

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

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 5:05 PM  
**To:** Stieber, Joan (CMS/OL)  
**Subject:** RE: Privacy Release from (b)(6) and explanation of matter (Provenge)

Can you call me now?

---

**From:** Stieber, Joan (CMS/OL)  
**Sent:** Monday, June 07, 2010 5:05 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Privacy Release from (b)(6) and explanation of matter (Provenge)

Interesting news!

Is it OK to convey that to the Senate staff?

Or should we say something less definitive like: "If (b)(6) (or his doctor) gets back in contact with the contractor, it's our understanding that coverage will be reconsidered"?

Or do you think such contact and commitment has already been made?

thanks again! -- Joan

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 4:53 PM  
**To:** Stieber, Joan (CMS/OL)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Subject:** RE: Privacy Release from (b)(6) and explanation of matter (Provenge)

Joan,

Called the CMD. Familiar with the case. Story is complicated. But they will cover (b)(6)

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**From:** Stieber, Joan (CMS/OL)  
**Sent:** Monday, June 07, 2010 3:58 PM  
**To:** Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ); Lewandowski, David S. (CMS/OL)  
**Subject:** FW: Privacy Release from (b)(6) and explanation of matter (Provenge)

More info on the question about coverage of Provenge – please see note below re: a specific case in California underlying the inquiry. It alleges that the Medicare contractor approved a first round of the treatment but then removed approval for a subsequent round. If that's accurate, would the patient have any recourse?

Your further thoughts on this would be appreciated.

thanks – Joan

**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) on the

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 (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. (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 concerned 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>.

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

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

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

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

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

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, June 29, 2010 8:50 AM  
**To:** ARTHUR.LURVEY@palmettogba.com  
**Subject:** RE: Availability

How about 11:15 today? I can call you

---

**From:** ARTHUR.LURVEY@palmettogba.com [mailto:ARTHUR.LURVEY@palmettogba.com]  
**Sent:** Monday, June 28, 2010 5:54 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Availability

Give me a time. Tomorrow afternoon is fine.

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](mailto:Arthur.Lurvey@PalmettoGBA.com)

<http://www.PalmettoGBA.Com/disclaimer>

---

**From:** Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]  
**Sent:** Monday, June 28, 2010 2:24 PM  
**To:** ARTHUR LURVEY  
**Subject:** RE: Availability

How about tomorrow afternoon?

---

**From:** ARTHUR.LURVEY@palmettogba.com [mailto:ARTHUR.LURVEY@palmettogba.com]  
**Sent:** Monday, June 28, 2010 4:59 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** Availability

You sent me an e-mail as to why I was not at the CMD meeting in Baltimore. I am available for a short phone call in the next several days---just tell me when. I know you are concerned about Provenge and other matters---so I am available for your wisdom at any time this week. Next week I travel to Honolulu for our CAC sequences.

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Director, J1 Medical Affairs  
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E-mail: [Arthur.Lurvey@PalmettoGBA.com](mailto:Arthur.Lurvey@PalmettoGBA.com)

<http://www.PalmettoGBA.Com/disclaimer>

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

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

Long time ago  
Sent from my Blackberry

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

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

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

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Monday, June 07, 2010 5:04 PM  
**To:** arthur.lurvey@palmettogba.com  
**Cc:** Warren, John F. (CMS/CMM); Syrek Jensen, Tamara S. (CMS/OCSQ); Bassano, Amy (CMS/CMM)  
**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  
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[Louis.Jacques@CMS.HHS.GOV](mailto:Louis.Jacques@CMS.HHS.GOV)



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

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 4:33 PM  
**To:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Subject:** RE: Question on Medicare coverage of Provenge

Just FYI, Provenge is really a combination of several different services such as blood collection, separation of the white blood cells, special treatment of those cells, and then injection of those cells back into the body.

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**From:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 4:31 PM  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Question on Medicare coverage of Provenge

Thanks Louis, I will let Ellen know.

*Shanterri Brown-Jones*  
Correspondence Liaison Specialist  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Email: [SBrownJones@cms.hhs.gov](mailto:SBrownJones@cms.hhs.gov)  
Tel: 410-786-6854  
Fax: 410-786-6857

---

**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 4:26 PM  
**To:** Brown-Jones, Shanterri M. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ)  
**Subject:** RE: Question on Medicare coverage of Provenge

There is no such provision that would change coverage. The 1861(t)(2)(B) compendia do not mandate coverage.

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**From:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 4:25 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Question on Medicare coverage of Provenge

Hi Tamara,

I spoke with Ellen and she wanted to ask you if there was some kind of special determination for cancer treatment that has been approved by the FDA and would that change the coverage requirement?

Thanks

*Shanterri Brown-Jones*  
Correspondence Liaison Specialist  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Email: [SBrownJones@cms.hhs.gov](mailto:SBrownJones@cms.hhs.gov)  
Tel: 410-786-6854  
Fax: 410-786-6857

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**From:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 4:02 PM  
**To:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)  
**Subject:** RE: Question on Medicare coverage of Provenge

Shanterri – there is not an open NCD or LCD on this issue. - tamara

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

---

**From:** Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Sent:** Wednesday, May 26, 2010 12:49 PM  
**To:** Syrek Jensen, Tamara S. (CMS/OCSQ)  
**Cc:** Ashby, Lori M. (CMS/OCSQ)  
**Subject:** FW: Question on Medicare coverage of Provenge  
**Importance:** High

Hi Tamara,

Kelly is in training this week and I am backing her up. Can you take a look at this question from the reporter on coverage of Provenge?

Thanks

*Shanterri Brown-Jones*  
Correspondence Liaison Specialist  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Email: [SBrownJones@cms.hhs.gov](mailto:SBrownJones@cms.hhs.gov)  
Tel: 410-786-6854  
Fax: 410-786-6857

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**From:** Griffith, Ellen B. (CMS/OEA)  
**Sent:** Wednesday, May 26, 2010 12:28 PM  
**To:** Anderson, Kelly (CMS/OCSQ); Brown-Jones, Shanterri M. (CMS/OCSQ)  
**Subject:** FW: Question on Medicare coverage of Provenge  
**Importance:** High

Don is out. Can you help me with this?

Thanks,  
Ellen

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**From:** Angela Maas [<mailto:amaas@aispub.com>]  
**Sent:** Wednesday, May 26, 2010 12:04 PM  
**To:** Griffith, Ellen B. (CMS/OEA)

**Subject:** Question on Medicare coverage of Provenge

**Importance:** High

Ellen,

I hope this finds you well. I'm working on an article on the recent approval of prostate cancer therapy Provenge for *Specialty Pharmacy News*, and one of my sources at a health plan says they're waiting to see what CMS does in terms of coverage of the treatment. Could you give me any information on what CMS will do as far as coverage of Provenge? If not, can you at least tell me when CMS may release its coverage information?

I'm on deadline, unfortunately, and am wrapping up the issue tomorrow. I apologize for the last-minute question (this actually just came up yesterday), but I really appreciate any information you can give me on this. Thanks in advance for your help!

Best regards,

Angela

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Angela Maas

Managing Editor, *Specialty Pharmacy News*, *Drug Benefit News*

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

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**From:** 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)

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

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**From:** Jacques, Louis B. (CMS/OCSQ)  
**Sent:** Tuesday, May 04, 2010 10:19 PM  
**To:** 'Paul.Deutsch@empireblue.com'  
**Cc:** Syrek Jensen, Tamara S. (CMS/OCSQ); SALIVE, Marcel (CMS/OCSQ); Rollins, James (CMS/OCSQ)  
**Subject:** Re: Coverage for Provenge

Paul

They saw us awhile ago. Aware of their process. I believe its coverable. Although a vaccine its not prevention. We'll look into it

Louis  
Sent from my Blackberry

---

**From:** DEUTSCH, PAUL G <Paul.Deutsch@Empireblue.com>  
**To:** Jacques, Louis B. (CMS/OCSQ)  
**Cc:** COSTANTINO, GEORGE <GEORGE.COSTANTINO@wellpoint.com>; Cunningham, Carolyn <Carolyn.Cunningham@anthem.com>  
**Sent:** Tue May 04 18:05:51 2010  
**Subject:** Coverage for Provenge

Louis,

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

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

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

Thank you for looking at this.

Paul

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

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

---

**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.

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Thank you for looking at this.

Paul

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