

FOIA Request #071220107008

Care to Live

Documents Reviewed for Interim Response # 2

Jacques, Louis B. (CMS/OCSQ)

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

Dear Chris:

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

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

Best regards,
Leslye

Leslye Fitterman, PhD.
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
7500 Security Boulevard
C1-09-06
Fax - 410-786-9286
Phone - 410-786-1806
Email - Leslye.Fitterman3@cms.hhs.gov

Jacques, Louis B. (CMS/OCSQ)

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

Lori:

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

Leslye

(Do not type date)

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

Dear Senators Specter and Kerry:

Thank you for your letter to the Administrator regarding the recently opened national coverage analysis (NCA), Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N) that includes PROVENGE®.

Shortly after Dendreon was given FDA approval to market PROVENGE® it was being covered on a case-by-case basis by some local Medicare administrative contractors. We became aware of differences in coverage policy across contractors as well as questions about whether this cellular immunotherapy would most appropriately be classified as a drug for Medicare purposes. We had also received several inquiries on this subject from members of Congress or their staffs.

These factors contributed to CMS' decision to open the NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with our published guidance document "Factors CMS Considers in Opening a National Coverage Determination," and with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes. Both documents support the use of NCDs to promote greater consistency in coverage across local contractors. The guidance document is available on the CMS website at https://www4.cms.gov/mcd/npc_view_document.asp?id=6. We are also convening a public meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on November 17, 2010 to consider the currently available evidence on this topic. While our analysis is progressing, local contractors retain their statutory authority to cover or not cover PROVENGE® within their jurisdictions. Upon publication of the NCD they must all comply with the national policy.

Based on the statutory time frames we expect that the proposed decision will be published on the CMS website by March 30, 2011 and that the final decision will be published no later than 60 days after the close of the public comment period on the proposed decision. We appreciate your interest in this issue.

Sincerely,

SUMMARY STATEMENT – ADMINISTRATOR’S CORRESPONDENCE

NAME OF CORRESPONDENTS:

Senator Arlen Specter and Senator John Kerry

SUBJECT/ISSUES RAISED BY CORRESPONDENTS:

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

MAJOR POINTS IN THE RESPONSE:

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

POLICY OPTIONS:

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

CLEARANCE COMMENTS:

- (b)(5) - Predecisional

CONTACT PERSONS:

James Rollins
Leslye Fitterman

Jacques, Louis B. (CMS/OCSQ)

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

Louis:

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

Thanks,


Leslye

SUMMARY STATEMENT – ADMINISTRATOR'S CORRESPONDENCE

NAME OF CORRESPONDENTS:

Senator Arlen Specter and Senator John Kerry

(b)(5) - Draft Document



Comment **(b)(1)**: Not sure what is called for here

CONTACT PERSONS:

James Rollins
Leslye Fitterman

United States Senate
WASHINGTON, DC 20510

August 20, 2010

Dr. Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Mailstop 314G
Washington, DC 20201

Dear Administrator Berwick:

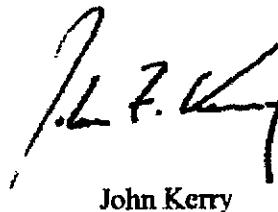
We are writing you regarding a National Coverage Analysis that the Centers for Medicare and Medicaid Services (CMS) issued on June 30, 2010, for autologous cellular immunotherapy treatment for prostate cancer. We are informed that this action was taken based on internal concerns regarding a new FDA-approved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

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

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

Sincerely,


Arlen Specter


John Kerry

(Do not type date)

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

Dear Senators Specter and Kerry:

(b)(5) - Draft Document



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Louis and Tamara:

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

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

Leslye

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

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Michelle

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

Thank you!

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Sent: Monday, September 13, 2010 10:03 AM
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I have been looking this up and I have not found the exact meeting yet. I will continue to look and as soon as I find it I will let you know.

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

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

Maria & Michele:

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Thanks in advance!

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I will relay the official position of CAG.

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Subject: FW: MEDCAC Presentations

Louis and Tamara:

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

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

Leslye

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

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

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Subject: RE: MEDCAC Presentations

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Michelle

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

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

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

Thanks
Michelle

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

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

Maria & Michele:

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

Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

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

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

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

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

I will relay the official position of CAG.

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

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

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

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

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

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

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

Therefore, do I say "no" to Dendreon?

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

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

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To: Jacques, Louis B. (CMS/OCSQ); Syrek Jensen, Tamara S. (CMS/OCSQ)
Cc: PASERCHIA, LORI A. (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ)
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Please let me know your thoughts on next steps with Dendreon.

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Subject: FW: MEDCAC Presentations

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Sent: Thursday, September 02, 2010 2:56 PM
To: Ellis, Maria A. (CMS/OCSQ); Atkinson, Michelle L. (CMS/OCSQ)
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Maria & Michele:

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Thanks in advance!

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

Yes, I still concur on that.

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

Cliff and Louis:

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

(b)(5) - Predecisional

Saty.

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

(b)(5) - Predecisional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Jacques, Louis B. (CMS/OCSQ) [mailto:Louis.Jacques@cms.hhs.gov]

Sent: Friday, September 03, 2010 11:23 AM

To: Goodman, Cliff

Cc: (b)(6) [gmail.com](mailto:(b)(6)@gmail.com); Syrek Jensen, Tamara S. (CMS/OCSQ); PASERCHIA, LORI A. (CMS/OCSQ); Fitterman, Leslye (CMS/OCSQ); Pencek, Eileen (CMS/OCSQ); Rollins, James (CMS/OCSQ); Ellis, Maria A. (CMS/OCSQ)

Subject: RE: November 17th MEDCAC Questions - re: "burden"

Cliff,

(b)(5) - Predecisional



Louis

(b)(5) - Predecisional



From: Goodman, Cliff

Sent: Tuesday, August 31, 2010 11:45 AM

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

Cc: (b)(6) [gmail.com](mailto:(b)(6)@gmail.com)

Subject: FW: November 17th MEDCAC Questions - re: "burden"

(b)(5) - Predecisional



(b)(5) - Predecisional



(b)(5) - Professional

Clifford Goodman, PhD

Vice President

The Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

tel 703.269.5626

fax 703.269.5501

clifford.goodman@lewin.com

www.lewin.com

From: Ellis, Maria A. (CMS/OCSQ) [mailto:Maria.Ellis@cms.hhs.gov]

Sent: Tuesday, August 31, 2010 11:29 AM

To: Goodman, Cliff; (b)(6)@gmail.com

Subject: November 17th MEDCAC Questions

Good Morning!

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

Maria H. Ellis

Health Insurance Specialist

Division of Operations and Information Management

Coverage and Analysis Group, OCSQ

(410) 786-0309

Maria.Ellis@cms.hhs.gov

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Jacques, Louis B. (CMS/OCSQ)

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

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Louis

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Jacques, Louis B. (CMS/OCSQ)

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

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

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

FYI

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

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

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

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

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

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

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

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

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

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

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

Hi John –

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

Please and thanks!

Cindy

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

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

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

By Tom Randall - Aug 2, 2010

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

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

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

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

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

28,000 Doctors

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

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

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

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

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

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

Jacques, Louis B. (CMS/OCSQ)

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

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

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

Jim:

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

Leslye

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

(b)(5) - Draft Document



(b)(5) - Draft Document



(b)(5) - Draft Document



Jacques, Louis B. (CMS/OCSQ)

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

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

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

Jim:

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

Leslye

Jacques, Louis B. (CMS/OCSQ)

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

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

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

Jim:

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

Leslye

+

(Do not type date)

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

(b)(6)

Dear Senator Brownback:

(b)(5) - Draft Document

(b)(5) - Draft Document

Sincerely,