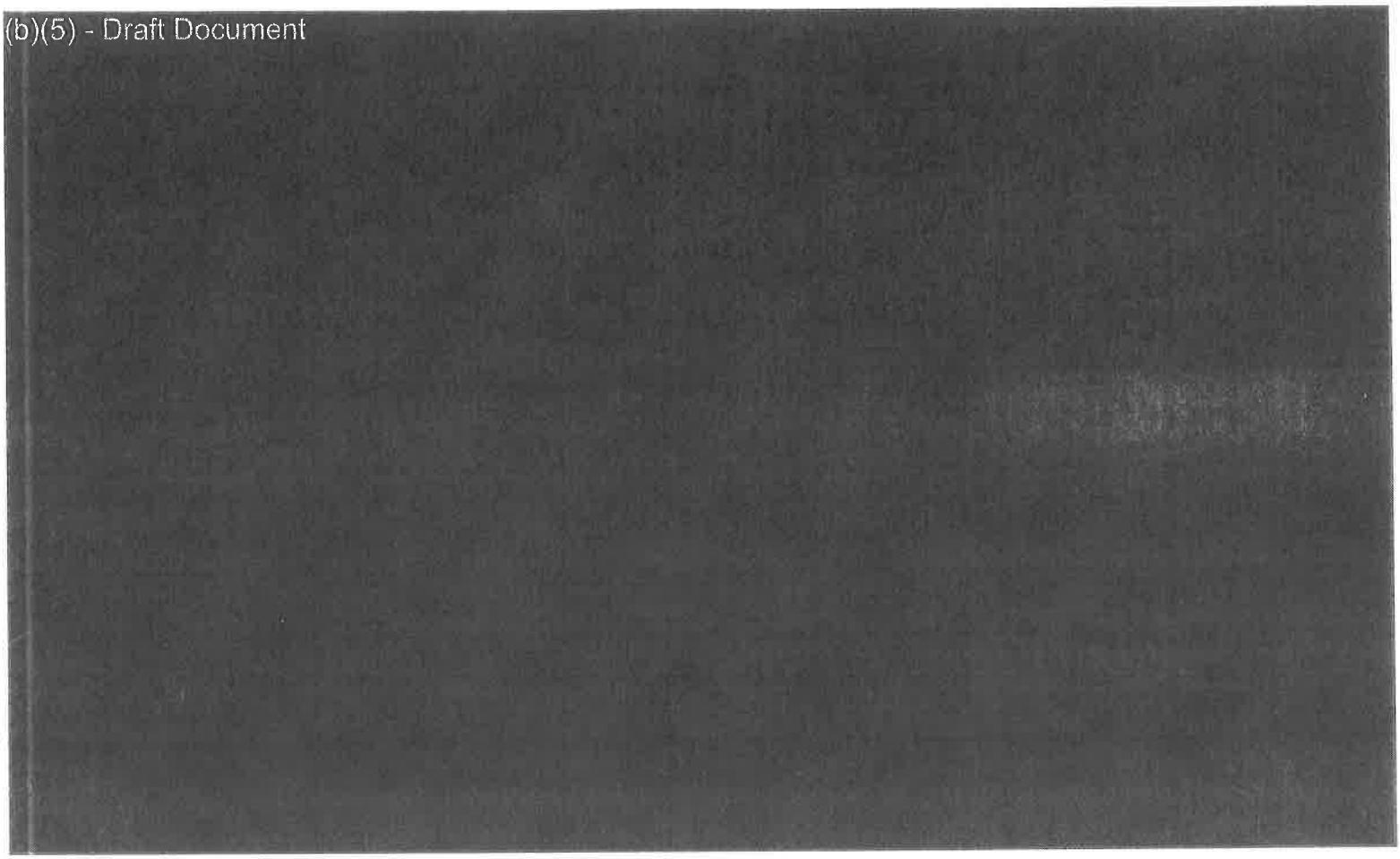

(b)(5) - Draft Document

Tracking Sheet

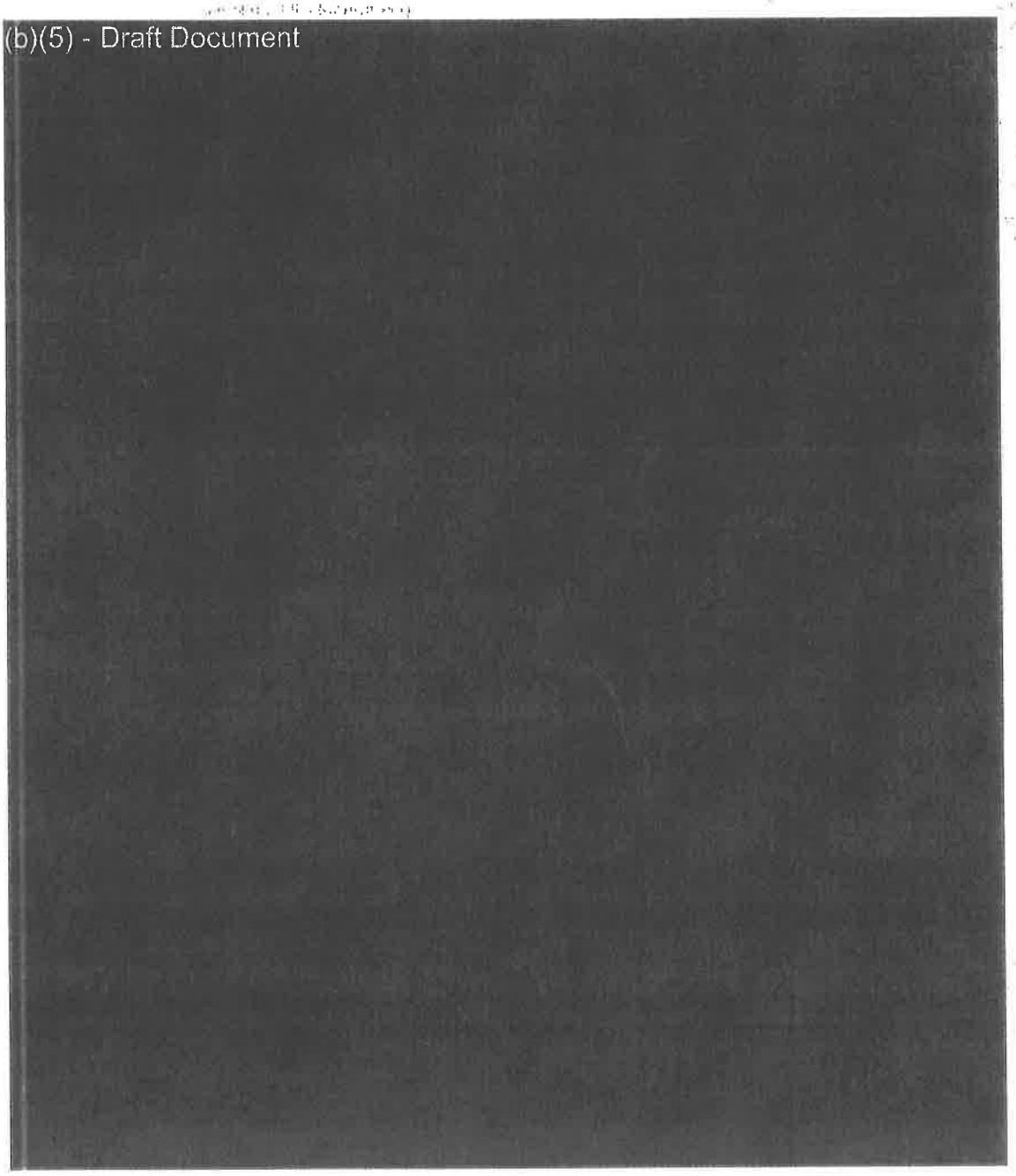
Tracking # CAG-004##N

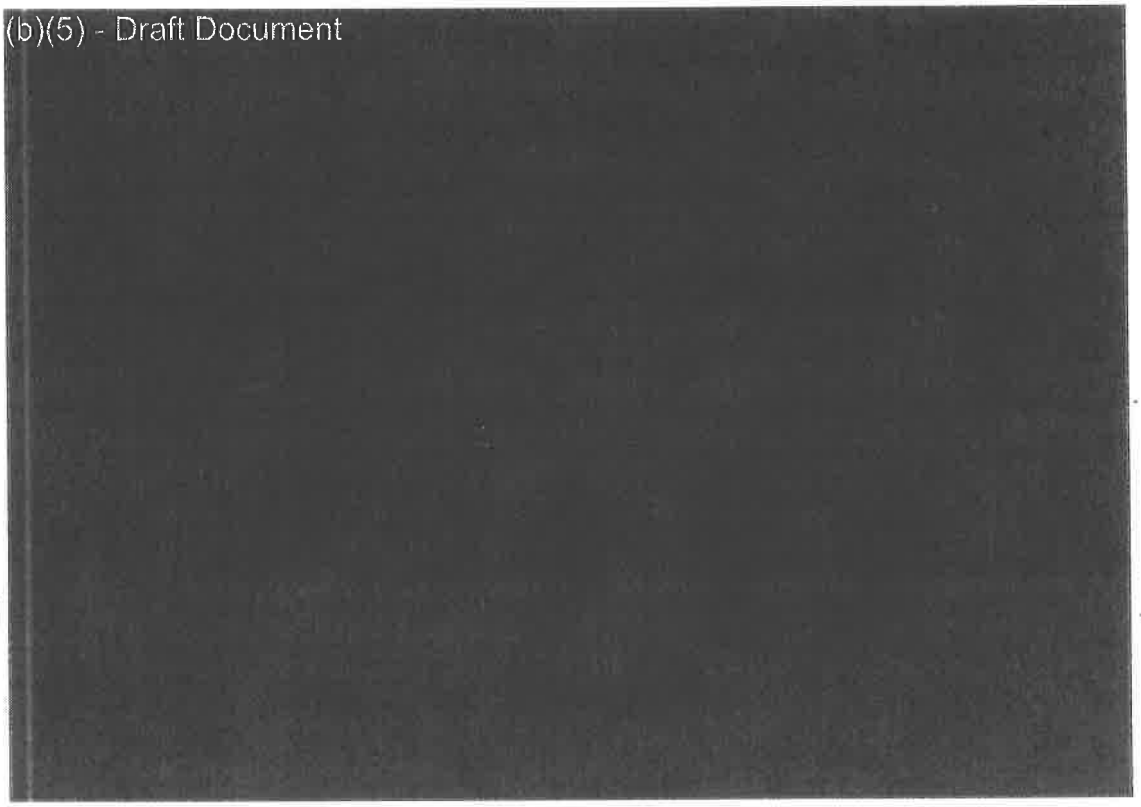


(b)(5) - Draft Document



il **Tracking Sheet**





Deleted: of

Jacques, Louis B. (CMS/OCSQ)

From: Dolina, Elaine L. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 12:35 PM
To: Jacques, Louis B. (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: RE: Provenge tracking sheet

Today is great, better than tomorrow. Just keep me posted.

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

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: Dolina, Elaine L. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 3:01 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: RE: Provenge tracking sheet

Will do!

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 3:00 PM
To: Dolina, Elaine L. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Graves, Patricia A. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: Re: Provenge tracking sheet

Ok to post after 4 today. Thanks
Sent from my Blackberry

From: Dolina, Elaine L. (CMS/OCSQ)
To: Jacques, Louis B. (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)
Sent: Wed Jun 30 12:35:07 2010
Subject: RE: Provenge tracking sheet

Today is great, better than tomorrow. Just keep me posted.

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

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: Anatol, Rachael F. (FDA)
Sent: Wednesday, June 30, 2010 3:17 PM
To: PASERCHIA, LORI A. (CMS/OCSQ)
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Witten, Celia (CBER)
Subject: Coverage Tracking Sheet

Hi Lori,

OCTGT does not have any comments on the draft tracking sheet for the NCD for Provenge.

We appreciate the opportunity to review.

Sincerely,
Rachael

Rachael F. Anatol, Ph.D.
Associate Director of Policy-New Legislation
Office of Cellular, Tissue and Gene Therapies
Food and Drug Administration
1401 Rockville Pike, HFM-705
Rockville, MD 20852
Phone: 301-827-5361
Fax: 301-827-9796

Jacques, Louis B. (CMS/OCSQ)

From: Dolina, Elaine L. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 4:03 PM
To: Jacques, Louis B. (CMS/OCSQ); 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); Manlove, John (CMS/OCSQ); Wagner, Dennis C. (CMS/OCSQ)
Subject: RE: Provenge DRAFT track sheet 062110 lbj.doc

Posted!

https://www.cms.gov/mcd/viewtrackingsheet.asp?id=247

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Dolina, Elaine L. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 4:04 PM
To: Jacques, Louis B. (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: RE: Provenge tracking sheet

FYI - I posted this version of the tracking sheet, but wanted to use the original note to announce the posting.

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

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: Warren, John F. (CMS/CMM)
Sent: Wednesday, June 30, 2010 4:56 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge

Congratulations. Now I know why my phone is ringing off the hook.

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

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 4:50 PM
To: Warren, John F. (CMS/CMM); Bassano, Amy (CMS/CMM)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Provenge

Amy and John,

We've opened an NCD.

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

Jacques, Louis B. (CMS/OCSQ)

From: Bassano, Amy (CMS/CMM)
Sent: Wednesday, June 30, 2010 4:56 PM
To: Jacques, Louis B. (CMS/OCSQ); Warren, John F. (CMS/CMM)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

Thanks for letting us know.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Wednesday, June 30, 2010 4:50 PM
To: Warren, John F. (CMS/CMM); Bassano, Amy (CMS/CMM)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Provenge

Amy and John,

We've opened an NCD.

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

Jacques, Louis B. (CMS/OCSQ)

From: Warren, John F. (CMS/CMM)
Sent: Thursday, June 24, 2010 8:19 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Beckerman, Peter [Peter.Beckerman@fda.hhs.gov]
Sent: Thursday, June 24, 2010 10:22 AM
To: PASERCHIA, LORI A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: Tyler, Bano (FDA); Witten, Celia (CBER); Beckerman, Peter
Subject: RE: Setting up provenge mtg

Hi. Are the CMS folks available for a call at 10:30 on Tuesday?

I've got a call in number we can use:

(866) 778-0520
Passcode: [redacted]

Leader code [redacted]

Thanks.

-Pete

Jacques, Louis B. (CMS/OCSQ)

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

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

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

Jacques, Louis B. (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)
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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Monday, June 28, 2010 10:12 AM
To: Manlove, John (CMS/OCSQ); 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); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge DRAFT track sheet 062110 lbj.doc

Thank you John.

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)
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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 5:10 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Tuesday, June 08, 2010 12:20 PM
To: Bernice.Hecker@noridian.com
Subject: Re:

Oops, 96k
Sent from my Blackberry

From: Bernice Hecker <Bernice.Hecker@noridian.com>
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Tue Jun 08 14:57:12 2010
Subject: RE:

Darling Boy, how do you figure for I would like to figure it the same way?!

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Tuesday, June 08, 2010 11:43 AM
To: Bernice Hecker
Subject: RE:

Only adds $96 if it's all ASP6 I think

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 2:42 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Tuesday, June 08, 2010 11:29 AM
To: Bernice Hecker
Subject: RE:

(b)(5) - Predecisional

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 2:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 11:10 AM

To: 'Jacques, Louis B. (CMS/OCSQ)'
Subject:

(b)(5) - Predecisional

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

Jacques, Louis B. (CMS/OCSQ)

From: Warren, John F. (CMS/CMM)
Sent: Wednesday, June 23, 2010 3:26 PM
To: Jacques, Louis B. (CMS/OCSQ); Hambrick, Edith L. (CMS/CMM); SALIVE, Marcel (CMS/OCSQ)
Subject: Provenge
Attachments: JSM Draft - Provenge is Part B drug (06232010).doc

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

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

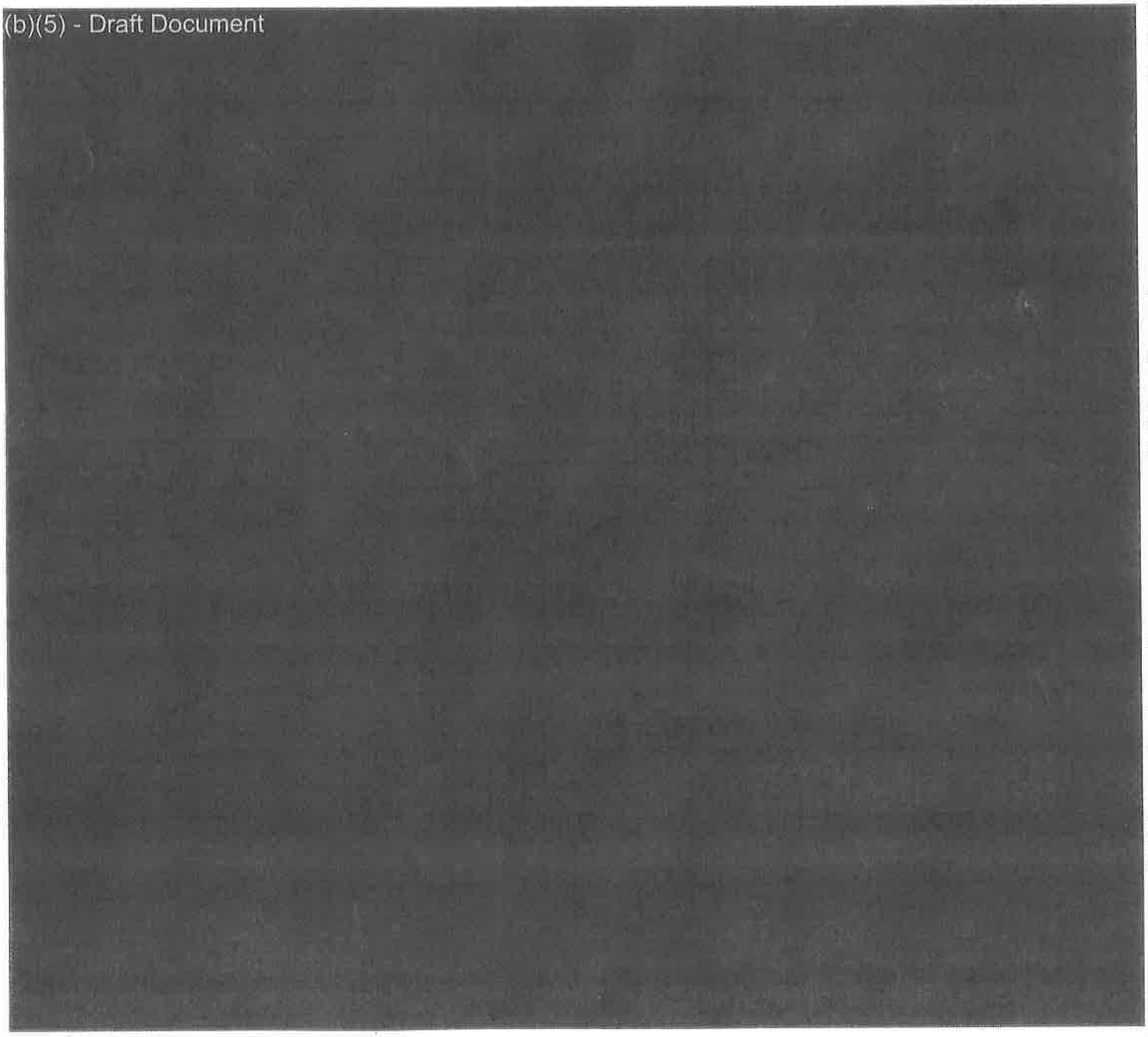
JSM/TDL-

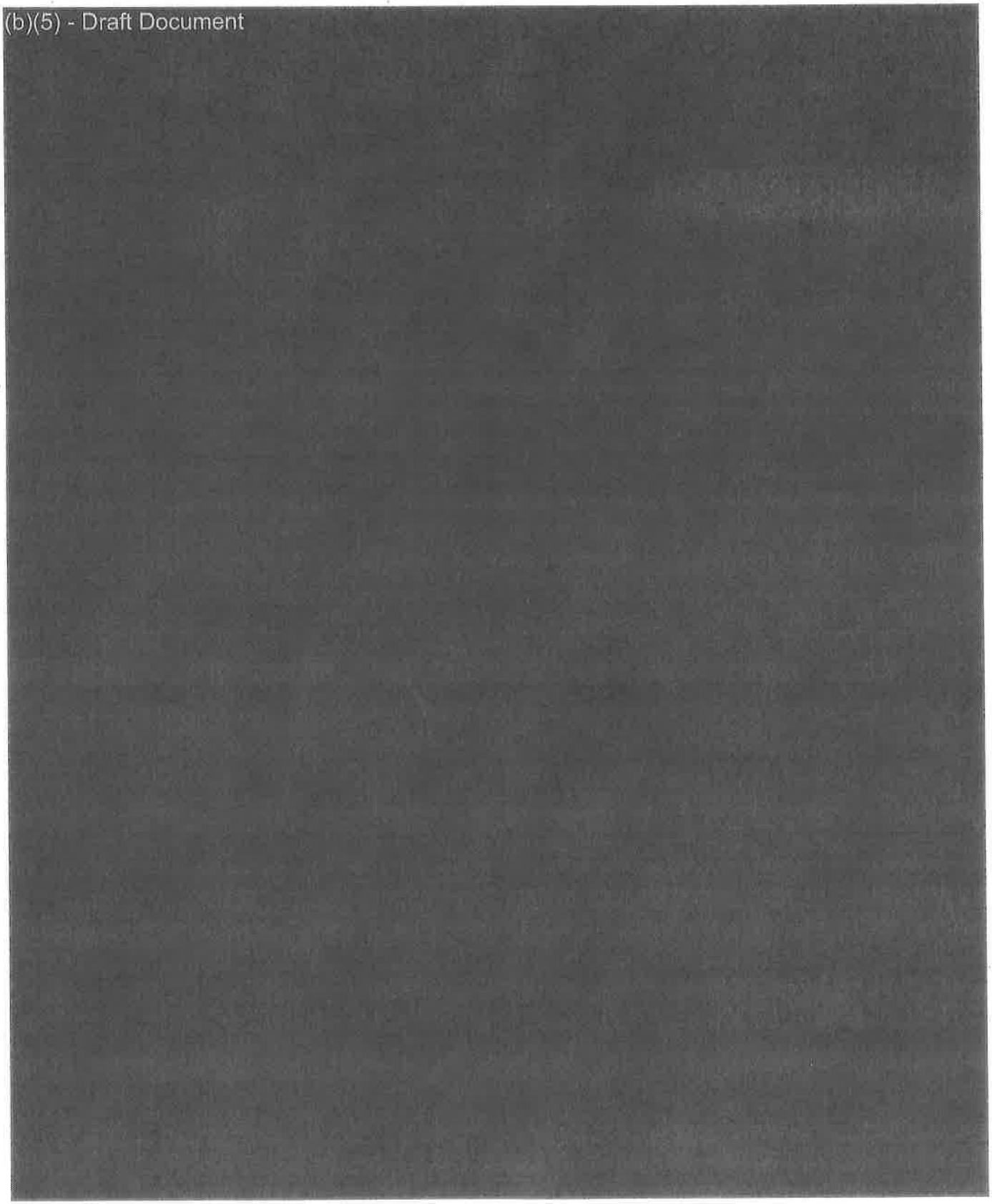
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

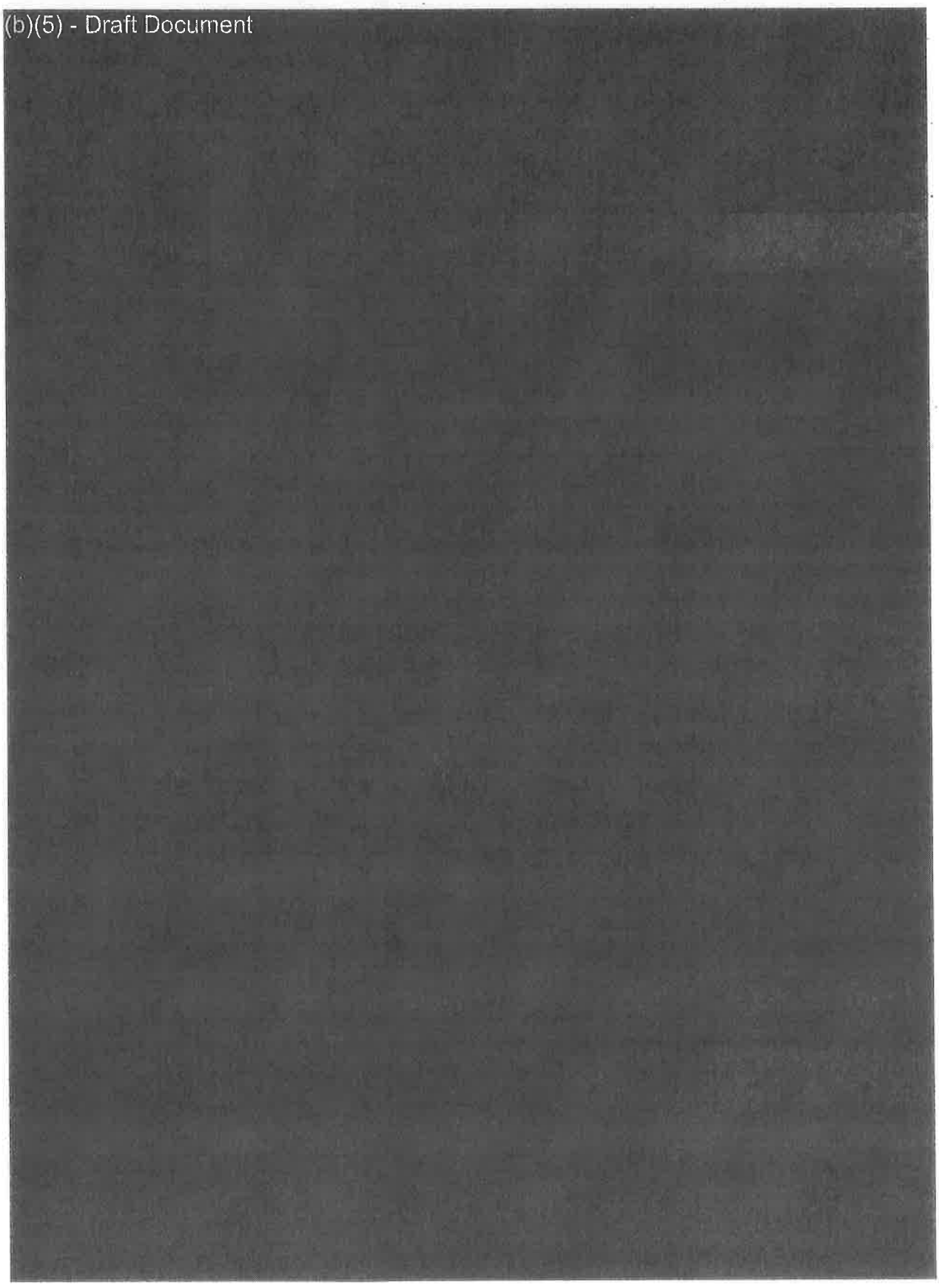
MEMORANDUM

DATE:

(b)(5) - Draft Document




(b)(5) - Draft Document


(b)(5) - Draft Document


(b)(5) - Draft Document

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
Hospital and Ambulatory Policy Group
Division of Ambulatory Services
RECORD OF SIGN OFFs

Prepared by:	Warren	**Phone:**	63633
Alternate:	Warren	**Phone:**	63633
Typed by:	Warren	**Phone:**	63633

File location: **g:\das\drug issues\provenge\jsm** draft - provenge is part b drug (06232010).doc
CIS Reference: N/A

	SURNAME	OFF/DIV/BR	DATE
CLEARED BY	Anne Hauswald	Acting Deputy Director, DAS	
CLEARED BY	John Warren	Director, DAS	
CLEARED BY	Marc Hartstein	Deputy Director, HAPG	
CLEARED BY	Amy Bassano	Director, HAPG	

V5.0.06212010.jfw

Jacques, Louis B. (CMS/OCSQ)

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.

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
410.786.2115

Jacques, Louis B. (CMS/OCSQ)

From: Berliner, Elise (AHRQ)
Sent: Friday, June 11, 2010 2:20 PM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: A few things

Louis, Tamara and Jim,

A few things:

1. The CMD evidence meeting: ECRI can meet on Wednesday 10-11 or 12-2. Which time is best for you for a conference call?

2. The Duke epo project: We had discussed the question of whether the Duke renal project needs to have a peer review. It is AHRQ policy that reports that are made final should be peer reviewed. However, we could submit it as a draft for CMS and Beth's internal use only and skip the peer review. If you want to make the report public we should have a peer review. But let us know.

3. I am still waiting for a budget from BCBS on Provenge. Right now it looks like we are going to spend out the X-account, hopefully we will have enough money for all these projects.

Thanks,
Elise

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 2:42 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

[redacted]

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Tuesday, June 08, 2010 11:29 AM
To: Bernice Hecker
Subject: RE:

(b)(5) - Predecisional

[redacted]

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 2:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

[redacted]

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

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 11:10 AM

To: 'Jacques, Louis B. (CMS/OCSQ)'
Subject:

(b)(5) - Predecisional

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

Jacques, Louis B. (CMS/OCSQ)

From: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Tuesday, June 08, 2010 8:51 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge option

That's what's her names center? Maybe I can ask Pete Beckman (my contact for the MOU). He works in the office of the commissioner. Let's strategize with Jim

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

-----Original Message-----
From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, June 08, 2010 8:50 AM
To: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Provenge option

No cber contacts
Sent from my Blackberry

----- Original Message -----
From: Syrek Jensen, Tamara S. (CMS/OCSQ)
To: Jacques, Louis B. (CMS/OCSQ)
Sent: Tue Jun 08 08:48:04 2010
Subject: RE: Provenge option

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

-----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

(b)(5) - Predecisional

[redacted]

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 2:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Tuesday, June 08, 2010 11:10 AM
To: 'Jacques, Louis B. (CMS/OCSQ)'
Subject:

(b)(5) - Predecisional

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

Jacques, Louis B. (CMS/OCSQ)

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 CEd 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

-----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: Rogers, William D. (CMS/OEA)
Sent: Tuesday, June 08, 2010 7:40 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: F/U New Tech call: Provenge

We discussed this on the last CMD call. $93,000 per treatment adds four months to life, 27,000 patients a year $2.6 billion dollars a year.
(b)(5) - Predecisional

William D Rogers MD FACEP
Director Physicians Regulatory Issues Team
Centers for Medicare and Medicaid Services
202-236-3338

Please consider the environment before printing this email

From: Medicare Contractor Medical Directors [mailto:MEDICARE-CMDS@LIST.NIH.GOV] **On Behalf Of** Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 9:05 PM
To: MEDICARE-CMDS@LIST.NIH.GOV
Subject: Re: F/U New Tech call: Provenge

Absent CMS instructions to the contrary, local contractors have discretion to cover or noncover the various components of the Provenge autologous immunotherapy program.

-----Original Message-----
From: Bernice Hecker [mailto:bernice.hecker@noridian.com]
Sent: Fri 6/4/2010 12:41 PM
To: MEDICARE-CMDS@LIST.NIH.GOV
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
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)

Jacques, Louis B. (CMS/OCSQ)

From: Medicare Contractor Medical Directors [MEDICARE-CMDS@LIST.NIH.GOV] on behalf of Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 9:05 PM
To: MEDICARE-CMDS@LIST.NIH.GOV
Subject: Re: F/U New Tech call: Provenge

Absent CMS instructions to the contrary, local contractors have discretion to cover or noncover the various components of the Provenge autologous immunotherapy program.

-----Original Message-----
From: Bernice Hecker [mailto:bernice.hecker@noridian.com]
Sent: Fri 6/4/2010 12:41 PM
To: MEDICARE-CMDS@LIST.NIH.GOV
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
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)

Jacques, Louis B. (CMS/OCSQ)

From: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Monday, June 07, 2010 8:06 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: Fw: F/U New Tech call: Provenge

I think this prompted call from amy to george.

Sent from 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)

you are not the intended recipient(s), please contact the sender by replying to this e-mail and destroy/delete all copies of this e-mail message.

Jacques, Louis B. (CMS/OCSQ)

From: Stieber, Joan (CMS/OL)
Sent: Monday, June 07, 2010 5:34 PM
To: Hayes, Mark (Finance-Rep)
Cc: Clapton, Erin M. (CMS/OL); Lewandowski, David S. (CMS/OL)
Subject: RE: Privacy Release from (b)(6) and explanation of matter

Hi Mark.

As previously noted, there are some unresolved benefit category questions about this procedure that would need to be addressed before general coverage decisions could be made at either the national or local level.

However, in regard to this particular case: If (b)(6) (or his doctor) were to get back in touch with the local contractor (Palmetto GBA), it's our understanding that coverage will be reconsidered *in this specific case.*

I hope that information is helpful. If you have any further questions, please let me know.

-- Joan

From: Hayes, Mark (Finance-Rep) [mailto:Mark_Hayes@finance-rep.senate.gov]
Sent: Monday, June 07, 2010 4:47 PM
To: Stieber, Joan (CMS/OL)
Cc: Clapton, Erin M. (CMS/OL)
Subject: RE: Privacy Release from (b)(6) and explanation of matter

Thank you for getting back to me. Very much appreciated. I'll await further word and would appreciate any suggestions on recommended next steps for the beneficiary.

From: Stieber, Joan (CMS/OL) [mailto:Joan.Stieber@cms.hhs.gov]
Sent: Monday, June 07, 2010 3:50 PM
To: Hayes, Mark (Finance-Rep)
Cc: Clapton, Erin M. (CMS/OL)
Subject: RE: Privacy Release from (b)(6) and explanation of matter

Hi Mark. Erin forwarded your inquiry about Provenge to me to look into, in consultation with our coverage staff.

As a general matter: there are currently no national or local coverage policies for this treatment. There are some unresolved questions about what statutory benefit category would apply to this procedure, which involves a combination of several different types of services. Identification of a benefit category is a prerequisite to a formal coverage policy. Once that issue is resolved, it's possible that we may consider a national coverage determination on this topic.

In the meantime, coverage decisions are made at the discretion of the local Medicare contractor.

That said, I will check back with the staff to see if there is any further information that would be relevant to this specific case and I'll get back to you soon.

-- Joan

Joan Stieber, CMS Office of Legislation (202) 690-6884 / joan.stieber@cms.hhs.gov

---

From: Hayes, Mark (Finance-Rep) <Mark_Hayes@finance-rep.senate.gov>
To: Clapton, Erin M. (CMS/OL)
Sent: Mon Jun 07 15:14:39 2010
Subject: FW: Privacy Release from (b)(6) and explanation of matter

Erin – here is the full information regard the CMS coverage of Provenge and the email from earlier today. We have a privacy release from (b)(6) To be clear, I'm only inquiring as to status and to get accurate information on the situation related to this case.

Thank you for your assistance and let me know if we should discuss further,

Mark

From: (b)(6)
Sent: Monday, June 07, 2010 2:07 PM
To: Hayes, Mark (Finance-Rep)
Subject: Privacy Release from (b)(6) and explanation of matter

Dear Mark,

Attached is the signed Privacy Release from (b)(6)

Here is a summation of what has happened ...

(b)(6) has gotten caught in a Catch 22 by Medicare and has potentially life-saving treatment ripped right out from under him. He has been fighting prostate cancer since 2001. He has been one of the fortunate folks to be one of the first to go through a treatment called Provenge. Provenge is a brand new treatment that seeks to use the human immune system to defeat prostate cancer. It is approved by the FDA and in its clinical trials it showed efficacy in extending the life of prostate cancer patients.

Mark, here is the situation. (b)(6) began this treatment on May 18, 2010. It requires going to a facility called (b)(6) and at his own expense, spent the night in a hotel to make sure that he would be there for this procedure, which starts at 6:30 in the morning. The procedure is a difficult and somewhat painful one in which steel needles are inserted into the veins in both of your arms and you are put in a chair where you have to sit perfectly still and not bend your arms for approximately four hours. During that time the blood is taken out of your body through one of these steel needles, run through a machine in a process called leukapheresis and then returned to your body. The machine extracts the white blood cells from your body until they get a sufficient quantity of white blood cells. The blood cells are then packaged up in a very sterile manner and sent off to Dendreon Corporation. While at Dendreon the white blood cells are cultured and sensitized to a primary protein that makes up the devastating cells that constitute prostate cancer. The theory and practice of this, tested over a long period of time and approved by the FDA, is that these cells will then be reinfused into your body, with the knowledge of how to recognize the cancer cells. Once the white blood cells are sensitized properly they can recognize the cancer cells. And once your immune system recognizes the cancer cells it can go to work and kill them.

Provenge had very good success in its trials and the FDA has finally approved it after many years. We are all so grateful that he is one of the people to be able to go through this treatment.

He went for his first treatment on May 18 and had the blood taken. It was sent to Dendreon, which is located back east. Unfortunately there are many things that can go wrong along the way. Not the least is there can be some small amount of contamination that enters into the system. There are a number of things to cause the sample to fail. In his case the sample did unfortunately fail, and he was scheduled to go in for a second leukapheresis. Usually the second one is tremendously successful. Some men have had to go for as many as two or three before they finally got a successful sample. The full course of treatment consists of three infusions over an approximate one month period.

He prepared for this second leukapheresis. He bought equipment for it to make his stay in the chair a little more tolerable. He bought these things out of his own pocket. and even went to his doctor's office in (b)(6) every day this past week to get a shot of Leukine that increases your white blood cells to insure that they could collect enough white cells for the treatment. He was all prepared to go for this leukapheresis the second time on Monday, June 7. Unfortunately this past Friday June 4 Medicare notified his physician, Dr. (b)(6), (b)(6), that they had put the treatment on hold pending the creation of a "policy". This policy process, as you may know, can take a very long time.

He had already started the treatment and Medicare had already approved coverage for his treatment. He could not have gone in for the first leukapheresis if Medicare had not approved it. Three men before him had embarked upon the treatment, but had not finished it, but they were allowed to go on through. For some reason, Medicare, in some apparently random fashion, decided to cut (b)(6) off.

Mark, this is a devastating thing to have happen. (b)(6) has fought long and hard to stay alive. He is in stage 4 metastatic cancer and his life is under imminent threat. He is surviving fairly well thanks to Dr. and Dr. (b)(6) But this could change at any time and Provenge is the best hope that we have to survive at this time. There is nothing greater than this.

The treatment has been shown to extend life up to four months in men who are terminal and extends life for many years in men who are not imminently terminal.

The reason I am writing to you and the Senator is to ask you to do everything in your power to get Medicare to allow him to complete the treatment that he has begun. He is scheduled for another leukapheresis on Tuesday, June 15, but will not be able to go unless Medicare reverses their decision. The stress and anguish that Medicare's current decision has caused him is unspeakable. Due to the nature of this disease and the devastating effects that it can have, time is of the essence. And every day that goes by with his fate in the hands of some unknown Medicare panel just adds more stress and anguish. Had he not started the treatment, it wouldn't be quite so bad, but having begun the treatment and endured the pain and discomfort of having the first sample taken and then to be cut off, is unbelievably painful and traumatic.

(b)(6) is also concerend because the fates of many thousands of men who are fighting prostate cancer hang in the balance. He realizes that this is a difficult time for the government and that we are in difficult straits as far as our budget goes. However, with billions and billions of dollars being spent on projects that do not have to do with human life, it does seem that a priority should be given to men who have served this country well, made a good living, paid their taxes and are now fighting for their very lives and depending on the hope that this treatment offers in order to survive.

(b)(6) as I explained, and owing to the Senator efforts got the FDA to fasttrack Provenge for all men, and now when it is his turn to have his life saved he is being cut off. Therefore we are asking you for two things – one is for (b)(6) but also for all of the men who really need this treatment and who may have their lives extended or even saved by it, to intervene or to exert your influence in any way you can, to have Medicare reverse this rather brutal and cruel decision.

If you have any questions or need any more information, including my Medicare number, feel free to call (b)(6) directly on his cell phone at (b)(6) or myself at (b)(6) He would be glad to speak with you directly if needed.

Thank you so much Mark and of course, from the bottom of our hearts, thank Senator Grassley.

Sincerely,
(b)(6)

You can find a more detailed explanation of the process at http://www.provenge.com/pdf/PROVENGE-FAQs.pdf.

Jacques, Louis B. (CMS/OCSQ)

From: Bassano, Amy (CMS/CMM)
Sent: Monday, June 07, 2010 5:48 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Warren, John F. (CMS/CMM)
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)

Jacques, Louis B. (CMS/OCSQ)

From: Warren, John F. (CMS/CMM)
Sent: Monday, June 07, 2010 5:15 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: 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
Mailstop C1-09-06
7500 Security Blvd
Baltimore MD 21244
(410) 786-4512

(410) 786-9286 (FAX)
Louis.Jacques@CMS.HHS.GOV

Jacques, Louis B. (CMS/OCSQ)

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
Mailstop C1-09-06
7500 Security Blvd
Baltimore MD 21244
(410) 786-4512
(410) 786-9286 (FAX)
Louis.Jacques@CMS.HHS.GOV

Jacques, Louis B. (CMS/OCSQ)

From: ARTHUR.LURVEY@palmettogba.com
Sent: Monday, June 07, 2010 5:08 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge

Thank you very much and we will see you in about 2 weeks.

Arthur Lurvey, MD, FACP, FACE
Director, J1 Medical Affairs
Palmetto GBA
P.O. Box 1476
Augusta, Georgia 30903-1476
Phone: (310) 476-5760 fAX (803) 462-3918
E-mail: Arthur.Lurvey@PalmettoGBA.com

-----Original Message-----
From: Louis.Jacques@cms.hhs.gov [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Monday, June 07, 2010 2:05 PM
To: ARTHUR LURVEY
Cc: John.Warren@cms.hhs.gov; tamara.syrekjensen@cms.hhs.gov; amy.bassano@cms.hhs.gov
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 Mailstop C1-09-06 7500 Security Blvd Baltimore MD 21244
(410) 786-4512
(410) 786-9286 (FAX)
Louis.Jacques@CMS.HHS.GOV

Jacques, Louis B. (CMS/OCSQ)

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 2:11 PM
To: Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

OK. I will send this question to BCBSA TEC

From: Rollins, James (CMS/OCSQ)
Sent: Monday, June 07, 2010 2:05 PM
To: Berliner, Elise (AHRQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

I like your approach, but would be more focused on the research question (PICO)

For patients 65 and older, does the use of provenge result in clinically meaning benefits (e.g., improved quality of life, prolonged survival, etc.) compared to other forms of therapy for prostate cancer. Jarollins

---

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 1:56 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

I know you are all busy, so I will take a first stab at the question. Naomi at BCBSA really likes to see the question before committing to a budget...

Let me know if this reflects the scope that you have in mind:

Update the TEC special report on vaccines in prostate cancer with all data published to date, including data publicly available at FDA to address the following question:
What are the comparative benefits and harms of Provenge compared to alternatives in treating prostate cancer.
Study selection criteria: randomized and non-randomized comparative studies
Patients: Adults with prostate cancer (describe specific patient characteristics in the studies)
Intervention: Provenge
Comparator: any other prostate cancer treatment directly compared to Provenge or placebo (describe any treatments received by patients in the control arm over the course of the study).
Outcomes: survival, progression of cancer, quality of life (describe methods and validity of outcomes assessment in the studies)
Other issues: describe concurrent and prior treatments for both arms in the studies

If you haven't seen this, there is an interesting article in Forbes about the data:
http://www.forbes.com/2009/04/28/dendreon-provenge-cancer-business-healthcare-provenge.html which includes this thought from Don Berry:
"Much of the skepticism about Provenge until now has related to the perceived limitations of the 500-person study that Kantoff helped run. It was too small, some experts thought, and had an unusual design in which patients who did not

receive Provenge and saw their cancer get worse would receive a frozen-then-thawed version of the vaccine. This is unusual and may be unprecedented, says Donald Berry, head of biostatistics at the M.D. Anderson Cancer Center. It is possible that this frozen-then-thawed vaccine is actually different from Provenge; if it somehow harmed patients (there's no proof it does), it would actually make Provenge appear more effective. He asks how patients did after their cancer had progressed."

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 11:27 AM
To: Rollins, James (CMS/OCSQ); Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Provenge

Just pay for update
Sent from my Blackberry

From: Rollins, James (CMS/OCSQ)
To: Berliner, Elise (AHRQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Mon Jun 07 10:53:35 2010
Subject: RE: Provenge

I was able to go out to bcbs' TEC assessment website, and this report is available. Do we have to pay for this assessment since its available in public domain? (b)(5) - Predecisional
(b)(5) - Predecisional

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:48 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

Here is the preliminary report from BCBSA (completed in April before FDA approval):
http://www.bcbs.com/blueresources/tec/vols/24/24_06.pdf

Do you have questions for a report?

Do you want a cost effectiveness analysis?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

OK to talk now

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

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

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: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 1:56 PM
To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

I know you are all busy, so I will take a first stab at the question. Naomi at BCBSA really likes to see the question before committing to a budget...

Let me know if this reflects the scope that you have in mind:

Update the TEC special report on vaccines in prostate cancer with all data published to date, including data publicly available at FDA to address the following question:
What are the comparative benefits and harms of Provenge compared to alternatives in treating prostate cancer.
Study selection criteria: randomized and non-randomized comparative studies
Patients: Adults with prostate cancer (describe specific patient characteristics in the studies)
Intervention: Provenge
Comparator: any other prostate cancer treatment directly compared to Provenge or placebo (describe any treatments received by patients in the control arm over the course of the study).
Outcomes: survival, progression of cancer, quality of life (describe methods and validity of outcomes assessment in the studies)
Other issues: describe concurrent and prior treatments for both arms in the studies

If you haven't seen this, there is an interesting article in Forbes about the data:
http://www.forbes.com/2009/04/28/dendreon-provenge-cancer-business-healthcare-provenge.html which includes this thought from Don Berry:
"Much of the skepticism about Provenge until now has related to the perceived limitations of the 500-person study that Kantoff helped run. It was too small, some experts thought, and had an unusual design in which patients who did not receive Provenge and saw their cancer get worse would receive a frozen-then-thawed version of the vaccine. This is unusual and may be unprecedented, says Donald Berry, head of biostatistics at the M.D. Anderson Cancer Center. It is possible that this frozen-then-thawed vaccine is actually different from Provenge; if it somehow harmed patients (there's no proof it does), it would actually make Provenge appear more effective. He asks how patients did after their cancer had progressed."

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 11:27 AM
To: Rollins, James (CMS/OCSQ); Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Provenge

Just pay for update
Sent from my Blackberry

From: Rollins, James (CMS/OCSQ)
To: Berliner, Elise (AHRQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Mon Jun 07 10:53:35 2010
Subject: RE: Provenge

I was able to go out to bcbs' TEC assessment website, and this report is available. Do we have to pay for this assessment since its available in public domain? (b)(5) - Predecisional

(b)(5) - Predecisional

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:48 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

Here is the preliminary report from BCBSA (completed in April before FDA approval):
http://www.bcbs.com/blueresources/tec/vols/24/24_06.pdf

Do you have questions for a report?

Do you want a cost effectiveness analysis?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

OK to talk now

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

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

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

See below—I figured that you might want to answer this since you plan to talk to Barry about it on Thursday.

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>
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

Jacques, Louis B. (CMS/OCSQ)

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:56 AM
To: Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

This report would need to be updated since it was completed before FDA approval, so it does not include all the latest data. But hopefully the price will be low, since the majority of the work is done (maybe this is wishful thinking??).

The question about including cost effectiveness analysis is up to you, let us know what you want to do.

From: Rollins, James (CMS/OCSQ)
Sent: Monday, June 07, 2010 10:54 AM
To: Berliner, Elise (AHRQ); Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

I was able to go out to bcbs' TEC assessment website, and this report is available. Do we have to pay for this assessment since its available in public domain? (b)(5) - Predecisional
(b)(5) - Predecisional

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:48 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

Here is the preliminary report from BCBSA (completed in April before FDA approval):
http://www.bcbs.com/blueresources/tec/vols/24/24_06.pdf

Do you have questions for a report?

Do you want a cost effectiveness analysis?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

OK to talk now

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

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

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: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:48 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

Here is the preliminary report from BCBSA (completed in April before FDA approval):
http://www.bcbs.com/blueresources/tec/vols/24/24_06.pdf

Do you have questions for a report?

Do you want a cost effectiveness analysis?

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Berliner, Elise (AHRQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

OK to talk now

From: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

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

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: Bernice Hecker [bernice.hecker@noridian.com]
Sent: Friday, June 04, 2010 12:42 PM
To: MEDICARE-CMDS@LIST.NIH.GOV
Cc: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
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)

Jacques, Louis B. (CMS/OCSQ)

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: Berliner, Elise (AHRQ)
Sent: Monday, June 07, 2010 10:37 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Subject: RE: Provenge

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

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: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Thursday, June 03, 2010 1:12 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Thursday, June 03, 2010 9:47 AM
To: Bernice Hecker
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE:

B,

Re your earlier emails

My edits below

(b)(5) - Predecisional

L

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Thursday, June 03, 2010 11:56 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Wednesday, June 02, 2010 4:46 PM
To: Bernice Hecker
Subject: RE:

Not seeing light at the end of this one yet.

-----Original Message-----
From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Wed 6/2/2010 6:55 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

So, you and CMM in Woodlawn. Quaint. Everything all fixed?

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Wednesday, June 02, 2010 3:49 PM
To: Bernice Hecker
Subject: RE:

And we're in Woodlawn, not Towson :-)

-----Original Message-----
From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Wed 6/2/2010 6:02 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject:

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

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Thursday, June 03, 2010 11:56 AM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Wednesday, June 02, 2010 4:46 PM
To: Bernice Hecker
Subject: RE:

Not seeing light at the end of this one yet.

-----Original Message-----
From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Wed 6/2/2010 6:55 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE:

So, you and CMM in Woodlawn. Quaint. Everything all fixed?

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

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]
Sent: Wednesday, June 02, 2010 3:49 PM
To: Bernice Hecker
Subject: RE:

And we're in Woodlawn, not Towson :-)

-----Original Message-----
From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Wed 6/2/2010 6:02 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject:

(b)(5) - Predecisional

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

Jacques, Louis B. (CMS/OCSQ)

From: Syrek Jensen, Tamara S. (CMS/OCSQ)
Sent: Thursday, June 03, 2010 12:31 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Provenge

(b)(5) - Predecisional

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

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, June 03, 2010 12:25 PM
To: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

Comments before I send?

B,

Re your earlier emails

My edits below

(b)(5) - Predecisional

From: Bernice Hecker [mailto:Bernice.Hecker@noridian.com]
Sent: Wednesday, June 02, 2010 3:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: Provenge
Importance: High

(b)(5) - Predecisional

(b)(5) - Predecisional

[redacted]

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

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Wednesday, June 02, 2010 3:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: Provenge

Importance: High

(b)(5) - Predecisional

[redacted]

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

Jacques, Louis B. (CMS/OCSQ)

From: Warren, John F. (CMS/CMM)
Sent: Tuesday, June 01, 2010 3:35 PM
To: Jacques, Louis B. (CMS/OCSQ)
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

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

(b)(5) - Predecisional

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 Generex. 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)

Jacques, Louis B. (CMS/OCSQ)

From: Bernice Hecker [Bernice.Hecker@noridian.com]
Sent: Tuesday, June 01, 2010 2:45 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: fyi-yiyi

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 Generex. 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)

Jacques, Louis B. (CMS/OCSQ)

From: Hambrick, Edith L. (CMS/CMM)
Sent: Wednesday, May 19, 2010 2:37 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Warren, John F. (CMS/CMM); Mason-Wonsley, Marsha M. (CMS/CMM); Simon, Kenneth B. (CMS/CMM)
Subject: Provenge

Hi,

(b)(5) - Predecisional

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
Please do not include PHI in e-mails to this address.

Jacques, Louis B. (CMS/OCSQ)

From: COSTANTINO, GEORGE [GEORGE.COSTANTINO@wellpoint.com]
Sent: Wednesday, May 05, 2010 8:33 AM
To: DEUTSCH, PAUL G; Jacques, Louis B. (CMS/OCSQ)
Cc: Cunningham, Carolyn
Subject: RE: Coverage for Provenge

Paul,

You bring up a good point, the company markets this as a vaccine.

George

George N Costantino, MD
Medical Director
National Government Services, Inc.
300 East Park Avenue
Harrisburg, PA 17111-2729
tel - 215.369.2765
fax - 215.369.8213

Please identify PHI in Subject line when sent to this email address

---

From: DEUTSCH, PAUL G
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
Please do not include PHI in e-mails to this address.

Jacques, Louis B. (CMS/OCSQ)

From: DEUTSCH, PAUL G [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
Please do not include PHI in e-mails to this address.