

خميس ٤
Jacques, Louis B. (CMS/OCSQ)

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

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

Is there anything more you'd be willing to share about this, apart from what's already said on the coverage website? – e.g., the Tracking Sheet says: “*CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®.*”

thanks – Joan in OL

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

Dear Joan:

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

Sincerely,

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

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

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

Thanks.

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

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

Subject: NCA Question

Hi Juneous,

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

Many thanks in advance for your help.

Best,
Megan

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

Jacques, Louis B. (CMS/OCSQ)

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

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

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

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

thanks -- Joan

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

We have a foia
Sent from my Blackberry

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

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

Is there anything more you'd be willing to share about this, apart from what's already said on the coverage website? – e.g., the Tracking Sheet says: *"CMS received informal inquiries for a national coverage determination (NCD) for autologous cellular immunotherapy treatment of prostate cancer. This interest arose upon the recent FDA approval of the Sipuleucel T treatment regimen, marketed as Provenge®."*

thanks – Joan in OL

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

Dear Joan:

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

Sincerely,

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

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

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

Thanks.

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

Hi Juneous,

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

Many thanks in advance for your help.

Best,
Megan

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

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

28,000 Doctors

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

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

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

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

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

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

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

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

Hi John -

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

Please and thanks!

Cindy

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

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

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

By Tom Randall - Aug 2, 2010

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

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

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

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

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

28,000 Doctors

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

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

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

Will do. Jarollins

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Tuesday, August 03, 2010 9:06 AM
To: Rollins, James (CMS/OCSQ)
Subject: Dendreon

With Sebelius here today, pls make sure Leslye is out in time to get Dendreon at security. Thanks.

From: Rollins, James (CMS/OCSQ)
Sent: Tuesday, August 03, 2010 8:08 AM
To: Jacques, Louis B. (CMS/OCSQ)
Cc: Ellis, Maria A. (CMS/OCSQ)
Subject: FW: Web Posting

Louis, here is the January MEDCAC minutes and transcripts to be posted. Jarollins

From: Ellis, Maria A. (CMS/OCSQ)
Sent: Tuesday, March 16, 2010 11:01 AM
To: Rollins, James (CMS/OCSQ)
Cc: Roche, Jeffrey (CMS/OCSQ); Eggleston, Lisa J. (CMS/OCSQ); Miller, Susan (CMS/OCSQ)
Subject: Web Posting

Good Morning!

Please find attached the signed meeting minutes and transcript from the January 27th MEDCAC meeting on Pharmacogenomic for clearance/approval for web posting. Please let me know if I can be of further assistance.

Maria A. Ellis

*Health Insurance Specialist
Division of Operations and Information Management
Coverage and Analysis Group, OCSQ
(410) 786-0309*

Maria.Ellis@cms.hhs.gov

Jacques, Louis B. (CMS/OCSQ)

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

Dr. Jacques,

Here is out list attendees for our meeting tomorrow;

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

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

Chris Lockett
Sr. Director Government Affairs
Dendreon Corporation

Beth Roberts
Partner
Hogan Lovells

Regards,

Chris

This email message including any attachments is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the sender's Email System Administrator.

Jacques, Louis B. (CMS/OCSQ)

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

FYI

Sent from my iPhone

Begin forwarded message:

From: "Brad Loncar" <(b) (6)>
Date: August 1, 2010 7:05:56 AM EDT
To: Leslye.fitterman3@cms.hhs.gov
Subject: Sipuleucel-T Review Unethical

On page 14 of the U.S. Food and Drug Administration's Summary Basis of Regulatory Approval of sipuleucel-T, the agency states that "Because D9902B provides substantial evidence of improved survival, a second study would be neither **ethical** nor feasible."

In other words, the FDA is saying that substantial scientific evidence confirms that this therapy works and to investigate it further and add delay to cancer patients receiving it would be **unethical**.

Yet this is exactly what you are doing. On behalf of the tens of thousands of men who are suffering from this debilitating disease, I strongly recommend that your agency drop its NCA of sipuleucel-T, or at the very least publicly clarify what the aims and scope of your NCA is.

Through your lack of transparency about what is going on here, you are adding a de facto 2nd regulatory hurdle to usage of a FDA approved drug. Which is very alarming for these men and medicine in general because it (1) creates an unnecessary barrier for men to receive this life-prolonging therapy and (2) hurts innovation in this country by raising the bar of risk the scientific community will face when deciding whether to attempt new discoveries. Please reconsider and/or clarify to the public what you are doing.

Sincerely,
Brad Loncar

Jacques, Louis B. (CMS/OCSQ)

Subject: Meeting with Dendreon
Location: N3-06-11

Start: Tue 08/03/2010 11:00 AM
End: Tue 08/03/2010 12:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Fitterman, Leslye (CMS/OCSQ)

Required Attendees: Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); HAKIM, ROSEMARIE B. (CMS/OCSQ); Debnam, Theresa T. (CMS/OCSQ)

Please see LOCATION

Jacques, Louis B. (CMS/OCSQ)

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

After discussing with Pat we did not post this one.

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

Leslye-

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

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

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

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

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

Top level conferences were held in the old Reichstag conference room and they decided that jacksobeer might not make much as much money any more.

When I spoke up on behalf of "that crap" Provenge, some guys with funny "SS" marks on their arms roughly ushered me out and took away my party membership card.

I was shown some pictures of what looked like a big outdoor barbeque pit and told to keep quiet.

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

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

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

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 22, 2010 4:02 PM
To: Meister, Mike (HHS/OGC); Burns, Julie (HHS/OGC); Fisher, Barbara (HHS/OGC); Mantoan, Patricia (HHS/OGC); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: Provenge Public Comments

Dear All,

Following up on the issue of anonymous public comments and allegations of death threats to physicians/commenters who are critical of Provenge, I think we should set up a meeting or telecon with relevant Federal participants, which may include FDA and DOJ, to coordinate how we will respond to the allegations, especially if the commenters were to allege scientific misconduct or fraud re: the materials submitted to FDA. So I'd like to get a sense of who should be included from OGC, and whether you have FDA or DOJ contacts who should be included.

We do accept anonymous comments, and I note that some of the names clearly appear to be made up anyway.

So far the comments are largely "my (father/grandfather/husband) (has/had) prostate cancer and Medicare should pay for it..." A few say we should not cover. Some say we should cover but ask us to clearly define the appropriate population and maybe require CED. Some commenters are verbally sniping at each other and alleging that other commenters conflict of interest. Here are two, the first anonymous the second had a name which I redacted.

There is major trial design flaw in trials.FDA/CMS need to investigate further before any reimbursement. Placebo patients received significantly less cells than Provenge arm patients (pbo only received 1/3 cells back). This difference could have led to effect, but because of harm in pbo arm. Full analysis here: <http://mfi.re/?zdiewnyttq4vnz> Provenge Analysis Apologies for anon. Very sorry for patients and appreciate there is very vocal support, which has become very threatening to some researchers therefore staying anon. Even if this is redacted, do examine the trial design analysis to see the massive flaw

Dear CMS Reviewers, Unfortunately, during the last few years, skepticism about Provenge efficacy and calls for a new thorough review have all been unjustly labelled as disguised attempts of financial entities set to profit from Dendreon's demise. However, you as well as the American public ought to appreciate that there is a large community of physicians and scientists who once were and still remain unconvinced of Provenge efficacy and are committed to saving our fragile cancer patients from receiving an expensive and medically futile treatment. Sadly, there are of course those who do not want

us to speak. ~~We have been driven into silence and anonymity because we do value our own life~~ as we value that of our cancer patients: the last few oncology experts who publicly expressed doubts on Provenge were forced out of the scientific debate by murder threats. The FDA approved Provenge under extreme duress, asphyxiating lobbying and congressional pressure. This outside interference was able to crack the system and enable Provenge to escape without receiving appropriate scrutiny. Yet, we appreciate that it would be unfair to ask you to reject the national coverage of Provenge based on the failures of another agency. Then, we simply encourage you to perform full and detailed diligence on Provenge efficacy before offering it to patients at the national expense. We encourage you to consult multiple experts, scrutinize every available data set, employ every alternative perspective outside of the box. Above all, we encourage you to conduct a fair and independent review, unswayed by lobbying efforts and political pressure. Free scientific dialogue and rigorous review are not the killers of hope and miracles, although they are being denounced as such. We encourage you to promote and embrace free dialogue: it is essential for the enunciation of truth. Respectfully,

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

Jacques, Louis B. (CMS/OCSQ)

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

Please include Pat since her division is responsible for comments.

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 22, 2010 4:02 PM
To: Meister, Mike (HHS/OGC); Burns, Julie (HHS/OGC); Fisher, Barbara (HHS/OGC); Mantoan, Patricia (HHS/OGC); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: Provenge Public Comments

Dear All,

Following up on the issue of anonymous public comments and allegations of death threats to physicians/commenters who are critical of Provenge, I think we should set up a meeting or telecon with relevant Federal participants, which may include FDA and DOJ, to coordinate how we will respond to the allegations, especially if the commenters were to allege scientific misconduct or fraud re: the materials submitted to FDA. So I'd like to get a sense of who should be included from OGC, and whether you have FDA or DOJ contacts who should be included.

We do accept anonymous comments, and I note that some of the names clearly appear to be made up anyway.

So far the comments are largely "my (father/grandfather/husband) (has/had) prostate cancer and Medicare should pay for it..." A few say we should not cover. Some say we should cover but ask us to clearly define the appropriate population and maybe require CED. Some commenters are verbally sniping at each other and alleging that other commenters conflict of interest. Here are two, the first anonymous the second had a name which I redacted.

There is major trial design flaw in trials. FDA/CMS need to investigate further before any reimbursement. Placebo patients received significantly less cells than Provenge arm patients (pbo only received 1/3 cells back). This difference could have led to effect, but because of harm in pbo arm. Full analysis here: <http://mfi.re/?zdiewnyttqg4vz> Provenge Analysis Apologies for anon. Very sorry for patients and appreciate there is very vocal support, which has become ~~very threatening to some researchers therefore staying anon. even if this is redacted, do examine the trial design analysis to see the massive flaw~~

Dear CMS Reviewers, Unfortunately, during the last few years, skepticism about Provenge efficacy and calls for a new thorough review have all been unjustly labelled as disguised attempts of financial entities, set to profit from Dendreon's demise. However, you as well as the American public ought to appreciate that there is a large community of physicians and scientists who once were and still remain unconvinced of Provenge efficacy and are committed to saving our fragile cancer patients from receiving an expensive and medically futile treatment. Sadly, there are of course those who do not want us to speak. ~~We have been driven into silence and anonymity because we do value our own life~~ as we value that of our cancer patients: the last few oncology experts who publicly expressed doubts on Provenge were forced out of the scientific debate by murder threats. The FDA approved Provenge under extreme duress, asphyxiating lobbying and congressional pressure. This outside interference was able to crack the system and enable Provenge to escape without receiving appropriate scrutiny. Yet, we appreciate that it would be unfair to ask you to reject the national coverage of Provenge based on the failures of

another agency. Then, we simply encourage you to perform full and detailed diligence on Provenge efficacy before offering it to patients at the national expense. We encourage you to consult multiple experts, scrutinize every available data set, employ every alternative perspective outside of the box. Above all, we encourage you to conduct a fair and independent review, unswayed by lobbying efforts and political pressure. Free scientific dialogue and rigorous review are not the killers of hope and miracles, although they are being denounced as such. We encourage you to promote and embrace free dialogue: it is essential for the enunciation of truth. Respectfully,

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

Jacques, Louis B. (CMS/OCSQ)

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

Will schedule a meeting today if possible.

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

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

(b)(5) - Predecisional



Sent from my Blackberry

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

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

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

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

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 22, 2010 10:16 PM
To: Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: RE: Meeting with Dendreon at CMS

(b)(5) - Predecisional



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

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thu 7/22/2010 4:19 PM
To: clockett@dendreon.com
Cc: Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)

Subject: Meeting with Dendreon at CMS

Dear Mr. Lockett:

We have scheduled a meeting with you and your colleagues at our office in Baltimore, MD for August 3, 2010 11:00 am to 12 noon. I will follow-up with you early next week when we have composed questions. I will also clarify what I mean by "effectiveness" and "comparative effectiveness".

We looking forward to meeting with you on August 3rd.

Regards, Leslye

Leslye Fitterman, PhD.

Centers for Medicare and Medicaid Services

Office of Clinical Standards and Quality

Coverage and Analysis Group

7500 Security Boulevard

C1-09-06

Fax - 410-786-9286

Phone - 410-786-1806

Email - Leslye.Fitterman@cms.hhs.gov

Jacques, Louis B. (CMS/OCSQ)

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

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

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

From: Jacques, Louis B. (CMS/OCSQ)
Sent: Thursday, July 22, 2010 10:16 PM
To: Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ)
Subject: RE: Meeting with Dendreon at CMS

(b)(5) - Privileged



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

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Thu 7/22/2010 4:19 PM
To: clockett@dendreon.com
Cc: Rollins, James (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: Meeting with Dendreon at CMS

Dear Mr. Lockett:

We have scheduled a meeting with you and your colleagues at our office in Baltimore, MD for August 3, 2010 11:00 am to 12 noon. I will follow-up with you early next week when we have composed questions. I will also clarify what I mean by "effectiveness" and "comparative effectiveness".

We looking forward to meeting with you on August 3rd.

Regards, Leslye

Leslye Fitterman, PhD.

Centers for Medicare and Medicaid Services

Office of Clinical Standards and Quality

Coverage and Analysis Group

7500 Security Boulevard

C1-09-06

Fax - 410-786-9286

Phone - 410-786-1806

Email - Leslye.Fitterman3@cms.hhs.gov

Jacques, Louis B. (CMS/OCSQ)

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

From: Berliner, Elise (AHRQ)
Sent: Thursday, July 22, 2010 3:17 PM
To: Rollins, James (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); 'Aronson, Naomi'
Cc: Wittenberg, Kim (AHRQ/COE)
Subject: RE: provenge

Jim and Naomi,

(b)(5) - Predecessor



Thanks,
Elise

From: Rollins, James (CMS/OCSQ)
Sent: Thursday, June 24, 2010 8:29 AM
To: Berliner, Elise (AHRQ)
Cc: Wittenberg, Kim (AHRQ/COE)
Subject: RE: provenge

The proposal looks fine. What about the budget? Jarollins

From: Berliner, Elise (AHRQ)
Sent: Tuesday, June 22, 2010 9:55 AM
To: Rollins, James (CMS/OCSQ)
Cc: Wittenberg, Kim (AHRQ/COE)
Subject: provenge

Jim,

Attached is the proposal from BCBSA TEC on Provenge.

Please let me know if you approve this, or if you have any questions or comments. If possible, please send a reply by COB today, we are trying to set up all the paperwork quickly.

Thanks,
Elise

Jacques, Louis B. (CMS/OCSQ)

From: Clapton, Erin M. (CMS/OL)
Sent: Monday, July 19, 2010 5:34 PM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)
Cc: Leung, Isabella (CMS/OL); Stieber, Joan (CMS/OL)
Subject: RE: autologous cellular immunotherapy treatment of prostate cancer
Attachments: image001.gif

Importance: High

Hi everyone. We received some follow-up questions on this issue from the Senate Finance Committee. More specifically, they are interested in the following:

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

Thanks for your help on this.

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

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

Maria,

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

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

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

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

Louis

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

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

I got the e-mail below on Friday afternoon 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: Monday, July 19, 2010 8:06 PM
To: Jacques, Louis B. (CMS/OCSQ)
Subject: Re: autologous cellular immunotherapy treatment of prostate cancer

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

Leslye

Sent from my iPhone

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

Erin,

I'm offsite tomorrow and Wednesday, so here are some quick replies.

1. This is largely done on a case by case basis rather than by LCD, so any number will be less than fully informative. We did not canvass the MACs.
2. The scientific evidence base is sparse. Provenge failed its initial clinical studies. The Provenge regimen appears to be a collection of discrete services. FDA labeling notes stroke risk and requirement for more research about risk.
3. We don't track this unless it's in the annual report to Congress (I don't know), but maybe a third to a half are CMS initiated. Depends on whether reconsiderations of the same NCD are counted separately. We could try to come up with a better estimate if they really want to know.
4. Yes (Recent examples include Abarelix, Zevalin, Bexxar, 4 GI cancer drugs in NCI trials). Doing 20-25 NCDs total a year would not expect that cancer drugs would necessarily be frequent topics.

As an aside, Provenge is not a typical drug in the usual sense, since it's really immunotherapy using the patient's cells. So the question itself is a bit presumptive in calling it an NCD about a cancer drug. We do plenty of NCDs on cancer topics.

5. Yes, but TAs don't "meet" so the question doesn't really make sense. We have commissioned the TA from AHRQ.

6. No. November 17, 2010.

7. We are receiving public comment on the opening of the NCD. The next notable event is the MEDCAC. By law (1862(I)) the proposed decision is due in a bit under 9 mos, the final 3 mos after the proposed.

Louis

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

From: Clapton, Erin M. (CMS/OL)
Sent: Mon 7/19/2010 5:34 PM
To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Rollins, James (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ)

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

Hi everyone. We received some follow-up questions on this issue from the Senate Finance Committee. More specifically, they are interested in the following:

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

Thanks for your help on this.

Erin M. Clapton

Director

Medicare Part A & Part B Analysis Group

CMS Office of Legislation

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

Subject: RE: autologous cellular immunotherapy treatment of prostate cancer

Maria,

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

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

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

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

Louis

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

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

I got the e-mail below on Friday afternoon 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) <http://www.cms.gov/mcd/public_comment.asp?nca_id=247&basketitem=>

Issue

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

As described on the FDA website at <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm213559.htm>, "PROVENGE® (Sipuleucel T, APC8015) is an autologous cellular immunotherapy product consisting of peripheral blood mononuclear cells (PBMCs) obtained from patients by leukapheresis and activated in vitro with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF). FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

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

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

Requestor Name(s)

Internally generated by CMS

Formal Request Accepted and Review Initiated

6/30/2010

Expected NCA Completion Date

6/30/2011

Public Comment Period

6/30/2010 - 7/30/2010

Proposed Decision Memo Due Date

3/30/2011

Lead Analyst(s)

Leslye Fitterman, PhD

Leslye.fitterman3@cms.hhs.gov <<mailto:Leslye.fitterman3@cms.hhs.gov?subject=WEB%20EMAIL%20-%20CAG-00422N>>

1-410-786-1802

Lead Medical Officer(s)

Lori Paserchia, MD

Actions Taken

June 30, 2010

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

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

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

<image001.gif>

Jacques, Louis B. (CMS/OCSQ)

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

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

-Al

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

Maria,

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

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

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

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

Louis

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

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

I got the e-mail below on Friday afternoon 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, Marla (CMS/OL) [mailto:Marla.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 (PBMNCs) obtained from patients by leukapheresis and activated *in vitro* with a recombinant fusion protein (prostatic acid phosphatase fused with GM-CSF)...FDA will require the sponsor to complete a post marketing study to evaluate the risk of stroke in patients who receive sipuleucel-T."

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

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

Requestor Name(s)

Internally generated by CMS

Formal Request Accepted and Review Initiated

6/30/2010

Expected NCA Completion Date

6/30/2011

Public Comment Period

6/30/2010 - 7/30/2010

Proposed Decision Memo Due Date

3/30/2011

Lead Analyst(s)

Leslye Fitterman, PhD
Leslye.fitterman3@cms.hhs.gov
1-410-786-1802

Lead Medical Officer(s)

Lori Paserchia, MD

Actions Taken

June 30, 2010

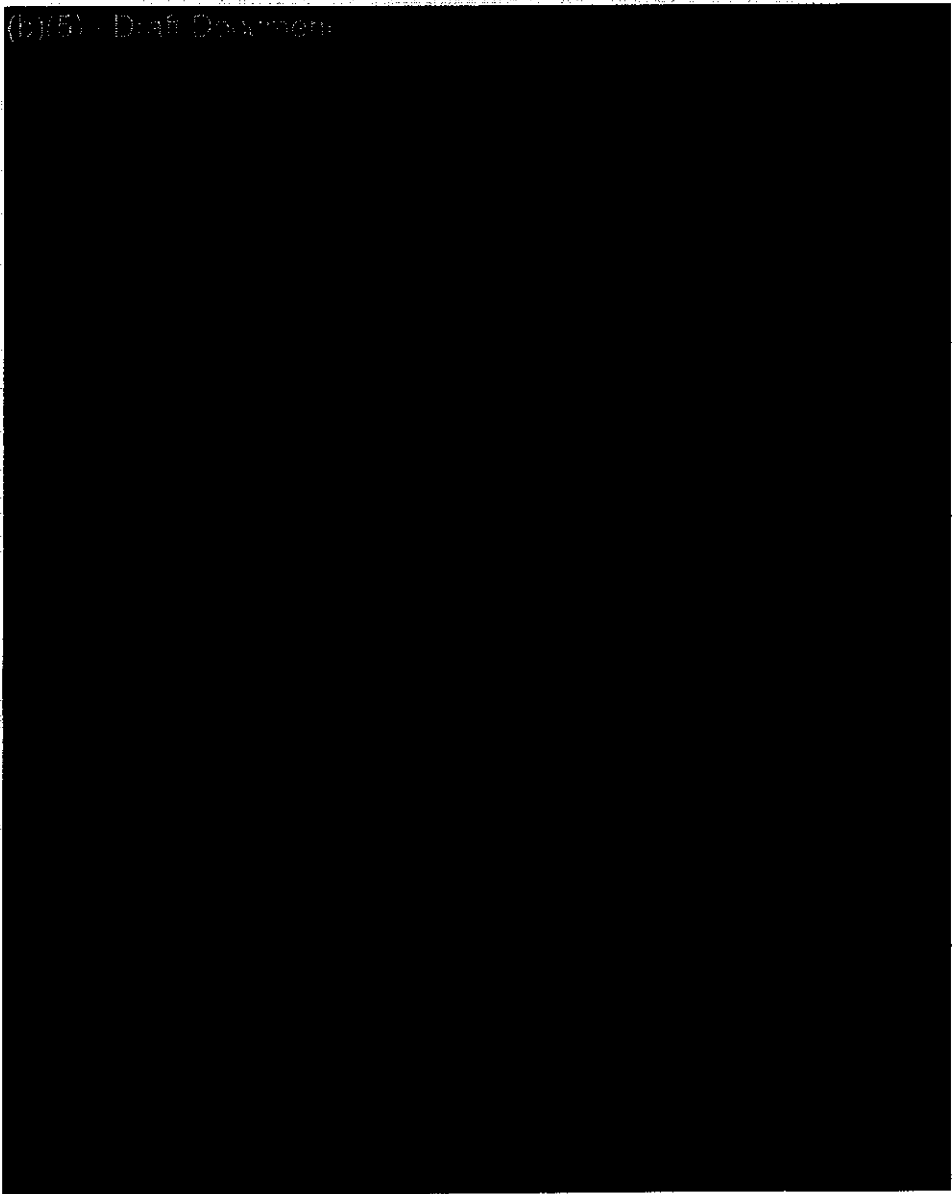
CMS opens this NCA for autologous cellular immunotherapy treatment of prostate cancer. CMS is requesting public comments on the evidence regarding the effects of this treatment on health outcomes in patients with prostate cancer. The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review. CMS is commissioning a technology assessment from an external entity and plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in 2010. Instructions on submitting public comments can be found at http://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp. You can also submit

a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**

(1 inch margins all around)

(Do not type date)

(b)(5) - Draft Document



Formatted: Highlight

Formatted: Highlight

Jacques, Louis B. (CMS/OCSQ)

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

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

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

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

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

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

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

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

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

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

Hi John –

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

Please and thanks!

Cindy

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

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

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

By Tom Randall - Aug 2, 2010

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

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

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

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

(b)(6) - Do not Document



(2 lines)

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

(4 lines)

(type name of signer)

(2 lines)

Enclosure

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

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

cc:

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:49 PM
To: Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ)
Subject: RE: Response to Senator Webb
Attachments: Webb provenge lkf 070810 (2) kr.doc

Leslye,

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

Karen

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

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

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

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

Leslye,

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

Karen

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

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

I attached it to the my email.

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

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

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

Leslye,

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

Karen

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

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

From: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:59 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Response to Senator Webb

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

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

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

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

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

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

Leslye,

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

Karen

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

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

Second attachment is the incoming.

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

Karen:

The pdf is the correspondence from Senator Webb.

Thanks for your assistance.

Leslye

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

Jim:

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

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

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

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

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

Jim:

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

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

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 09, 2010 3:07 PM
To: Rinker, Karen A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Response to Senator Webb
Attachments: Palmetto GBA - Jurisdiction 1 Part B - Drugs & Biologicals Provenge.mht

SEE ATTACHED

From: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:59 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Response to Senator Webb

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

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

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

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

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

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

Leslye,

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

Karen

From: Fitterman, Leslye (CMS/OCSQ)

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

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

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

Subject: Response to Senator Webb

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

STAND CORRECTED – THANKS

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

It's an article

From: Fitterman, Leslye (CMS/OCSQ)
Sent: Friday, July 09, 2010 3:07 PM
To: Rinker, Karen A. (CMS/OCSQ); Jacques, Louis B. (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Response to Senator Webb

SEE ATTACHED

From: Rinker, Karen A. (CMS/OCSQ)
Sent: Friday, July 09, 2010 2:59 PM
To: Jacques, Louis B. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ashby, Lori M. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Subject: RE: Response to Senator Webb

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

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

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

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

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

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

Leslye,

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

Karen

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

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

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

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

Thanks,

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

Sure, sell me down the river.

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

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