

DANA ROHRABACHER
46th District, California



WASHINGTON OFFICE:
2300 Rayburn House Office Building
Washington, DC 20515-0546
(202) 225-2415 FAX: (202) 225-0145

DISTRICT OFFICE:
101 Main Street, Suite 380
Huntington Beach, CA 92649-8118
(714) 960-6483 FAX: (714) 960-7806

South Bay: (310) 377-9493
<http://rohrabacher.house.gov>

Committees:
FOREIGN AFFAIRS
Ranking Republican, Subcommittee on
International Organizations, Human
Rights and Oversight
Subcommittee on
Asia, the Pacific, and
the Global Environment
Subcommittee on the
Middle East and South Asia
SCIENCE AND TECHNOLOGY
Subcommittee on
Space and Aeronautics

Congress of the United States House of Representatives

FAX TRANSMISSION FORM

To: CMS
Attn: Dave Lewandowski
Fax: 202-690-8168

FROM:

RECEIVED
AUG , 2 2010
OSORA, DIVISION
OF CORRESPONDENCE
MANAGEMENT

- Congressman Dana Rohrabacher
- Justin Ahn
- Paul Berkowitz
- Fess Cassels
- Tony DeTora
- Rick Dykema
- Other: _____
- Kip Payne
- James Schmidt
- Tara Setmayer
- Jeff Vanderslice

NUMBER OF PAGES (INCLUDING TRANSMISSION SHEET): 2

COMMENTS: Dave,
Please pass the attached
on to the appropriate party.
Best, Kip

IF THERE ARE PROBLEMS WITH THIS TRANSMISSION, CALL (202) 225-2415

DANA ROHRABACHER
46th District, California

Committees:

FOREIGN AFFAIRS

Ranking Republican, Subcommittee on
International Organizations, Human
Rights and Oversight

Subcommittee on
Asia, the Pacific, and
the Global Environment

SCIENCE AND TECHNOLOGY

Subcommittee on
Space and Aeronautics

Subcommittee on
Investigations and Oversight



Congress of the United States
House of Representatives

July 29, 2010

WASHINGTON OFFICE:

2300 Rayburn House Office Building
Washington, DC 20515-0546
(202) 225-2415 FAX: (202) 225-0145

DISTRICT OFFICE:

101 Main Street, Suite 380
Huntington Beach, CA 92648-8118
(714) 960-6483 FAX: (714) 960-7806

South Bay: (310) 377-9493

<http://rohrabacher.house.gov>

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
Washington, DC 20201
Via facsimile: (202) 690-8168

RE: National Coverage Analysis for Autologous Cellular Immunotherapy Treatment of
Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Berwick,

I respectfully request the Centers for Medicare and Medicaid Services' careful consideration of inquiries for a national coverage determination pertaining to a Sipuleucel T treatment called Provenge. A uniquely effective prostate cancer treatment, Provenge is FDA-approved and manufactured by an American biotechnology company called Dendreon.

As the available literature regarding Provenge attests, this treatment is a significant alternative to chemotherapy for those people battling prostate cancer. Dendreon, which was founded in California in 1992, is constructing a production facility for this treatment in Seal Beach, California, which will be a welcome partner in my district's economy.

Thank you for your attention to this matter. I trust you will keep this information in mind as you weigh the relevant evidence as to whether Provenge is reasonable and necessary under sections 1862(a)(1)(A) and/or 1862(a)(1)(E) of the Social Security Act.

Sincerely,

Dana Rohrabacher
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-09-06
Baltimore, Maryland 21244-1850



AUG 3 0 2010

Patti A. Davenport
Government Relations Liaison
Alabama Cancer Congress
8805 N. 145th East Ave. (Suite 203)
Owasso, OK 74055

Dear Ms. Davenport:

Thank you for your letter on behalf of Stephen L. Davidson, M.D. to the Administrator regarding Dendreon Corporation's PROVENGE® product. Dr. Davidson believes that since PROVENGE® is approved for marketing by the Food and Drug Administration, CMS does not have the authority to deny coverage for labeled indication.

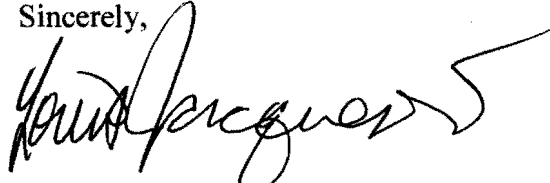
Shortly after Dendreon was given FDA approval to market PROVENGE® it was being covered on a case-by-case basis by some local Medicare administrative contractors. We became aware of differences in coverage policy across contractors as well as questions about whether this cellular immunotherapy would most 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 a NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes, which implies that NCDs should be considered to promote greater consistency in coverage across local contractors. 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.

Page 2 cont. Patti A. Davenport

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,

A handwritten signature in black ink, appearing to read "Louis Jacques", with a long, sweeping horizontal stroke extending to the right.

Louis Jacques, MD
Director
Coverage and Analysis Group
Office of Clinical Standards and Quality

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Correspondence Cover Sheet

Doc ID: **082320104040** *Date Due:*
Corr. From: **Patti Davenport** *Task Date:*
On Behalf Of:
Letter Date: **7/29/2010** *Folder Created:* **8/23/2010**

Subject: **Provenge National Coverage Analysis**
Synopsis: **Provenge National Coverage Analysis**
Primary Issues: **Medicare Coverage**

Program Office Assigned:

Action Required: **Direct Reply** *Signature Level:* **Div Dir Sig**

Coordinator: **Linda Howard** *Data Entry By:* **Brenda McCray**

Instructions: None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

082320104040 OCSA

Clark, Apryl C. (CMS/OP)

From: Patti Davenport [patti@mjexecmgmt.com]
Sent: Thursday, July 29, 2010 5:52 PM
To: Berwick, Donald (CMS/OA)
Subject: FW: Provenge Commentary
Attachments: Provenge ACC.pdf

RECEIVED

AUG 1 0 2010

OSORA, DIVISION
OF CORRESPONDENCE
MANAGEMENT

Dr. Berwick – attached please find a copy of Dr. Stephen L. Davidson’s CMS commentary on Provenge.

Sincerely,

Patti A. Davenport

Government Relations Liaison
Alabama Cancer Congress

On behalf of Stephen L. Davidson, M.D.
President, Alabama Cancer Congress

8805 N. 145th East Ave. (Suite 203)
Owasso, OK 74055

Ph (918) 274-8374
Fx (918) 274-8354

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Alabama Cancer Congress

Education. Advocacy & Community

7/29/10

Donald Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Donald.Berwick@CMS.hhs.gov

Dear Dr. Berwick,

Now that Provenge has been cleared by the FDA, eligible patients are understandably anxious to have access to it. CMS' National Coverage Analysis has the potential to delay treatment to patients with little to no options left in their fight against prostate cancer. Provenge is FDA approved; there is no legal or medical basis to deny Medicare coverage for the approved FDA indication. Provenge has shown a clear survival advantage over chemotherapy with a much lower side effect profile. Provenge also reduced the risk of death by 22.5 percent compared to the control group. This new bioengineered targeted therapy has a median survival of 25.9 months, and a 3-year survival rate of 34.1%. This is a clear benefit over standard care. Those that feel the price is not justified by the incremental survival are not factoring in the quality of life aspect. Provenge side effect profile includes flu-like symptoms. Plus, many of the study subjects are still alive today.

Customized treatment is the way of the future. My hope is that CMS does not choose to delay or impede access to this new innovative therapy.

Sincerely,

Stephen L. Davidson, MD
President, Alabama Cancer Congress
Montgomery Cancer Center
4145 Carmichael Road
Montgomery, AL 36106

PH: 334 273-7000
FAX: 334 273-2282

Ashby, Lori M. (CMS/OCSQ)

From: Jacques, Louis B. (CMS/CCSQ)
Sent: Friday, September 03, 2010 10:50 AM
To: (b)(6)
Subject: Provenge

Dear Dr. DiBenedetto:

Thank you for your email to the Administrator regarding the national coverage analysis (NCA) for 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 a NCA, a comprehensive review of the clinical evidence that leads to a national coverage determination (NCD). This is consistent with Section 1862(l) of the Social Security Act governing Medicare's national and local coverage determination processes, which implies that NCDs should be considered to promote greater consistency in coverage across local contractors. 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.

We have posted a tracking sheet to announce the opening of the NCA. It is available on the CMS website at <https://www4.cms.gov/mcd/viewtrackingsheet.asp?id=247>, and will be updated periodically. The first 30 day comment period ended on July 30, 2010. 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.

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Correspondence Cover Sheet

Doc ID: **082320104015** *Date Due:*
Corr. From: **Joseph DiBenedetto** *Task Date:*
On Behalf Of:
Letter Date: **7/20/2010** *Folder Created:* **8/23/2010**

Subject: **Provenge National Coverage Analysis**
Synopsis: **Provenge National Coverage Analysis**
Primary Issues: **Medicare Coverage; Medicare Coverage**

Program Office Assigned:

Action Required: **Direct Reply** *Signature Level:* **Div Dir Sig**

Coordinator: **Linda Howard** *Data Entry By:* **Brenda McCray**

Instructions: None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

082320104015

OCSA

Clark, Apyl C. (CMS/OP)

From: Joseph DiBenedetto (b)(6)
Sent: Tuesday, July 20, 2010 3:14 PM
To: Berwick, Donald (CMS/OA)
Subject: Provenge National Coverage Analysis

RECEIVED

AUG 10 2010

OSORA DIVISION
OF CORRESPONDENCE
MANAGEMENT

Dear Dr. Berwick,

The following are my comments on Provenge.

Provenge is a FDA approved therapy and the proposed course of action is inconsistent with the Medicare statute in treating patients. Provenge has shown a clear survival advantage over standard chemotherapy, and the patients experience less side effects than the chemotherapeutic drugs available. There is no basis to deny Medicare coverage for the approved FDA indication. This is an anti-cancer treatment, not a vaccine and should not be confused with such. The proposed National Coverage Analysis could take several months and may delay treatment to our patients with cancer of the prostate.

Respectfully submitted,

Joseph DiBenedetto Jr., M.D.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Correspondence Cover Sheet

Doc ID: **090920104003**

Date Due:

Corr. From: **Jeff Bingaman**

Task Date:

On Behalf Of: (b)(6)

Letter Date: **8/24/2010**

Folder Created: **9/9/2010**

Subject: **Two New FDA Approved Treatments Provenge and Jevtana.**
Synopsis: **Expediting Billing Code Two New FDA Approved Treatments Provenge and Jevtana.**

Primary Issues: **Medicare Coverage**

Program Office Assigned:

Action Required: **Direct Reply**

Signature Level: **RA Sig**

Coordinator: **LaShawn Reese**

Data Entry By: **Brenda McCray**

Instructions: None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

090920104003

United States Senate

August 24, 2010

RD 6

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 314 G Humphrey Building
Washington, District of Columbia 20201-0001

Dear Ms. Frizzera:

I have been contacted by my constituent, (b)(6), regarding his request for assistance in expediting the billing code of two new FDA approved treatments, Provenge and Jevtana.

Because of the desire of this office to be responsive to all inquiries, I would appreciate it if you would look into this matter and advise me of your findings so that I may respond to my constituent. Please send your response to the attention of Gabe Long at the address checked on the bottom of this letter.

Thank you for your assistance in this matter.

Sincerely,



Jeff Bingaman
United States Senator

JB/sgl

PLEASE REPLY TO:

- 625 SILVER AVENUE, SW, SUITE 130
ALBUQUERQUE, NM 87102
(505) 346-6601
- 106-B WEST MAIN
FARMINGTON, NM 87401
(505) 325-5030
- 148 LORETTO TOWNE CENTRE
505 SOUTH MAIN, SUITE 148
LAS CRUCES, NM 88001
(575) 523-6561
- 200 EAST 4TH STREET, SUITE 300
ROSWELL, NM 88201
(575) 622-7113
- 119 EAST MARCY, SUITE 101
SANTA FE, NM 87501
(505) 988-6647
IR#3 000012

United States Senate

Due to the Enactment of the "Right to Privacy Act," it is necessary for you to complete and sign this form authorizing me and members of my staff to obtain the information needed to respond to your request for assistance. The information obtained will be only that which is relative to the problem you presented to my office.

Date: AUGUST 4, 2010

Name: (b)(6)

Address: (b)(6)

City: (b)(6) Zip Code: (b)(6)

Telephone: (b)(6)

Email: (b)(6)

U.S. Senator Jeff Bingaman has my permission to make inquiries into my personal records and/or files as necessary to assist me in the matter I have presented to his office.

Signature: (b)(6)

Date of Birth: (b)(6)

Social Security Number: (b)(6)

Do you currently have a case pending before a local, state, of federal court in regard to this matter?: NO

Is another Congressional office assisting you in this matter?: NO

If so, which office?: We have sent letters to Sen. Udall & Cong. Lujan but have not received responses to date.

PLEASE REPLY TO:

- 625 SILVER AVENUE, SW, SUITE 130
ALBUQUERQUE, NM 87102
(505) 346-6601
- 148 LORETTO TOWNE CENTRE
505 SOUTH MAIN, SUITE 148
LAS CRUCES, NM 88001
(505) 523-6561
- P.O. BOX 1977
118 BRIDGE STREET, SUITE 3
LAS VEGAS, NM 87701
(505) 454-8824
- 200 EAST 4TH STREET, SUITE 300
ROSWELL, NM 88201
(505) 622-7113
- 119 EAST MARCY, SUITE 101
SANTA FE, NM 87501
IR#0500047

July 30, 2010

Senator Jeff Bingaman
Santa Fe, New Mexico

Re: Recent approval by FDA of two new treatments for advanced prostate cancer and failure of Medicare to issue billing codes so patients can be covered financially

Dear Senator Bingaman,

I am writing on behalf of (b)(6). (b)(6) is a Medicare/AARP supplemental insurance patient of 68 who has been treated for prostate cancer in New Mexico since 2006. His oncologist is (b)(6) in Los Alamos, NM. (b)(6) has been treated with all of the standard treatments for his disease and his cancer continues to progress.

This summer the FDA approved an exciting immunotherapy treatment called Provenge, made by Dendreon and shortly thereafter a new chemotherapy called Jevtana, made by Sanofi Aventis. (b)(6) is a good candidate for both treatments.

No medical center in New Mexico has been approved as a treatment site for Provenge so we have traveled to Dallas, TX to Texas Oncology at Baylor University to try and get him treated with Provenge. In Dallas we would have to pay the \$93,000 up front because Trailblazer, the Medicare Administrative Contractor for TX and NM, has not issued a billing code and is not likely to do so for a year. We checked into two centers in Colorado, and they both require up front payment for the same reason.

With Jevtana, the new chemotherapy, the billing code hasn't been issued yet, and there is no date when it might be. We are caught in an impossible situation right now. Time is of the essence in getting (b)(6) treated right away. Jevtana is \$8,500 a treatment & it is given every 3 weeks. Our income is not low enough to qualify for patient assistance from the drug companies.

It was our understanding that we would be financially covered for FDA approved treatments when those treatments are approved specifically for a medical condition. Is there any way you can assist us in getting Trailblazer to speed up their issue of the billing codes so Los Alamos Medical Center and Texas Oncology at Baylor can treat (b)(6) (b)(6) and hundreds of other men with advanced prostate cancer this summer?

Sincerely,

(b)(6)

(b)(6)

and

(b)(6)

c.c. (b)(6), Los Alamos Medical Center

091620104022

September 21, 2010

The Honorable Saxby Chambliss
416 Russell Senate Office Building
Washington, DC 20510-1007

Dear Senator Chambliss:

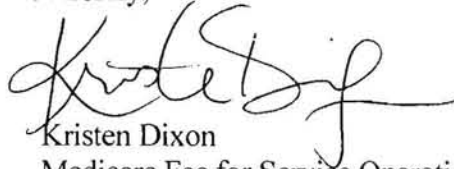
Thank you for your inquiry on behalf of your constituent, (b)(6), (b)(6) has expressed concern about the potential for discrimination of Georgia residents by Medicare. Specifically, he wants to know when Medicare will allow coverage of a new drug called Provenge for Georgia residents. Provenge was recently approved by the Food and Drug Administration to treat prostate cancer.

Medicare does not yet have a national policy for this treatment. The Centers for Medicare and Medicaid Services (CMS) is considering all currently available evidence regarding the impact of labeled and unlabeled use of autologous cellular immunotherapy treatment of patients with metastatic prostate cancer. In absence of a national policy, our Medicare contractor, Cahaba GBA, has the authority to determine if this treatment is covered in the states of Georgia, Florida and Mississippi. The decision to allow coverage is based on local medical practice patterns, medical and scientific documentation.

If a claim is submitted for payment, Cahaba will determine if the drug is medically necessary. If the drug is determined to be medically necessary, Medicare will allow reimbursement. After a claim is filed, (b)(6) physician may be asked to submit additional supporting medical documentation.

I hope this information has been helpful. If you have further questions, please feel free to contact me by telephone at (404) 562-7368.

Sincerely,



Kristen Dixon
Medicare Fee for Service Operations
Division of Financial Management
& Fee for Service Operations

091620104022

SAXBY CHAMBLISS
GEORGIA

COMMITTEES:
AGRICULTURE
RANKING MEMBER

AGING

ARMED SERVICES

INTELLIGENCE

RULES

United States Senate

WASHINGTON, DC 20510-1007

September 7, 2010

RECEIVED

SEP 15 2010

OSORA, DIVISION
OF CORRESPONDENCE
MANAGEMENT

Maria Martino
Centers for Medicare and Medicaid Services
U.s. Department Of Health And Human Services
Hubert Humphrey Building, Room 314
Washington, D.C. 20201

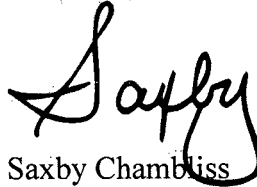
Dear Maria:

I have enclosed a copy of a letter from my constituent, (b)(6), of Acworth, Georgia, who has contacted me concerning the prostate cancer drug, Provenge.

I would very much appreciate your review of (b)(6) concerns.

If you need further information, please contact Mark Olsen of my staff at 202-224-3521. I look forward to your response.

Very truly yours,



Saxby Chambliss

SC:mo

E-Mail Viewer

Message	Details	Attachments	Headers	Source
---------	---------	-------------	---------	--------

HTML

From: "WebServer Reserved UID" <webservd@p-ess-www6.senate.gov>
Date: 8/18/2010 12:22:50 PM
To: "webmail@chambliss-iq.senate.gov" <webmail@chambliss-iq.senate.gov>
Cc:
Subject: Discrimination of Georgia residents by Medicare

(b)(6)

<ISSUE>hth</ISSUE>
<AFFL>reply</AFFL>
<MSG>I am having a issue with Medicare. The FDA has approved a prostate cancer drug called Provenge made by Dendreon.


Medicare is reviewing to what extent they will pay for the treatment, which is very unusual given it's FDA approval. What is more unusual and the subject of my email is that Medicare has left the interim decision on payments to the regional CMS contractors.

The local carrier in GA, Cahaba, has refused to give my physican a local coverage determination, so we don't yet know if they will cover the Provenge. My physician will not treat me unless it is covered. The local carrier in North Carolina is covering treatments and I am forced to travel to Charlotte for multiple treatment events.

My question is how can Medicare discriminate based on geographic location? Do I have legal recourse here?

</MSG>
</APP>

CENTERS FOR MEDICARE & MEDICAID SERVICES

REPORT OF CONTACT		
Name/Organization/Telephone Number of Person Contacted: Marilyn Jones Seator Mark Warner jones@warner.senate.gov		MTN#: 69526 Swift Doc ID #: 072620104007
Constituent Name /Address/Telephone Number: Paul F. Schellhammer, MD Medical Director, Sentara Interstate Corporate Center, Bld. 16 Norfolk, VA 23502 757.457.5100		Date of Contact: 08/17/2010 via email <hr/> Phone: In Person:
SUBJECT: Medicare Coverage of Provenge		
DISCUSSION/STATUS: Dr. Shellhammer wanted to speak with the Medical Director of Trailblazer to discuss coverage of his prostate cancer drug so Sentara Health Plan can also cover drug. Trailblazer will discuss this matter with Dr. Shellhammer as requested.		
ACTION REQUIRED: N/A		
Prepared By: 	Phone Number: 215-861-4194	Date Closed: 8/17/2010

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Correspondence Cover Sheet

Doc ID: **072620104007** *Date Due:*
Corr. From: **Mark R. Warner** *Task Date:*
On Behalf Of: **Paul Schellhammer**
Letter Date: **7/12/2010** *Folder Created:* **7/26/2010**

Subject: **Medicare Coverage For the Drug Provenge.**
Synopsis: **Medicare Coverage For the Drug Provenge.**
Primary Issues: **Medicare Coverage**

*Program Office
Assigned:*

Action Required: **Direct Reply** *Signature Level:* **RA Sig**
Coordinator: **Linda Howard** *Data Entry By:* **Brenda McCray**

Instructions: None

Please send your responses to the Office of Strategic Operations and Regulatory Affairs.

07252010 4007

United States Senate

WASHINGTON, DC 20510-4606

COMMITTEES:
BANKING, HOUSING, AND
URBAN AFFAIRS
COMMERCE, SCIENCE, AND
TRANSPORTATION
BUDGET
RULES AND ADMINISTRATION
JOINT ECONOMIC COMMITTEE

203

July 12, 2010

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department Of Health And Human Services
200 Independence Avenue, Sw, Room 341h
Washington, DC 20201-0001

Dear Ms. Frizzera:

I am writing to bring to your attention the enclosed comments from my constituent, Dr. Paul F. Schellhammer.

I would appreciate your reviewing this correspondence and preparing a reply on the stated concerns. Please send your reply to my state office:

The Honorable Mark R. Warner
919 E. Main Street, Suite 630
Richmond, Virginia 23219

My constituent and I appreciate your assistance in this matter. I am grateful for all you can do to resolve this matter within the existing laws, rules and regulations of the Centers for Medicare and Medicaid Services.

Thank you for your time and courtesy.

Sincerely,

MARK R. WARNER
United States Senator

RECEIVED

JUL 19 2010

OSORA, DIVISION
OF CORRESPONDENCE
MANAGEMENT

MRW/mj

Enclosure(s)

180 WEST MAIN STREET
ABINGDON, VA 24210
PHONE: (276) 628-8158
FAX: (276) 628-1036

101 WEST MAIN STREET
SUITE 4900
NORFOLK, VA 23510
PHONE: (757) 441-3079
FAX: (757) 441-6250

919 EAST MAIN STREET
SUITE 630
RICHMOND, VA 23219
PHONE: (804) 775-2314
FAX: (804) 775-2319

129B SALEM AVENUE, SW
ROANOKE, VA 24011
PHONE: (540) 857-2676
FAX: (540) 857-2800

8000 TOWERS CRESCENT DRIVE
SUITE 200
VIENNA, VA 22182
PHONE: (703) 442-0670
FAX: (703) 442-0408

Urology of Virginia
Sentara Medical Group

June 11, 2010

Senator Mark R. Warner
8000 Towers Crescent Drive
Suite 200
Vienna, Virginia 22182

Fax: 703-442-0408 / 757-441-6250 (Norfolk)

Dear Senator Warner:


I am enclosing several e-mails that are self-explanatory with regard to the position of Trailblazers, our geographic Medicare carrier, concerning coverage of a recently improved immunotherapy for men with advanced prostate cancer. The product is called **PROVENGE**[®]. It was approved in late April by the FDA. Our patients in Tidewater Virginia have been denied coverage, and our efforts to meet the medical director have also led to a denial. On discussing coverage in other geographic locations, I have obtained feedback that coverage approval by Medicare carrier has been forthcoming.

Patients with metastatic androgen independent prostate cancer face chemotherapy as their only current strategy to improve survival. **PROVENGE**[®] also improve survival but with much lower toxicity than chemotherapy.

I would like very much to be able to provide immunotherapy, **PROVENGE**[®], to patients in our practice who have advanced metastatic prostate cancer.

I would appreciate any help that you might give.

Sincerely,


Paul F. Schellhammer, MD

PFS/kk

Interstate Corporate Center, Bldg. 16
Norfolk, VA 23502 Tel: 757.457.5100

400W. Brambleton Avenue, Suite 100
Norfolk, VA 23510 Tel: 757.457.5170

1200 First Colonial Road, Suite 100G
Virginia Beach, VA 23454 Tel: 757.481.3556

9536 Hospital Avenue
Nassawadox, VA 23413 Tel: 757.442.8050

113 Gaineborough Square, Suite 202
Chesapeake, VA 23320 Tel: 757.457.5480

3150 Western Branch Boulevard
Chesapeake, VA 23321 Tel: 757.686.1873

100 Kingsley Lane, Suite 404
Norfolk, VA 23505 Tel: 757.489.411

www.sentara.com

- Victor M. Brugh, III, M.D.*
- Jack R. Drucker, M.D.*
- Gregg R. Eura, M.D., F.A.C.S.*
- Michael D. Fabrizio, M.D., F.A.C.S.*
- Robert W. Given, M.D., F.A.C.S.*
- Nathan P. Goldin, M.D.*
- Jose E. Gonzales, M.D.*
- Gerald H. Jordan, M.D., F.A.C.S., F.A.A.P.(Hon)*
- William A. Julian, M.D.*
- P. Gary Katz, M.D.*
- Joseph J. Konefal, M.D.*
- Peter O. Kwong, M.D.*
- Raymond S. Lance, M.D.*
- John S. Liu, M.D. F.A.C.S.*
- Donald F. Lynch, Jr., M.D. F.A.C.S.*
- Kurt A. McCammon, M.D., F.A.C.S.*
- Guillermo H. Mosquera, M.D., F.A.C.S.*
- William H. Rawls, M.D., F.A.C.S.*
- Edwin L. Robey, M.D., F.A.C.S.*
- Paul F. Schellhammer, M.D., F.A.C.S.*
- Steven M. Schlossberg, M.D., F.A.C.S.*
- James D. Young, M.D.*
- Carol A. Ascher, M.S.N., F.N.P., B.C.
- Stephanie C. Oldfield, N.P.C.
- Bonnie L. Gallo, M.S.N., F.N.P., B.C.
- Chely S. Oscar, M.S.N., F.N.P., B.C.
- Valerie A. Paschang, A.P.R.N., B.C.

*Diplomate of the American Board of Urology



SENTARA

Subj: **FW: Provenge - Medicare's response to inquiry**
Date: 5/19/2010 9:15:55 A.M. Eastern Daylight Time
From: DPROSENB@sentara.com
To: CMVAUGH1@sentara.com, KDRAMSEY@sentara.com, (b)(6)
(b)(6)
(b)(6) CSOSCAR@sentara.com, JPESPINO@sentara.com

FYI--The SMG CBO has made contact with our local Medicare carrier, Trailblazers, to see their position on Provenge. Please read below.

Thanks
Dana

From: CINDY A TAYLOR
Sent: Wednesday, May 19, 2010 9:11 AM
To: DANA ADAMS; DORIS G PRINCE
Subject: Provenge - Medicare's response to inquiry

Good morning,

Per CMS, there is no payment policy for Provenge. Since Provenge is a vaccine, it is considered a preventive service and will not be covered at this time. The patient will be liable for any charges incurred relating to receiving this treatment.

Despite the fact that it is considered a non-covered service, an ABN will still be required in order for SMG to bill the patient.

Please let me know if you have any questions.

Thank you
Cindy

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Subj: Meeting with Trailbalzers to discuss Provenge
Date: 6/10/2010 2:12:12 P.M. Eastern Daylight Time
From: DPROSENB@sentara.com
To: (b)(6)
CC: KDRAMSEY@sentara.com, CMVAUGH1@sentara.com

As you can see, SMG has attempted to get the contact information for the Medicare Medical Director for a discussion on Provenge. Below is the response. I am surprised by this, as we have always been able to contact the Medical Director in the past.

Dana

From: CINDY A TAYLOR
Sent: Thursday, June 10, 2010 1:40 PM
To: DANA ADAMS
Cc: DORIS G PRINCE
Subject: Contact Information - In follow up for Trailblazer Health

Dana,

I just receive the following from Carolyn McNamar at Trailblazer Health:

" Hello, I just spoke to Dr. Haley. He regrets he is unable to meet with Dr. Schlossberg but suggested he attend one of our Open CAC meetings, the next one will be in September. The date for this meeting has not been set yet but the registration is on our web-site around the second week of September. You may also send Dr. Haley any informational materials for him to review. His schedule until December is completely taken."

For your records, Ms McNamar's email address is: carolyn.mcnamar@trailblazerhealth.com

I am a little unsure of her response related to the fact that Dr Haley "is unable to meet with Dr. Schlossberg" . . . here is my original inquiry to her:

Good day Ms. McNamar,
 I am in need of some assistance. One of our Medical Directors, Steven Schlossberg, MD, would like to talk to Charles Haley, MD at Trailblazer Health. I have been unable to locate a phone number that I can provide to Dr Schlossberg. Would you please let me know what phone number he should use in order to call Dr Haley?

Dr Schlossberg would like to discuss a newly FDA approved autologous cellular immunotherapy biologic manufactured by Dendreon called Provenge (NDC# 30237-8900-6). Medicare currently does not have any coverage policies pertaining to this biologic and we have Medicare patients interested in receiving the treatment.

I look forward to hearing from you.

Thank you for your assistance regarding this matter,

Cindy

Friday, June 11, 2010 (b)(6)

At this point, I feel that I have exhausted all means at my level. You may have more success if one of the physicians were to make a call to them as the suggestion to attend an Open CAC meeting in September does not seem conducive to our plan to begin treating Medicare patients immediately.

Thank you
Cindy

Friday, June 11, 2010 (b)(6)

IR#3 000024



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

JUL 28 2010

7500 Security Boulevard
Baltimore, MD 21244-1850

The Honorable Jim Webb
United States Senate
222 Central Park Avenue
Suite #120
Virginia Beach, VA 23462

Dear Senator Webb:

Thank you for your letter concerning the issue raised by Dr. Shellhammer, #610031, regarding the local Medicare Administrative Contractor (MAC) decision to deny coverage for PROVENGE®, an autologous cellular immunotherapy used to treat some patients with metastatic prostate cancer.

Each MAC has authority under statute (section 1869(f)(2)(B) of the Social Security Act) to cover or not cover particular items or services within its jurisdiction. We understand that, in light of the available scientific evidence, some local Medicare contractors are covering it while others are not. We also understand that there has been some discussion as to whether the constituent parts of the PROVENGE® regimen, for the purposes of the Medicare program, are most appropriately characterized singly or collectively as a drug, biologic, immunotherapy, vaccine or other item or service.

The Centers for Medicare and Medicaid Services has opened a National Coverage Analysis (NCA) to make a National Coverage Determination (NCD) to address these issues. We will evaluate the scientific evidence, obtain public comment and develop uniform national Medicare coverage policy on the use of PROVENGE® for prostate cancer. We are aware that this is a novel type of anticancer treatment, and that the Food and Drug Administration is requiring post approval clinical studies. It is our hope that the opening of the NCD, the commissioning of an external technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ), and the convening of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) will, in a publicly transparent manner, encourage a broad understanding of the current evidence as well as any important evidence gaps.

We have posted a tracking sheet to announce the opening of the NCA. It is available on the CMS website at <https://www4.cms.gov/mcd/viewtrackingsheet.asp?id=247>, and will be updated periodically. While our analysis is progressing, local MACs 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.