

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 Pharnalot

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 Pharnalot

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 Pharnalot

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:pharnalot@gmail.com>]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharnalot

Hi Ellen,

My name is Ed Silverman and I run the Pharnalot 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
Pharnalot
ed@pharnalot.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 regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

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

Any info you have would be appreciated. Thanks!

Maria

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

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

Any progress?

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

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

Thanks,
Maria

From: PSC Myers, John (Specter)
Sent: Friday, July 02, 2010 3:04 PM
To: Fitzgerald, Erin (HHS/ASL)

Cc: Martino, Maria (CMS/OL)
Subject: RE: RE:

Thanks. I appreciate it.

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

Thanks
John

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

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

Thanks
Erin

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

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

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

John
4-5862

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

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:pharnalot@gmail.com]
Sent: Tuesday, July 06, 2010 2:52 PM
To: Griffith, Ellen B. (CMS/OEA)
Subject: question from Ed at Pharnalot

Hi Ellen,

My name is Ed Silverman and I run the Pharnalot 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
Pharnalot
ed@pharnalot.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 regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

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

Any info you have would be appreciated. Thanks!

Maria

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

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

Any progress?

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

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

Thanks,
Maria

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

Thanks. I appreciate it.

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

Thanks
John

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

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

Thanks
Erin

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

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

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

John
4-5862

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.

Copyright © 2010 The Associated Press. All rights reserved.

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](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.

Copyright © 2010 The Associated Press. All rights reserved.

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)

Confidentiality Notice: This e-mail message and any attachments are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, distribution or copying is prohibited. If 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.

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)

Confidentiality Notice: This e-mail message and any attachments are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, distribution or copying is prohibited. If 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.

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)

Confidentiality Notice: This e-mail message and any attachments are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, distribution or copying is prohibited. If 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: 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 regarding our decision to do a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer.

The Congressional staffer wants to know:

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

Any info you have would be appreciated. Thanks!

Maria

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

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

Any progress?

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

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

Thanks,
Maria

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

Thanks. I appreciate it.

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

Thanks
John

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

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

Thanks
Erin

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

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

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

John
4-5862

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

I'll 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

The information contained in this communication is intended for the use of the designated recipients named above. If the reader of this communication is not the intended recipient, you are hereby notified that you have received this communication in error, and that any review, dissemination, distribution or copying of this communication is strictly prohibited.

If you have received this communication in error, please notify The Associated Press immediately by telephone at +1-212-621-1898 and delete this e-mail. Thank you.

[IP_US_DISC]

msk dccc60c6d2c3a6438f0cf467d9a4938

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



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

Robert W. Baird & Co. Incorporated does not accept buy, sell or other transaction orders by e-mail, or any instructions by e-mail that require a signature. This e-mail message, and any attachment(s), is not an offer, or solicitation of an offer, to buy or sell any security or other product. Unless otherwise specifically indicated, information contained in this communication is not an official confirmation of any transaction or an official statement of Baird. The

information provided is subject to change without notice. This e-mail may contain privileged or confidential information or may otherwise be protected by other legal rules. Any use, copying or distribution of the information contained in this e-mail by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer on which it exists. Baird, in accordance with applicable laws, reserves the right to monitor, review and retain all electronic communications, including e-mails, traveling through its networks and systems. E-mail transmissions cannot be guaranteed to be secure, timely or error-free. Baird therefore recommends that you do not send any sensitive information such as account or personal identification numbers by e-mail.

.....

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.

