

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




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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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)

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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)

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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



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Sent: Tuesday, June 08, 2010 2:22 PM
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Subject: RE:

(b)(5) - Predecisional




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Subject:

(b)(5) - Predecisional



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

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

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

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

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

(b)(5) - Professional



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)

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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.

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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

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. (b)(6) 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 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>.

The New Busy is not the too busy. Combine all your e-mail accounts with Hotmail. [Get busy.](#)

Hotmail has tools for the New Busy. Search, chat and e-mail from your inbox. [Learn more.](#)

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

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Bernice Hecker MD, MHA, FACC
Medicare, Contractor Medical Director
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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)
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To: Jacques, Louis B. (CMS/OCSQ)
Subject: Re: Provenge

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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

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

-----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

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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)
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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)
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To: Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ)
Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Provenge

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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:
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Study selection criteria: randomized and non-randomized comparative studies
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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."

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Cc: Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Re: Provenge

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Sent from my Blackberry

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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

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Subject: Provenge

Elise,

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

Jacques, Louis B. (CMS/OCSQ)

From: Stieber, Joan (CMS/OL)
Sent: Monday, June 07, 2010 12:22 PM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Rollins, James (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Subject: RE: Provenge

Thanks Louis and Jim. So it sounds like contractors are not covering Provenge at this time pending resolution of those benefit category questions, is that correct?

Can I publicly share this explanation? And/or can I say that we are actively looking at the benefit category questions so coverage could be addressed soon?

Also, have there been any external requests for an NCD or is it one we would initiate internally?

thanks -- Joan

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

Joan,

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

Louis

Louis B. Jacques, MD
Director, Coverage & Analysis Group
Office of Clinical Standards and Quality
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Baltimore MD 21244
(410) 786-4512
(410) 786-9286 (FAX)
Louis.Jacques@CMS.HHS.GOV

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)
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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)

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.

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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)

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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

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
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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)

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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)

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Subject: RE:

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Medicare, Contractor Medical Director
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Subject:

(b)(5) - Predecisional

Bernice Hecker MD, MHA, FACC
Medicare, Contractor Medical Director
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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



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

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Jacques, Louis B. (CMS/OCSQ)

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

Importance: High

(b)(5) - Predecisional



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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 (nilotinib), 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
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Sent: Tuesday, June 01, 2010 2:45 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: fyi-yiyi

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The Pink Sheet Daily. 2010 May 24, E Hayes

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Price Sounds Right To Other Sponsors

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

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

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

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

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

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Jacques, Louis B. (CMS/OCSQ)

From: 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) - Personal

Edith

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

P, G and C,

Have CC's a few CMSers on this reply.

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

Louis

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

Louis,

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

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

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

Thank you for looking at this.

Paul

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

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Jacques, Louis B. (CMS/OCSQ)

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

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