

Cryo
Pymt/kats

31-0
(5)

4 of 31

AUG 11 2005

4385 Stillwaters Dr.
Merritt Island, FL 32952

August 5, 2005

Mark B. McClellan, M.D., PhD.
Administrator
CMMS / DHHS Attn: CMA-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Hart
Saw
Bazell
Kane

Dear Doctor McClellan,

I am concerned about the impact that "APC 674 - Cryosurgery of the Prostate" (Federal Registry - July 2005) will most likely have on the future of Cryosurgery for treating prostate cancer. My logic train tells me that three effects are probable:

- 1.) Hospitals will probably discontinue to offer Cryo of the Prostate as an outpatient procedure - because the rate proposed in APC 674 would not cover the actual hospital costs.
- 2.) Hospitals that offer Cryo will probably require overnight stays for Cryo - thereby driving up the overall cost to Medicare and the patient..
- 3.) Hospitals not yet offering outpatient or inpatient Cryosurgery will probably tend to back away from offering Cryosurgery rather than suffer the effect of inadequate outpatient remuneration from Medicare.

I see that the bottom line is that future Prostate Cancer patients will suffer by not having the full spectrum of choices for treatment, which includes outpatient Cryosurgery, if hospitals don't offer it because of inadequate coverage by Medicare. I don't want to see that happen. Please help the cause of Patients that choose Cryo by elevating the proposed payment schedule for APC 674 to adequately cover the associated hospital costs.

I had Cryosurgery of the Prostate in 1999, as an outpatient. Overall costs were reduced at least 50%. My co-pays were greatly reduced by not having to pay the Medicare hospital admittance fee. And, Medicare saved by not having to pay any inpatient hospital costs. Medicare approved Cryosurgery of the Prostate in July 1999. That helped pave the way for other health insurers to cover Cryo. Medicare led the way then. Medicare should lead the way now by elevating outpatient hospital coverage via APC 674.

Cryo is a patient friendly, very effective procedure for fighting Prostate Cancer. Recovery is rapid and hospital stays are not required unless health of the patient so dictates. In 1999 it was difficult to find a Cryo doctor and a facility that offered Cryo. Now there are many trained and experienced doctors that offer Cryosurgery, across the USA. For the Patients' benefit, doctors need to have hospitals that offer outpatient Cryosurgery. In the long run Medicare would benefit greatly thru decreased inpatient costs. Patients, doctors and hospitals need your help. Many thanks in advance from a concerned PCa Cryo survivor.

Sincerely,

Lawrence Junker



32

CRYO
PAYM RATES

AUG 15 2005

Stan Wilkes

From: "Stan Wilkes" <swilkes1935@sbcglobal.net>
To: <mark.mcclellan@cms.hhs.gov>
Cc: <james.hart@cms.hhs.gov>
Sent: Tuesday, August 09, 2005 11:24 AM
Subject: Medicare reimbursement rates for outpatient cryosurgery - APC 674

Hart
Saxner
Barcel
Kane

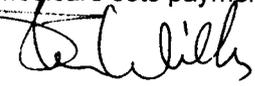
I am a cancer survivor giving credit to cryosurgery, done a little over a year ago, for my quick recovery and continued enjoyment of life with little disruption to my personal situation.

It has been brought to my attention that new proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006 apparently will not cover hospital costs for those procedures.

Because cryosurgery addressed my prostate cancer on an outpatient basis, being virtually non-invasive and with little side effects, I have been able to go on with my life as a financially productive member of our society, contributing to the economy, paying taxes, etc. without the "down time" of other types of procedures used with prostate cancer patients.

It would seem logical to me that your department should take all available steps to provide for the broad (even broader) availability of cryosurgery because of benefits not only to the patient but also to the public at large in minimizing loss of productivity by Americans who are otherwise willing and able to continue useful lives. I respectfully encourage you to take those steps by assuring that Medicare sets payment rates to cover a hospital's actual cost to perform cryosurgery.

Stan Wilkes
Attorney at Law
Arlington, Texas



Read by IFM
AUG 30 2005
Payment/Devices/Device Cat Barry Levi
APC/Gen Dana Buelley
Payment for D/B/R
gsk

GlaxoSmithKline

GlaxoSmithKline
Three Franklin Plaza
P.O. Box 13619
Philadelphia, PA
19101-3619
Tel. 215 751 4000
Fax. 215 751 3400
www.gsk.com

CC

Sabrina Ahmed
Chris Ritter
Rebecca Kane
Joan Sanson
Jim Hart
Carol Bazell

August 29, 2005

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

GSK appreciates the opportunity to comment on the proposed Hospital Outpatient Prospective Payment System (HOPPS) rule. Our comments focus on one aspect of the proposed rule – the reimbursement to hospitals for radiopharmaceuticals. GSK manufactures and markets one such product, the BEXXAR® Therapeutic Regimen, for the treatment of follicular non-Hodgkin's lymphoma.

GSK greatly appreciates the thoughtful approach taken by CMS regarding the reimbursement of radiopharmaceuticals. There are different types of radiopharmaceuticals, both therapeutic and diagnostic, and a variety of processes associated with preparing each product for patient use. The proposed rule would establish an interim approach to providing reimbursement for the provision of radiopharmaceuticals, including handling, distribution, storage and related costs of the products for FY 2006, while collecting information that can be used to establish a permanent solution in future years.

Support of Proposed Radiopharmaceutical HOPPS Reimbursement

GSK strongly supports CMS' interim solution and encourages its inclusion in the final rule. We also believe that CMS should clarify how that solution can be implemented by hospitals so that all hospitals have the opportunity to receive appropriate reimbursement for the provision of radiopharmaceuticals. It is especially important that hospital charges reflect the array of costs incurred when a radiopharmaceutical is used. Current hospital charge setting practices focus on charging for the product, without enough attention paid to the costs incurred to put the product in use.

The interim solution would request that each hospital report all their charges associated with each radiopharmaceutical claim, not just their charges for the radiopharmaceutical.

Fiscal intermediaries would then apply the hospital-wide cost to charge ratio for each hospital to determine an estimated cost, which would then be provided to the hospital in reimbursement for that claim.

The interim solution has a number of advantages:

- It provides maximum flexibility in providing reimbursement since radiopharmaceuticals may differ in how they are delivered and prepared.
- The reimbursement amount would be closer to actual acquisition and associated costs, if hospitals prepare accurate and complete claims.
- It provides a level playing field for companies that produce radiopharmaceuticals by allowing hospitals to choose the most appropriate therapy for patients without considering issues of differential reimbursement.
- Hospitals have some experience with this approach as it was used for pass-through devices and brachytherapy sources. That experience will make it easier for hospitals to become educated about implementing this proposal for radiopharmaceuticals.

Suggestions Regarding Implementation of Proposal

The advantages of this proposal will be realized if each hospital clearly understands how claims should be prepared. Because hospitals are, by nature, complex, it can be difficult to ensure that all personnel in each department of a hospital have all of the information that they need to facilitate the reporting of accurate charges and an appropriate claim. GSK believes that CMS should assist this process by

1. Providing further clarification in the final rule regarding exactly which cost to charge ratio would apply to each hospital.

Ideally, the final rule would include an appendix that would clearly specify the exact cost to charge ratio that would be applied to each hospital. This table can be formatted as follows (examples included):

| <u>Name of Hospital</u> | <u>Address of Hospital</u> | <u>Value of Cost to Charge Ratio</u> |
|-------------------------|---------------------------------|--------------------------------------|
| County General | 1 Main Street, Anytown, USA | 0.50 |
| Best Hospital Ctr. | 100 First Avenue, Big City, USA | 0.55 |

2. Providing a template that hospitals may use to prepare their claims for radiopharmaceutical, including handling and other costs.

A template would help ensure that all departments in each hospital understand the exact items that should be included in the claims for radiopharmaceuticals and would provide some guidance to hospitals as they determine their charges for each of those items, based on their actual costs and the applicable cost to charge ratio.

Ideally, the template would specify items of cost for hospitals who purchase radiopharmaceutical services from external radiopharmacies as well as for hospitals with in-house radiopharmacies. Examples of potential templates are presented in attachments A and B.

3. Provide contemporaneous instructions, either as a separate publication or as an appendix to the final rule that reflects the direction that will be given to fiscal intermediaries regarding the implementation of this structure.

GSK believes that these instructions could be a modification of current instructions for implementing the reimbursement for pass-through devices and brachytherapy sources. The contemporaneous publication of these instructions will assure CMS that the final rule is uniformly implemented.

4. Provide, in the final rule, an invitation for hospitals and other interested parties, including manufacturers to work together and with CMS to ensure smooth implementation.

Specific Issues with Regards to BEXXAR

Assuming that (1) the costs of the BEXXAR product, including the non-radioactive dose of BEXXAR, and associated product handling and product preparation costs are included in a hospital's claim and (2) CMS allows existing applicable product infusion codes to continue in the hospital outpatient setting, the proposal should appropriately provide Medicare reimbursement for BEXXAR in the hospital outpatient settings.

GSK is aware that the HCPCS coding panel is considering revisions to the existing product codes for the dosimetric and therapeutic doses of BEXXAR. Given the way that the product is manufactured, distributed and administered to patients, GSK is hopeful that the revised code descriptors will define both of the radioactive doses on a "per dose" basis. To our knowledge, however, the coding panel is not considering a product code for the non-radioactive doses of BEXXAR therapy.

To accompany the work of the HCSPCS coding panel regarding the radioactive components of BEXXAR, GSK suggests that G3001, currently applicable to both doses of the non radioactive component (tositumomab) and its administration, be amended to be applied to only the non radioactive component of the regimen. We recommend that hospitals be allowed to use 90784 (APC 359) for the administration of the non radioactive portion of BEXXAR. This would allow hospitals to identify the product accurately in their claims with a familiar product code and receive appropriate reimbursement for the infusion of the product

In addition, local carriers also use G3001, to process claims for BEXXAR in the free standing nuclear medicine radiation oncology facilities that provide BEXXAR therapy. GSK strongly urges CMS to retain G3001 as a product only code so that these facilities can continue to provide treatment to Medicare beneficiaries

Summary

In summary, GSK strongly supports CMS' approach for the interim rule for radiopharmaceutical reimbursement. Furthermore, we recommend that CMS provide guidance for hospital claims submission. Guidance will assure that CMS reimburses hospitals for their costs as accurately as possible. The implementation of this proposal assures that hospitals have the opportunity to claim and receive appropriate reimbursement for most of their costs associated with providing radiopharmaceuticals. Further, the reimbursement structure is flexible enough to accommodate the variability in radiopharmaceutical products and associated services. Finally, the implementation of this proposal will eliminate the need for additional codes for compounding certain products such as BEXXAR, which would otherwise be necessary to insure that hospitals received sufficient reimbursement for important, medically necessary radio diagnostic and therapeutic agents.

Thank you again for this opportunity to comment on this proposed rule. Please feel free to contact us with any questions or requests for additional information.

Sincerely,



Barry Gershon
Director, Public Policy and Advocacy

Attachment A
Potential Template for Calculating Appropriate Radiopharmaceutical Claims for Hospitals Using External Radiopharmacies

| | <i>Item of Cost</i> | <i>Amount of Cost</i> |
|----------|---|--|
| | (Please insert costs for each of these categories if applicable for the specific claim) | |
| A | <p>Product – cost of purchasing all products associated with the radiopharmaceutical claim that do not have a separate payment associated with a HCPCS code. This would include radioactive and non-radioactive products that are required for the diagnostic or therapeutic procedure as well as other supplies required to complete the procedures¹. Each product element can be listed separately, along with the associated cost.</p> <p>Hospitals using an external radiopharmacy typically will purchase the actual product from the external radiopharmacy, who will invoice the hospital. There may be cases, however, where the hospital purchases the product from other sources (e.g., manufacturer) and then arranges for the external radiopharmacy to provide necessary services. Both the cost of the product and the cost of additional services would be included.</p> | |
| B | <p>Radiopharmacy Services – the exact services provided will vary with each radiopharmaceutical. The costs of these services may be separate line items on the invoice from the radiopharmacy or may be included in the cost of acquiring the product from the radiopharmacy. Specific services include (but are not limited to)</p> <p>Dose preparation Handling Distribution</p> | |
| C | <p>Other Hospital Costs -- Hospitals also incur costs in providing radiopharmaceuticals. Costs that are not included in other associated procedure codes (e.g, administration) should be listed. Examples include</p> <p>Waste disposal Storage Room preparation</p> | |
| D | Total Costs | <i>(sum of A,B and C)</i> |
| E | Hospital Cost to Charge Ratio | <i>(from CMS table in rule appendix)</i> |
| F | Calculated Charge included in Claim | <i>(D÷E)</i> |

¹ Using BEXXAR as an example, the product cost would include the purchase cost of two non-radioactive doses, a dosimetric dose containing low levels of radiation, and a therapeutic dose with patient specific levels of radiation. We would also recommend that infusion of the non-radioactive doses be reimbursed using code 90784 (APC 359)

Attachment B
 Potential Template for Calculating Appropriate Radiopharmaceutical Claims for
 Hospitals With In-House Radiopharmacies

| | <i>Item of Cost</i> | <i>Amount of Cost</i> |
|----------|---|----------------------------|
| | (Please insert costs for each of these categories if applicable for the specific claim) | |
| A | <p><u>Product</u> – cost of purchasing all products associated with the radiopharmaceutical claim that do not have a separate payment associated with a HCPCS code. This would include radioactive and non-radioactive products that are required for the diagnostic or therapeutic procedure as well as other supplies required to complete the procedure². Each product element can be listed separately, along with the associated cost.</p> <p>Hospitals with an in-house radiopharmacy will typically purchase the product from the manufacturer or other sources.</p> | |
| B | <p><u>Radiopharmacy Services</u> – the exact services provided will vary with each radiopharmaceutical. The cost of these services will be identified in the hospital’s internal accounting system.</p> <p>Dose preparation Handling Distribution</p> | |
| C | <p><u>Other Hospital Costs</u> -- Hospitals also incur costs in providing radiopharmaceuticals. Costs that are not included in other associated procedure codes (e.g, administration) should be listed. Examples include</p> <p>Waste disposal Storage Room preparation</p> | |
| D | <u>Total Costs</u> | <i>(sum of A, B and C)</i> |
| E | <u>Hospital Cost to Charge Ratio</u> | <i>(from appendix)</i> |
| F | <u>Calculated Charge included in Claim</u> | <i>(D÷E)</i> |

² Using BEXXAR as an example, the product cost would include the purchase cost of two non-radioactive doses, a dosimetric dose containing low levels of radiation, and a therapeutic dose with patient specific levels of radiation. We would also recommend that infusion of the non-radioactive doses be reimbursed using code 90784 (APC 359).

CRYO

Dana Buckley
Rebecca Kane
Joan Sano
Jim Hurst
Carol Buzell

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AUG 6, 05

AUG 15, 05

TO: HARRIS Mc CLELLAN, M.D., PH.D.

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES ET AL.

ATTN CMS-1501-P

PO BOX 8016

BALTIMORE, MD 21244-8018

RE: CMS-1501-P: MEDICARE PROGRAM; CHANGES FOR
SYSTEM FOR YEAR 2006 ANYMORE RATES AND RPE 679.
CRYO SURGERY OF THE PROSTATE

TO: DR McCLELLAN:

- AS A PROSTATE SURGERY "SURVIVOR" (9 YEARS).
I AM VERY PLEASED WITH MY DECISION TO HAVE
CRYO SURGERY OF THE PROSTATE
- THIS SURGERY HAS LEFT ME NORMAL IN ALL
RESPECTS, I.E. "SEXUAL CAPABILITY" ETC. AND
RAPID RECOVERY
- IN WRITING THIS LETTER I AM RESPONDING TO A
NOTICE IN THE JULY FEDERAL REGISTER THAT
INFORMED ME OF A NEW PROPOSED RATE THAT WILL
NOT PERMIT HOSPITALS TO RECOVER COSTS &
THIS WILL MEAN FEWER HOSPITALS WILL OFFER IT.
- MY EXPERIENCE WITH CRYO SURGERY HAS SAVED
ME RECOVERY COSTS & TIME TO RETURN TO
NORMALACY, I.E. WITHIN A FEW WEEKS I WAS
ABLE TO BE "NORMAL" PHYSICALLY & SEXUALLY
WHICH RESULTED FROM THE SHORT (VERY SHORT)
PHYSICAL RECOVERY TIME, INCLUDING INSURANCE
COSTS!
- THANK YOU!

J. R. BAKER JRB



Dana burley
Rebecca Kane
Sean Sanow
Jim Hartz
Carol Bazell

35

Knowledge.
Assistance.
Hope.™

July 28, 2005

Dear Friend,

We desperately need your help! Medicare's reimbursement rates to hospitals for outpatient cryosurgery are about to drop. This means fewer doctors will prescribe cryo, and fewer patients will have access to it. We know that when patients make their voices heard, it can influence the outcome. However, we cannot send out a simple form letter for each person to sign, as Medicare treats identical letters as one.

Would you be willing to draft a letter to the Administrator of Medicare, as well as, send a copy to Endocare? It has to be in your own words, but we have provided guidelines as well as 3 stamped, addressed envelopes the (original to Medicare, a copy to a staff person at Medicare that has been named as the contact person for this issue, and Mary Syiek, the staff person at Endocare coordinating this project).

Note that this can also be done by internet. The electronic address as well as the postal addresses are provided on the following page. Please Note: Individual letters—not form letters—have the most impact. On the following page is sample language to use or modify to explain your particular situation.

Your testimony matters. If we can barrage CMS, we can make a difference! Thank you for considering this request.

*On behalf of CryocarePCA and Endocare,
Karen Barrie and Janet Johnson*

Toll-Free Patient Support Line

(877) PCA-CRYO
(877-722-2796)

www.cryocarepca.org

Aug. 24 - 2005

To: Those who need to be Informed.

Subject: Cryocare - APC-674: Cryosurgery of Prostate

To Those with This Cancer This may be
The informed Treatment. It is less invasive
And more successful than other treatments
It can be used more than once, others can
Not.

I had The procedure and it worked, it
was my second go round. (Seeding of Prostate First)
Clear for two years 3 to go. Hospital cost
Need to be covered and more should
use this program if it was better known by Men.

Please Adjust proposed payment Rate upwards
For APC-674

This A Real Program that works - Give
Men A Chance and A choice.

JEFF CRAIG - Age 61
905 San Juan Ave
Ball Head City, AZ
85112

Copy to
that
Endorsement

APC/674
Cryo

Dana Burkly

Rebecca Kme

Joan Sano

Jim Hart

Carol Buzell

Halt Howe

797 Maplewood Dr

Xeller, Tx 76248

36

Mark B. Mc Clellan, M.D., Ph.D.

Administrator

Centers for Medicare + Medicaid Services

Dept. of Health + Human Services

Attn: CMS-1501-P

P.O. Box 8016

Baltimore, Md. 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. Mc Clellan:

Cryosurgery procedure is one of the best surgery to kill cancer. Recovery time is shorter than the other surgery. The surgery is done as out-patient and can be repeated if necessary.

From experience, I had cancer and had cryosurgery. Except for some complications, it is faster recovery and did clear me of the cancer. A relative had the pellets done several years ago and is still having problems.

According to the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006. I have been informed that the new proposed rate will not cover what the hospital costs are.

I would like to tell Medicare that I do want more access, more hospitals to offer it. The inadequate payment rate for 2006 will mean there will be fewer hospitals offering it.

I urge Medicare to adjust the proposed payment rate for APC 674 upward to reflect a hospital actual to perform the procedure.

The reason I chose prostate cryosurgery is because of less recovery time and the possibility of having to have the surgery redone. Also after this surgery I can still have a normal sex life and do not have to wear depends.

cc: James L. Hart CMS
Mary Dyck, Endocare
Sincerely,
Stall Howe

APC/Gen
Cryo

Dana burley
Rebecca Kane
Joan Sanson
Jim Harz
Carol Bazell

37

MARC A. MELSER, M.D., P.L.

3280 Tamiami Trail, Suite #27
Port Charlotte, FL 33952
Ph: (941)-235-7281

Diplomate American Board of Urology
Fellow, American College of Surgeons
Fax: (941)-235-0663

August 17, 2005

Center for Medicare & Medicaid Services
Dept. of Health & Human Services
Attention: CMS-1501-P
P. O. Box 8016
Baltimore, MD 21244-8018

RE: APC 674, Prostate Cryoablation

To Whom It May Concern:

I am a solo practitioner urologist in Port Charlotte, Florida. I have been here eleven years. I am writing to address the issue of the proposed hospital outpatient payment rates for prostate cryosurgery beginning in 2006. This notice appeared in the July 2005 Federal Register.

As you know, the Medicare proposed payment rate for APC 674, Prostate Cryoablation, is set at \$5,659.13. I can safely say that this would not cover the costs that my hospital incurs in order for me to perform this procedure. The hospital's expenses are approximately \$9,000.00.

I have been performing cryoablation of the prostate for over four years. During this time, I have treated over 70 men. I am happy to say that the large majority of them have tolerated the procedure very well. Furthermore, their clinical response, based on PSA, has also been quite favorable.

I am in a community that has three hospitals. Only one of them has allowed me to perform prostate cryosurgery. The other two denied my request for the procedure, primarily based on costs. Should the proposed payment rate stand, I am afraid the one hospital that allows me to perform cryosurgery will likely put the brakes on. I would hate to give up this procedure, and thereby deny my patients access to it based on costs.

I would like to encourage Medicare to adjust the proposed payment rate for APC 674 upward to reflect the hospital's actual cost to perform the procedure. I know there are studies done that show

Continued . . .

Center for Medicare & Medicaid Services
RE: APC 674
August 17, 2005
Page Two

cryosurgery is the most cost effective treatment for localized prostate cancer.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Marc A. Meiser". The signature is written in a cursive style with a large initial "M".

Marc A. Meiser, M.D., FACS

MAM/11

cc: James L. Hart
Mary Cyiek, Endocare Inc.

38 NPT DIB/R Sabrina Ahmed



Rebecca Kone
Joan Sano
Jim Hart
Carol Bazell

August 20, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attention: CMS – 1505 – P
Post Office Box 8016
Baltimore, Maryland 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS – 1505 – P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Dr. McClellan:

I am an Associate Professor in the Department of Dermatology and Cutaneous Surgery at the University of Miami School of Medicine and director of the University of Miami/Cedars Medical Center Wound Center in Miami, Florida. In that latter capacity I see a significant number of chronic wounds. As part of my treatment protocol we employ evidenced based therapies to care for our patients and as such I am extremely concerned with the proposed 2006 Medicare Hospital Outpatient payment rates for advanced wound products – Dermagraft [C 9201] and Apligraf [C 1305]. I therefore wish to comment on the Centers for Medicare and Medicaid Services [CMS] Proposed Rule published in the July 25, 2005, *Federal Register* titled, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule."

The 2 products impacted by the proposed rule are Dermagraft and Apligraf, unique living human tissue substitutes used to treat chronic wounds. Based on clinical evidence, they are FDA approved and in use for over a half decade. These products have improved the quality of life of thousands of Medicare beneficiaries who suffer from chronic leg and foot ulcers. As demonstrated in pivotal trials, many Medicare patients would have likely undergone amputations without the benefits of these products. Having extensive experience in many wound healing modalities, some of which scientific rigor, the ability to use these proven products severely limits, practicing physicians ability to deal with difficult chronic wounds.

Since 2002, both Apligraf and Dermagraft were paid as biologics under the Hospital Outpatient transitional pass through program. Additionally, both products have been paid for as sole-source biologics in 2004 and 2005 since the passage of the Medicare prescription Drug, Improvement and Modernization Act of 2003. In the proposed 2006 Medicare Hospital Outpatient Rule, CMS proposed to reimburse specified covered outpatient drugs at average sales price [ASP] plus six percent for the acquisition cost of the drug.

Department of Dermatology and Cutaneous Surgery
P.O. Box 016250 (R-250)
Miami, Florida 33101
305-243-6734
Fax: 305-243-6191
Location: 1600 N.W. 10th Avenue, RMSB 2023A

For some reason however, in the proposed rule both Dermagraft and Apligraf were incorrectly paid based on 2004 claims data instead of payment based on ASP. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

Medicare Hospital Outpatient

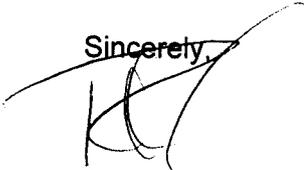
| | 2005 – Actual | 2006 – Proposed |
|---------------------|---------------|-----------------|
| Dermagraft [C 9201] | \$ 529.54 | \$ 368.32 |
| Apligraf [C 1305] | \$ 1,130.88 | \$ 766.84 |

Dermagraft and Apligraf have been reimbursed in the hospital outpatient setting as specified covered outpatient drugs and this payment methodology should continue in 2006 like other covered outpatient drugs. Without this, Medicare beneficiary access to these advance treatment options is jeopardized by the payment rates in the 2006 Medicare proposed rule.

I request that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule.

Thank you in advance for your immediate attention to this issue.

Sincerely,



Robert S. Kirsner, M.D., PhD
Department of Dermatology and Cutaneous Surgery
Department of Epidemiology and Public Health
University of Miami Miller School of Medicine

cc: Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Herb.Kuhn@CMS.HHS.gov

NT
Payment Device/Device Cost
Demand form D/B/R

Debbie Hunter 39
Barry Levi
Sabrina Ahmad
Kane
Sanaw
Hart
Bazell

August 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS - 1501 - P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Device-Dependent APCs, file code CMS-1501-P, APC 0039 & APC 0040

To Whom It May Concern at CMS:

Medtronic Neurological submitted an application for new technology add-on payments for its Restore® Rechargeable Implantable Neurostimulator for the treatment of chronic intractable pain. Medtronic Neurological states "the current technology standard for neurostimulators utilize internal sealed batteries with finite lives, and requires replacement when their power has been completely discharged." The applicant also states its "rechargeable technology represents a significant clinical improvement because patients can use any power settings that are necessary to achieve pain relief with less concern for battery depletion and subsequent battery replacement." Rechargeable batteries add no improvement in efficacy for the patient (high power requirements can currently be met with available radio frequency (RF) devices), add increased compliance requirements by the patient (versus non-rechargeable stimulators), and do not ensure fewer surgeries for the patient. In fact, the Restore® device may result in MORE surgeries because of the properties of the energy source in the Restore® device.

Ex-plant is a real concern for patients because Medtronic Neurological utilizes a conventional lithium ion battery in its Restore® device. All rechargeable batteries, lithium ion or others, naturally self-discharge (lose charge) while not in use if stored without re-charging. When stored for prolonged periods at a voltage less than 1.0V, a conventional lithium ion battery shows significant degrades in performance and reduced overall storage capacity. If a conventional lithium ion battery continues to operate below 2.5 V and is not recharged, it will naturally self-discharge to below 1.0V in less than six months. Restore's® battery possesses no deep discharge storage capability (the ability to go without use when at very low charge levels) and can be rendered useless if its charge reaches zero volts and cannot be revived. The conventional battery, while rechargeable, would have to be explanted if the charge fell to 0 V. This state could also happen if the batteries were left at a very low charge without recharging (can even happen if the device is not used). Discharging causes the copper chemistry in the battery to degrade significantly and can cause the battery to short.¹ These problems are not remedied even

¹ Hossain, Sohrab, Yong-Kyu Kim, Yousry Saleh, and Raouf Loutfy. "Comparative studies of MCMB and C---C composite as anodes for lithium-ion battery systems" Journal of Power Sources 114 (2003): 264-276.

after the battery has been fully recharged.² The performance and safety of the cell may be compromised.³ Additionally, the method of recharging a lithium ion battery can be of major influence to how long the battery lasts and how well it performs. While charging, if the charge is not adequately monitored to ensure charge does not get above C/2 (half the capacity of battery), the battery could enter into an overcharged state leading to thermal runaway (a state in which voltage is significantly high, causing some of the chemicals within the battery to breakdown and evolve gas, leading to self sustaining exothermic reactions. e.g. overheating) rendering the battery and implant device useless.⁴

In conclusion, there are no additional technological advantages associated with the rechargeable device and if anything, the conventional lithium battery, if not charged properly, could be a costly disadvantage. RF devices can deliver equivalent amounts of power as a rechargeable lithium ion battery and have no implanted power source (no risk of ex-plant). Additionally, there are many uncertainties related to the performance of lithium ion rechargeable batteries for implantable neurostimulators; the studies referenced in this letter show that the risk of ex-plant with rechargeable batteries is extremely high if exact levels of charge are not maintained, and the device's ability to perform can be severely degraded if precise charge levels are not maintained. An add-on payment is not warranted for this device as no new technological advantages have been proven and no increase in patient care can be supported.

Regards,


Tim Griffin

² Hossain, Sohrab, Yousry Saleh and Raouf Loutfy. "Carbon-carbon composite as anodes for lithium-ion battery systems" Journal of Power Sources 96 (2001): 5-13.

³ Carter, Boyd, James Matsumoto, Alonzo Prater, and Dennis Smith. "Lithium Battery Performance and Charge Control" Energy Conversion Engineering Conference, 1996. IECEC 96. Proceedings of the 31st Intersociety 1 (1996): 363-368.

⁴ Ohsaki, Takahisa *et al.* "Overcharge reaction of lithium-ion batteries." Journal of Power Sources (2005):2

40 APC/D-D

Anita Heggestad
Rebecca Kane
Joan Sanow
Jim Hart
Carol Buzell



14998 W. 6th Ave., Bldg E-700
Golden, CO 80401

August 19, 2005

The Honorable Mark McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates
Specifically: Addendum B. Payment Status by HCPCS Code and Related Information – CY 2006

Dear Dr. McClellan:

I am pleased to submit the following comments on behalf of Denver Biomedical, Inc. regarding the above-referenced "proposed rule." Denver Biomedical, a medical device manufacturer and marketer, is a world leader in management of refractive pleural effusions.

Denver Biomedical, Inc. welcomes the opportunity to work with you and the Centers for Medicare and Medicaid Services (CMS) in refining reimbursement policies for the Outpatient Prospective Payment System (OPPS) in 2006 and subsequent years.

We appreciate the opportunity to comment on the CY 2006 Outpatient PPS proposed rule published on July 25, 2005, specifically regarding the proposed assignment of CPT 32019 to APC 0070 (Thoracentesis/Lavage Procedures). We respectfully disagree with the proposed APC assignment. We feel the proposed assignment of CPT 32019 to APC 0070 should be reconsidered for the following reasons.

1. CPT 32019 is not comparable clinically and with respect to resource use with the other services and items within APC 0070.
 - a. From a clinical perspective, while insertion of the tunneled pleural catheter is often compared to insertion of a chest tube (CPT 32020) it is not a comparable procedure.
 - **Short-term vs. long-term use:** The insertion of a chest tube (CPT 32020) is considered for short-term use only (less than 7 days) whereas, the subcutaneous tunneling of the pleural catheter is intended to accommodate the long-term drainage of the effusion (typically in excess of 1 month).
 - **Single incision vs. multiple incisions and tunneling:** Unlike insertion of chest tube (CPT 32020), which involves single chest wall puncture and insertion of chest tube into the pleural space for drainage, insertion of an indwelling tunneled pleural catheter with cuff (CPT 32019) requires multiple incisions and subcutaneous tunneling of the indwelling pleural catheter through multiple incisions in the thorax into the pleural space.

- **Design difference:** The intended use for long-term drainage requires a catheter that is up to the rigor of long-term use and multiple draining. This intended use and design difference is diametrically different than the use and catheter design for short-term use.

- b. From a resource use perspective, CPT 32019 is not comparable with the majority of procedures listed in the proposed APC 0070 configuration. Insertion of a chest tube (CPT 32020) and other similar procedures are often done bedside at minimal cost to the hospital. In contrast, placement of an indwelling tunneled pleural catheter requires the use of a procedure room. Utilization of a procedure room adds substantial cost to the hospital in terms of resource utilization. In addition to the cost associated with use of the procedure room and an indwelling pleural catheter with cuff there are additional expenses incurred by the hospital such as a catheter introducer, pleural catheter-specific vacuum drainage bottle, anesthetic, etc.

A look at the current and proposed practice expense relative value units for the Physician Fee Schedules shows significantly higher RVUs for insertion of an indwelling tunneled pleural catheter with cuff compared to the practice expense RVUs for all of the procedures listed in APC 0070 except for CPT 32201 (Pneumonostomy; with percutaneous drainage of abscess or cyst).

From a resource and clinical perspective, we feel placement of the tunneled pleural catheter is most analogous to placement of a tunneled peritoneal catheter (CPT 49421-Insertion of intraperitoneal cannula or catheter for drainage or dialysis; permanent).

2. CPT 32019 is a device dependent procedure and costs/charges associated with the device (pleural catheter) should be incorporated when considering the APC assignment. We recommend reassigning this procedure to a device dependent APC such as 0652 (Insertion of Intraperitoneal Catheters). Assigning this procedure to a device dependent APC will ensure CMS is able to capture the true cost to the hospital for providing this service
3. APC 0070 (Thoracentesis/Lavage Procedures) appears to be in violation of the 2 times rule "...Services and items within an APC group cannot be considered comparable with respect to the use of resources if the highest median...for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or services within the same APC group"¹). The median cost for hospital outpatient services obtained from the CMS website <http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp> show the lowest median cost as \$163.57 and the highest median cost as \$3,997.68. According to Table 8 (Proposed APC Exceptions to the 2 Times Rule for CY 2006) APC 0070 is not an APC excepted from the 2 times rule².

We suggest it is more appropriate to move CPT 32019 (insertion of indwelling pleural catheter) into APC 0652 (Insertion of Intraperitoneal Catheters) where it is more comparable clinically and with respect to resource use than the APC it is currently assigned to.

¹ Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, I (A). 70 Federal Register 42677 (July 25, 2005).

² Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, III (B) (2). 70 Federal Register 42705 (July 25, 2005).

Mark McClellan, M.D.
August 19, 2005
Page 3

A high percentage of patients with refractive pleural effusions for which placement of an indwelling pleural catheter is an appropriate treatment modality are Medicare patients. Alternative treatments to this procedure are thoracoscopy with talc poudrage and chest tube pleurodesis, procedures, which usually require inpatient stays of 3 to 7 days. Keeping CPT 32019 (insertion of indwelling pleural catheter with cuff) in APC 0070 may deny Medicare patients access to this technology because hospitals will have no financial incentive to provide this service, despite the fact it improves patient care and reduces Medicare expenditures. If hospitals decide to not provide this service, it will force physicians to utilize alternative treatments, which will cost the patient and the Medicare program more money. We hope CMS will reconsider the APC assignment.

Thank you for taking the time to consider my comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Bonnie Vivian", written in a cursive style.

Bonnie Vivian
President and CEO

41

DLPadget Enterprises, Inc.

*Independence and Excellence
In Advocacy and Education*

P.O. Box 119
Simpsonville, KY 40067-0119
502/722-8873
502/722-5166 (Fax)

HCPCS - DIB/B
APC/Gm
APC/weights

Dennis L. Padget, MBA, CPA, FHFMA
President
ThePathAdvocate@bellsouth.net (email)
Sabrina Ahmed
Anita Heygster

Ref: Comment_ProposedRule_2006MCareOPPS_Filed082505.doc

25 August 2005

Centers for Medicare & Medicaid Services
U.S. Dept. of Health and Human Services
Attn: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8016

Rebecca Kane
Joan Sanow
Jim Haret
Carol Bazell

Re: File Code CMS-1501-P
Medicare program; proposed changes to the hospital outpatient
prospective payment system and calendar year 2006 payment rates

Dear Sir or Madam:

This letter comments on the proposed rule by the U.S. Dept. of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) published in the 25 July 2005 *Federal Register* entitled "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule" (file code CMS-1501-P). I respectfully ask that you consider the comments and suggestions below when developing the final rule.

1. Added Action Needed on Codes D0472-D0999: HCPCS Level II codes D0472-D0999 are classified as dental procedures, even though they describe basic anatomic pathology procedures such as microscopic examination of tissue slides and cytology smears, decalcifications, and special stains. These items fundamentally duplicate procedures described by CPT codes in the 88104-88199 and 88300-88399 ranges.

Correspondence with CMS officials the past eight months indicate codes D0472-D0999 shouldn't be billed by anyone—not a pathologist, a hospital lab, nor an independent lab. Instead, providers should use the appropriate CPT code to report the anatomic pathology procedure that's been rendered, regardless of the type of surgery—dental vs. any other—that generated the specimen. For example, on Jan. 24, 2005 a CMS official wrote to me saying in pertinent part: "[Pathologists] should be instructed to bill from the CPT coding book for pathology services regardless of the 'type' of specimen [that is, dental vs. other].... The D-codes you referenced [D0472-D0999] are not for Medicare billing purposes." Then on Feb. 9, 2005, the same CMS official said via email: "I know of no example whereas a hospital would use a D-code [such as D0472-D0999] to bill for technical [histopathology or cytopathology] services."

While I fully concur that the overall intent of the Medicare program is that codes D0472-D0999 aren't billable by providers of pathology services (regardless of specialty), my considerable research has uncovered no law, regulation, or program instruction that actually prohibits

Attn: CMS-1501-P
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providers from billing those codes or forbids fiscal intermediaries from making payment on those codes. In fact, CMS via the OPSS fee schedule in calendar year 2005 and earlier years allowed intermediaries to pay on six of the codes in that range; for example, see D0472-D0474, D0480 and D0502, each with status indicator S (significant service that's separately paid under OPSS via separate APC rate).

Attachment 1 chronicles the correspondence I've had with CMS the past eight months about these HCPCS Level II codes. It's always confusing when two different codes or sets of codes describe essentially the same medical services. However, of greater concern is the potential for abuse of the Medicare program, plus Medicaid agencies and private insurers who adopt the annual Medicare hospital outpatient fee schedule for their separate purposes. In particular, although in the past CMS reports receiving only a rare claim showing a code in the D0472-D0999 range, all that may change if providers figure out they can get a great deal more money from those codes compared to the generally accepted 88104-88199 and 88300-88399 CPT codes. It would be a shame for that to happen, especially since abuse prevention is so straightforward and inexpensive in this instance.

I note CMS has already taken the initiative via the 2006 OPSS proposed rule to prevent abuse by changing the status indicator for all codes in the D0472-D0999 range to B, meaning that they'll no longer be recognized for payment under OPSS. I applaud this action, and I fully concur with the wisdom and appropriateness of it. The final rule should precisely mirror the proposed rule in these regards.

Notwithstanding the status indicator change initiative, I respectfully suggest CMS take one other action in the final rule that's not reflected in the proposed rule. In particular, CMS should clearly state in the final rule why the cited codes have been assigned status indicator B starting in 2006, and providers should be instructed to report the applicable CPT code instead.

Additionally, the coverage issues and claims processing manuals in the Internet-only manual system should be updated not later than 1 Jan. 2005 by formal change request to declare codes D0472-D0999 off-limits to billing by *all* providers (including, without limit, oral surgeons, oral pathologists, dental offices, hospitals, and independent labs), regardless of circumstances or whether the provider is billing the physician professional component, the facility technical component, or the total service (professional and technical components combined). They should be advised to report the CPT code (88104-88199 or 88300-88399) that accurately describes the medical service that's been rendered. Carriers and fiscal intermediaries should be instructed to summarily deny any claim for a D0472-D0999 service, regardless of the provider, the specialty of the provider, the diagnosis, or any other factor.

2. Reclassify Code 86586 to Clinical Lab Fee Schedule: Code 86586 in *CPT 2005* describes *Unlisted antigen, each*. An appropriate use of this code is as an "each marker, not elsewhere specified" companion to immunology "total count" codes 86064, 86359, 86379 and 86587. (The B-cell, natural killer cell, and stem cell items are being recodified in CPT for 2006.) For example, if a particular immunodeficiency panel used the CD3, CD19 and CD28 markers, the American Medical Association says that'd be coded 86359, 86064 and 86586 respectively. CMS via the National Correct Coding Initiative (NCCI), with the AMA concurring, prohibits commingling the immunology "total count" codes with flow cytometry phenotyping codes 88184-88185 for the same panel.

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The problem is code 86586 doesn't appear in Medicare's clinical lab fee schedule (CLFS); it exists only in the OPPS fee schedule. Further, in the latter schedule, the code is part of the 86485 *Skin test* family: It doesn't belong there according to the American Medical Association, because 86586 is a standalone code separate and apart from all other codes.

This confusion over the proper placement of code 86586 is creating payment issues for hospital labs serving nonhospital patients and for independent labs. A more thorough analysis of the problem is set forth in Attachment 2, which is extracted from my 18 July 2005 oral testimony and written comments delivered at the CMS public meeting regarding the 2006 Medicare clinical lab fee schedule.

I respectfully ask CMS to change the status indicator for code 86586 in the OPPS final rule for 2006. The proper payment status indicator will be A, meaning, in this instance, that code 86586 is paid via the Medicare clinical lab fee schedule, not the OPPS. This request is predicated on the understanding that CMS will add code 86586 to the Medicare clinical lab fee schedule for 2006, as I asked be done during my 18 July 2005 testimony.

3. Physician Only Codes 80500-80502 and 88187-88189: Codes 80500-80502 and 88187-88189 are defined in all Medicare sources other than OPPS as physician laboratory services that don't have a recognized facility technical component; in other words, they're treated elsewhere (for example, the Medicare clinical lab fee schedule and the Medicare physician fee schedule) as physician professional (only) services that can't be billed other than to a Medicare Part B carrier using Form CMS-1500.

Codes 80500 and 80502 describe limited and comprehensive clinical pathology consultations respectively. As explained in the latest NCCI manual, the codes "indicate that a pathologist has reviewed and interpreted, with a subsequent written report, a clinical pathology test." The clinical test that's interpreted by the pathologist is billed by the laboratory using the appropriate 80048-87999 code, and rarely is any additional workup by a laboratory technologist needed before the pathologist conducts his or her examination that leads to the test's interpretation. The pathologist often enters the interpretation directly into the laboratory information system, in an interpretation field designed for that purpose. Neither a laboratory technologist nor a clinical laboratory scientist (Ph.D.) can render a medical consultation due to application of state law and pertinent provisions of the Social Security Act.

Codes 88187-88189 describe the interpretation and report on flow cytometry phenotyping panels of increasing size. The codes were first introduced in *CPT 2005*, replacing code 88180. Under the overall change in flow cytometry phenotyping coding implemented at the beginning of 2005, two codes now describe the technical aspects of the service (see 88184-88185), and one code in the range 88187-88189 is reported by the pathologist for the professional component (i.e., the interpretation). Neither the AMA nor CMS via the Medicare physician fee schedule makes provision for a hospital lab to claim some sort of technical component payment by reporting code 88187, 88188 or 88189; instead, the lab is to report codes 88184 and 88185. Neither a laboratory technologist nor a clinical laboratory scientist (Ph.D.) can bill an interpretation of a flow cytometry test due to application of the Social Security Act, nor can another entity bill on behalf of a laboratory technologist or Ph.D.

To avoid confusion and/or program abuse, I respectfully encourage CMS to change the status indicator of codes 80500-80502 and 88187-88189 per Addendum B in the 2006 OPPS final rule.

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Specifically, the status indicator should be M, referring to an item or service that's not billable to a fiscal intermediary, nor payable under the OPSS. This is appropriate because the cited codes should only be paid by a Medicare Part B carrier based on receipt of a valid Form CMS-1500 claim from an authorized provider (e.g., a physician or an independent lab).

* * * * *

I appreciate your attention to and consideration of the preceding comments and suggestions. Please call with questions or for added information on any topic addressed herein. Thank you.

Very truly yours,



Dennis L. Padget, MBA, CPA, FHFMA
President

Tissue Pathology and Cytology Level II HCPCS D-Codes (Dentistry Section)

From: Heygster, Anita M. (CMS) [mailto:Anita.Heygster@cms.hhs.gov]
Sent: Thursday, June 09, 2005 2:42 PM
To: ThePathAdvocate
Cc: Menas, James P. (CMS); Lutz, Barbara A. (CMS); Sanow, Joan H. (CMS); Mason-Wonsley, Marsha M. (CMS)
Subject: RE: HCPCS D-Codes with Pathology Impact

We have considered your comments in the context of the forthcoming 2006 OPPS NPRM. When it is issued, you may want to review it and reply during the public comment period.

I can tell you, however, that I looked up the frequency of these codes in the claims data. In the data we used from over 4500 hospitals to set the 2005 OPPS rates, only 2 units of D0999 were billed and paid. None of the other codes you list were billed in the claims data for these hospitals in 2003.

In the 2004 claims data, also from over 4500 hospitals, only 3 units of D0999 were billed and paid. Again none of the other codes you list were billed and paid.

D0999 is the unspecified dental code and hence there is no way of knowing if the services furnished were comparable to any of the other codes you list.

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Thursday, June 09, 2005 9:37 AM
To: 'AHeygster@cms.hhs.gov'
Cc: Jim Menas; 'BLutz@cms.hhs.gov'
Subject: HCPCS D-Codes with Pathology Impact

Ms. Anita Heygster
Centers for Medicare & Medicaid Services

Dear Ms. Heygster:

I'm curious as to the status of the HCPCS Level II D-code issue described in detail below. Would you mind giving me a brief status report? Are these codes likely to be formally "outlawed" for billing by hospitals near-term? If so, do you have an idea when the announcement will be made?

Thank you for your kind attention.

Sincerely,
Dennis Padget
DLPadget Enterprises, Inc.
Simpsonville, Ky.
502/722-8873

Attachment 1

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

From: Anita Heygster [mailto:AHeygster@cms.hhs.gov]
Sent: Thursday, March 10, 2005 5:12 PM
To: thepathadvocate@bellsouth.net
Cc: DONALD THOMPSON; James Menas
Subject: We are looking at the information you furnished regarding the dental codes and CPT codes with regard

We are looking at the information you furnished regarding the dental codes and CPT codes with regard to whether to change the payment status of these codes. Thanks for furnishing it.

Original Message

Dear Jim:

Thank you for getting back to me on this. Coincidentally, I spoke with Ms. Barbara Lutz a little earlier this afternoon about this issue, because I thought you might be “snowed under” with other things at the moment.

The Level II HCPCS codes in question are D0472, D0473, D0474, D0480 and D0502. (There are 10 additional codes between D0474 and D0502, but all have a status indicator of B—not paid under OPSS—in the 2005 OPSS APC fee schedule, so they’re not of particular concern.) These five codes have a status indicator of S in the 2005 OPSS APC fee schedule, meaning that they’re “paid under OPSS; separate APC payment.” Each crosswalks to APC 330 (Dental Procedure), which has a payment rate of \$801. The counterpart CPT codes (e.g., 88300, 88305, 88307, 88104) pay \$25-\$40 in round numbers per the 2005 APC fee schedule. A year-by-year comparison is attached as an Excel file.

I’ve talked to Ms. Marsha Mason-Wonsley about these D-codes, and she assures me it’s CMS’s intent that a hospital shouldn’t use them. I firmly believe Ms. Mason-Wonsley is accurately telling me CMS’s intent, but I can’t find where that policy is communicated anywhere that would make a difference. In other words, if I’m a hospital looking to code a biopsy from the mouth (oral biopsy), what’s to stop me from reporting D0473 and getting \$801 from Medicare instead of 88305 and getting \$25? What I’m saying is, beyond what Ms. Mason-Wonsley has told *me* via email, there’s nothing out there in a CMS policy manual, NCCI edict, etc. that tells me I can’t use D0473 instead of 88305.

There’s nothing special about oral biopsies that they should receive any different technical or professional payment than any other biopsy. The ADA says these D-codes exist so oral pathologists (yes, there is such a specialty!) will have them for use in billing their services. But skin pathologists (dermatopathologists), GI pathologists, etc. don’t get paid more for their biopsies, so why should an oral pathologist be paid more? Similarly, why should a hospital or other lab get paid more for processing an oral biopsy vs. any other biopsy?

I think what’s happened here is that a few dental codes—which CMS is bound to include in HCPCS by contract with the ADA—that fundamentally duplicate some pathology/lab service CPT codes have simply slipped through and become priced and payable by oversight. Nonetheless, I have to say it’s really hard to convince a hospital that’s looking to make an extra \$750 by using these codes that it’s not supposed to, because I can’t point to anything *in writing* from CMS.

Attachment 1

Anyway, that's where I'm at on this. Please let me know how I can help with this, if appropriate. Otherwise, I look forward to hearing back from someone soon.

Thanks for everything, Jim. Take care, and have a wonderful rest of the week.

Sincerely,
Dennis Padget
DLPadget Enterprises, Inc.
Simpsonville, Ky.
502/722-8873
502/722-5166
ThePathAdvocate@bellsouth.net

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

From: James Menas [mailto:JMenas@cms.hhs.gov]
Sent: Tuesday, March 01, 2005 1:45 PM
To: thepathadvocate@bellsouth.net
Subject: Re: Need a Conference Call with You

Dennis,

Could you give me more details in terms of the specific HCPCS codes? The outpatient PPS staff would likely contact you to discuss this further.

Jim

>>> "ThePathAdvocate" <thepathadvocate@bellsouth.net> 02/18/05 03:11PM >>>

Mr. Menas,

I've come across a HCPCS Level II vs. CPT code matter that opens the door to hospitals to garner as much as 36 times the expected Outpatient Prospective Payment System APC fee schedule amount for a limited number of pathology technical procedures. From my extensive research, this is a loophole that hospitals can "drive through" with impunity, because there's nothing in Medicare policy to restrict their ability to report the HCPCS instead of the CPT codes for these services.

I'd like to discuss this matter with you, because I think you'll want to carry it forward through the CMS channels to prevent an unintended loss of program funds. It may take 15 minutes or so for me to describe my findings during a phone conference.

Please let me know which day and what time next week would be good for me to call you. Any day and time next week works for me, except Tuesday and Thursday afternoon. Just let me know. Oh, I'll need the phone number you want me to call.

Attachment 1

Thanks for your attention, and I look forward to talking with you next week. Have a great weekend, and a fine holiday Monday.

Sincerely,
Dennis Padget
DLPadget Enterprises, Inc.
Simpsonville, KY
502/722-8873

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Thursday, February 10, 2005 10:45 AM
To: 'Marsha Mason-Wonsley'
Cc: 'ADavis3@cms.hhs.gov'; 'KTillman@cms.hhs.gov'
Subject: Still Need Answer, A Week Gone By

This is perfect! I wasn't looking for a particular answer—just interested in CMS policy, whichever way that went. Coincidentally, the answers you've given are what I was expecting. But as a consultant, I've got to have something authoritative to rely on, not just my feelings or best guess.

Again, thank you very much for helping me out. We're all after the same thing—doing it right: It's just that sometimes it's harder to find out what's right than at other times.

Sincerely,
Dennis Padget

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

From: Marsha Mason-Wonsley [mailto:Marsha.MasonWonsley@cms.hhs.gov]
Sent: Wednesday, February 09, 2005 4:49 PM
To: thepathadvocate@bellsouth.net
Cc: Conan Davis; Katherine Tillman
Subject: Still Need Answer, A Week Gone By

Dennis:

I know of no example whereas a hospital would use a D code to bill for technical services. I am sorry this may not be the answer you would like to hear but I have seen no Program memos or other documentation that advises hospitals to do so. You may want to check with your local Medicare carrier if there is any local Medical policy on this issue.

Marsha Mason-Wonsley
Health Insurance Specialist
Department of Hospital and Ambulatory Services
Division of Ambulatory Services
Center for Medicare and Medicaid Services

Attachment 1

>>> "ThePathAdvocate" 02/09/05 01:40PM >>>

Dear Ms. Mason-Wonsley

I'm sorry to keep bothering you, but I really need an answer to my Jan. 25 follow-up email. (See below.) I have several hospital clients who are pressing me for a definitive answer. I hesitate to recommend how a hospital should code its technical service based on the answer you earlier provided regarding a pathologist and the professional component: Medicare's expectations may be different for the hospital technical vs. the pathologist professional services.

I'll greatly appreciate you taking a moment to respond. Thank you very much for your help.

Sincerely,
Dennis Padget

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Wednesday, February 02, 2005 6:44 AM
To: 'Marsha Mason-Wonsley'
Cc: 'ADavis3@cms.hhs.gov'; 'KTillman@cms.hhs.gov'
Subject: Final Question on D-Codes

Dear Ms. Mason-Wonsley:

I still need an answer to my "last question" below. I understand what the pathologist is to do vis-a-vis his or her professional service, but conceivably the hospital might code its technical component (for preparing the oral tissue specimen) differently. Medicare sometimes requires physicians and hospitals to code differently for their respective—but related—services, and I need to know if this is one of those times.

Thank you again for your attention and assistance. Have a wonderful rest of the week, and take care.

Dennis Padget

Attachment 1

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Tuesday, January 25, 2005 6:23 PM
To: 'Marsha Mason-Wonsley'
Cc: 'ADavis3@cms.hhs.gov'
Subject: Final Question on D-Codes

Dear Ms. Mason-Wonsley:

Thank you so much for the advice below! Your answer eases my mind considerably; I couldn't see how a pathologist might legitimately use the D-codes for a microscopic tissue exam, but then again, I learn something new—and often surprising—every day.

LAST QUESTION: Does the answer you provided below apply as well to the technical component of a tissue biopsy or resection when the work is done by hospital personnel in a hospital lab? The reason I ask is because the same D-codes show up in the hospital Outpatient Prospective Payment System APC fee schedule.

Thank you ever so much for your attention to this matter and for your kind assistance. Take care, and have a wonderful rest of the week.

Sincerely,
Dennis Padget
DLPadget Enterprises, Inc.

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

From: Marsha Mason-Wonsley [mailto:Marsha.MasonWonsley@cms.hhs.gov]
Sent: Monday, January 24, 2005 10:40 AM
To: thepathadvocate@bellsouth.net; Conan Davis
Cc: Katherine Tillman
Subject: Please Respond

Mr. Paget:

Your question on coding has been forwarded to me for additional assistance. Hospital pathologist should be instructed to bill from the CPT coding book for pathology services regardless of the "type" of specimen it has received. The D codes you referenced are not for Medicare billing purposes. Thank you for your inquiry.

Marsha Mason-Wonsley
Health Insurance Specialist
Department of Hospital and Ambulatory Services
Division of Ambulatory Services
Center for Medicare and Medicaid Services

Attachment 1

>>> "ThePathAdvocate" 01/21/05 08:55AM >>>

Dear Mr. Davis-I don't want to be a pest, but a response to my Jan. 11 follow-up (below) will be greatly appreciated. Thank you, and have a wonderful weekend.-Dennis Padget

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Tuesday, January 11, 2005 11:18 AM
To: 'ADavis3@cms.hhs.gov'
Cc: 'KTillman@cms.hhs.gov'
Subject: Dental HCPCS Codes for Pathology Exams

Dear Mr. Davis:

Thank you for your Jan. 10 prompt response (reproduced below) to my inquiry last week about HCPCS codes D0472-D0999. If I understand correctly, if an oral surgeon were to perform a gingivectomy to remove a possibly cancerous lesion, the pathologist who examines the tissue should report the appropriate CPT code for the lab procedure, not one of the HCPCS codes in the range D0472-D0999. Similarly, the hospital at which the surgery was performed should report the appropriate CPT code for the technical component of the tissue preparation for pathologic examination. Is my understanding correct on both counts?

If I may impose, can you give me an example of a circumstance when a physician and a hospital would report one of the cited HCPCS codes instead of the applicable CPT code for a tissue exam?

I greatly appreciate your patience and your help with this matter. This is a rather puzzling aspect of HCPCS, and one that doesn't appear to be very obvious.

Sincerely,
Dennis Padget
DLPadget Enterprises, Inc.
Simpsonville, KY
502/722-8873
502/722-5166

Attachment 1

From: Conan Davis [mailto:ADavis3@cms.hhs.gov]
Sent: Monday, January 10, 2005
To: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Subject: Dental HCPCS Codes for Pathology Exams

Mr. Padget,

Let me say first that CMS has an agreement with the American Dental Association to include the CDT dental codes D0100-D9999 in HCPCS. The codes are primarily for use by dentists, oral surgeons, and other dental specialty groups.

Under most circumstances, when a physician is performing a medical procedure (even if in the mouth) it is more appropriate to use the CPT codes as you have suggested.

As you know Medicare does not cover dental services except in a very few instances.

I hope this helps.

Sincerely,
Conan Davis

From: ThePathAdvocate [mailto:thepathadvocate@bellsouth.net]
Sent: Tuesday, January 04, 2005 12:28 PM
To: 'KTillman@cms.hhs.gov'; 'ADavis3@cms.hhs.gov'
Subject: HCPCS Level II Pathology Codes

Ms. Kate Tillman and
Mr. Conan Davis
DHHS Centers for Medicare & Medicaid Services

Re: Level II HCPCS Codes for Histopathology Services

Dear Ms. Tillman and Mr. Davis:

I need your advice on a few Level II HCPCS codes in the D-series (dentistry). The codes, and my questions about them, are set forth below. If you'd rather I contact someone else at CMS on this matter, please let me know who that would be.

The codes of interest are in the range D0472-D0999. They describe primary histology or cytology lab services such as: gross exam of tissue; gross & microscopic exam of tissue; preparation and interpretation of exfoliative cytologic smears; and consultation on slides prepared elsewhere. Several secondary histology-type lab services are described in the range as well, such as: special stain for microorganisms; tissue in situ hybridization; and immunofluorescence.

These codes in the 2005 RBRVS physician fee schedule have an R-status, meaning that "special coverage instructions apply." The primary service codes (e.g., D0472-D0474 and

Attachment 1

D0480) in the 2005 hospital outpatient prospective payment system APC fee schedule have an S-status, also meaning that “special coverage instructions apply.” The secondary service codes don’t appear in the APC fee schedule, apparently indicating that they’re bundled for payment with the primary service.

These codes in the 2005 physician fee schedule are designated as “carrier-priced.” The allowed charge in the hospital outpatient APC fee schedule is \$801, which is something like **36 times more** than the counterpart CPT codes pay; for example, standard tissue biopsy gross and microscopic processing CPT code 88305 is priced at about \$22 in the APC fee schedule.

I’ve familiarized myself with the basic Medicare policies on coverage of dental care. I know that most dental care is excluded from coverage, as is a diagnostic service (e.g., an x-ray or a lab test) that may arise in conjunction with such care. I also know that, contrary to the general rule, dental care that’s aimed at diagnosing or treating a covered condition is covered by Medicare; for example, an oral biopsy to pinpoint an infection or suspected cancer in the mouth is a covered service, as is the pathologic examination of the biopsy.

What I’m confused about is: who’s supposed to use these codes, and when? In particular, I can’t figure out who would report a D0472-D0999 HCPCS Level II code for a histology or cytology lab service instead of an 88104-88399 CPT code, and in what circumstance they’d make the substitution. I can’t find any guidance in these regards via the Medicare Learning Network and the various carrier Web sites I’ve visited the past several days. That’s why I’m turning to you for help. Please respond to the following questions:

1. Assume a Medicare beneficiary is registered as an outpatient at Hospital A for a gingivectomy (excision of a portion of the gum) due to discovery of what may be a cancerous lesion. Surgery is performed by a general surgeon (not a doctor of dental surgery). The excised tissue is sent to the hospital’s histology lab for processing and for microscopic examination by a pathologist. The pathologist examines the tissue and its margins, and issues a written report; she equates the exam from a work perspective to a *Soft tissue mass, biopsy/simple excision* (CPT 88307).
 - a. How should Hospital A report the outpatient surgical procedure and the technical component of the gross and microscopic tissue exam on its UB-92 claim to the fiscal intermediary: (i) as CPT 41820 (*Gingivectomy, excision gingiva, each quadrant*) and CPT 88307; (ii) as CPT 41820 and HCPCS D0474 (gross & micro tissue exam, with margins); or (iii) as HCPCS D0474 alone? (The HCPCS table instructs that CPT 41820 is to be reported, because its HCPCS Level II equivalent isn’t recognized by Medicare.)
 - b. How should the pathologist report her professional service for diagnosing the tissue: (i) as CPT 88307-26; or (ii) as HCPCS D0474-26?
2. A Medicare beneficiary registers as an outpatient at Hospital B for a gingivectomy to remove a lesion that’s possibly cancerous. Surgery is performed by a doctor of dental surgery. The excised tissue is sent to the hospital’s histology lab for processing and for microscopic exam by a pathologist. The pathologist examines the tissue and its margins, and issues a written report; he equates the exam from a work perspective to a *Soft tissue mass, biopsy/simple excision* (CPT 88307).

Attachment 1

- a. How should Hospital B report the outpatient surgical procedure and the technical component of the gross and microscopic tissue exam on its UB-92 claim to the fiscal intermediary: (i) as CPT 41820 and CPT 88307; (ii) as CPT 41820 and HCPCS D0474; or (iii) as HCPCS D0474 alone?
- b. How should the pathologist report his professional service for diagnosing the tissue: (i) as CPT 88307-26; or (ii) as HCPCS D0474-26?
3. A general surgeon performs a gingivectomy as an office procedure on a Medicare beneficiary due to the presence of a suspicious lesion. The excised tissue is sent to an independent laboratory for processing, microscopic examination, and diagnosis. How should the independent lab report this service: (i) as CPT 88307; or (ii) as HCPCS D0474?
4. A doctor of dental surgery performs a gingivectomy as an office procedure on a Medicare beneficiary due to the presence of a suspicious lesion. The excised tissue is sent to an independent lab for processing, microscopic exam, and diagnosis. How should the independent lab report this service: (i) as CPT 88307; or (ii) as HCPCS D0474?
5. If HCPCS Level II code D0474 is not reportable in any of the scenarios outlined above, please explain the circumstances under which that code would be reported to a Medicare contractor, and by whom (i.e., a hospital, an independent lab, some other legal entity, a physician who isn't a doctor of dental surgery or dental medicine, and/or a doctor of dental surgery or dental medicine).

I apologize for the large number of questions, due to several combinations of providers and circumstances that need to be considered. If there's one simple answer that covers all the questions, I don't have to have each question answered individually. Also, you're welcome to call me at 502/722-8873 to discuss this topic, if that's easier for you.

I greatly appreciate your attention to this inquiry. Thank you in advance for your kind assistance and advice. With gratitude, I am...

Dennis L. Padget
DLPadget Enterprises, Inc.
Simpsonville, Kentucky
ThePathAdvocate@bellsouth.net
January 4, 2005

**Excerpt from Padget's 18 July 2005
Testimony and Written Comments Delivered
At the CMS Public Meeting Regarding the
2006 Medicare Clinical Lab Fee Schedule**

Move Code 86586 from the OPSS-APC to the CLFS

Code 86586 in *CPT-2005* describes *Unlisted antigen, each*. A note on page 149 of *CPT 2005 Changes: An Insider's View* (AMA) and correspondence from the AMA's CPT Information Services unit confirm that an appropriate use of this code is as an "each marker, not elsewhere specified" companion to immunology "total count" codes 86064, 86359, 86379 and 86587. (The B-cell, natural killer cell, and stem cell items are being recodified in CPT for 2006.) For example, if a particular immunodeficiency panel used the CD3, CD19 and CD28 markers, the AMA says that'd be coded 86359, 86064 and 86586 respectively. (I've made up a simplistic example merely to demonstrate the point; such a simple panel likely doesn't exist in the real world.) Both the AMA and CMS, the latter via the National Correct Coding Initiative (NCCI), say labs can't commingle the immunology "total count" codes with flow cytometry phenotyping codes 88184-88185 for the same panel, because the latter are reserved for uses centered on "the assessment of potential hematolymphoid neoplasia."

The problem now being experienced by hospital laboratories for nonhospital patients and by independent laboratories for their general patient population is that code 86586 today exists only in Medicare's outpatient prospective payment system ambulatory payment classification (OPSS-APC) fee schedule; which is to say, the code isn't in Medicare's clinical laboratory fee schedule (CLFS). Independent laboratories don't have access to the OPSS-APC fee schedule, and hospital laboratories billing for nonhospital patient tests are paid via the CLFS instead of the OPSS-APC fee schedule; therefore, in both instances, when labs correctly bill immunology panels that include at least one marker properly coded 86586, that charge is denied.

The AMA states code 86586 was always intended to be a standalone code, separate and distinct from each other code in the immunology series. Unfortunately, starting in the 1993 text through the 2004 revision, the descriptor for code 86586 was indented under the 86485 *Skin test* family. This undetected typographical error presumably caused CMS to capture 86586 in the OPSS-APC fee schedule, the same as other tests in the *Skin test* family, instead of in the CLFS, as with all other general immunology tests.

To correct this serious problem, to bring the OPSS-APC fee schedule and the CLFS into alignment with contemporary CPT coding principles, and to permit laboratories to receive proper payment for all medically necessary markers in the immunology panels ordered for Medicare beneficiaries, I respectfully ask CMS to take the following actions with respect to the fiscal year 2006 CLFS. First, code 86586, *Unlisted antigen, each*, should be removed from the OPSS-APC fee schedule and added to the CLFS. Second, code 86586 in the CLFS should be priced the same as other "total count" codes, particularly, for example, 86064, 86379 and 86587 (as designated in *CPT-2005*; see the 2006 revised digits). These changes should be effective 1 October 2005.

American Medical Association

Physicians dedicated to the health of America



CPT Information Services

515 North State Street
Chicago, Illinois 60610

800 634-6922
312 464-4841 Fax

February 1, 2005

Mr. Dennis L. Padget, MBA, CPA, FHFMA
President
Padget & Associates
PO Box 119
Simpsonville, KY 40067-0119

Dear Mr. Padget:

This is written in response to your facsimile dated December 8, 2004, and received to the CPT Information Services (#121505) on January 21, 2005, requesting clarification for reporting immunology CPT T-cell codes 86359-86361 and skin test code 86586.

As you were informed last week by telephone conversation with AMA CPT Information Services staff, code 86586 is not a revised code and has always intended to be a "stand alone" code that can be reported for each additional unlisted antigen tested with code 86064. According to College of American Pathology staff, a clarification will be printed in a future issue of *CAP Today* regarding these codes.

Regarding your questions pertaining to codes 86359-86361, please be advised that this issue and the coding examples provided have been forwarded to the CPT Pathology and Laboratory Advisors for review. A formal reply will be forthcoming, upon receipt of the Advisory opinion.

Thank you for your inquiry. I hope this information will be of assistance to you.

Respectfully,

/s/

Grace M. Kotowicz
CPT Information Services

This information is intended only for medical coding purposes and only for the individual use of the person or organization to whom it is addressed and may contain confidential and/or privileged material. Any other use (including without limitation, reprint, transmission or dissemination of all or part of this information), without the express written permission of the American Medical Association (AMA), is strictly prohibited.

This information is being provided based on the facts you provided. The AMA has not verified the information you provided and is not responsible for the accuracy or completeness of such information or for your failure to provide additional information pertinent to the AMA's response. Information provided by the AMA does not constitute clinical advice nor does it dictate a payer's reimbursement policy. In all cases, the practitioner performing a procedure is responsible for the correct coding of that procedure and information provided by the AMA is not a substitution for the professional judgment of the practitioner involved.

The AMA does not undertake to update any information provided to you. If you received this information in error, please notify the sender immediately and delete or destroy this information.

Cryo

Dana Buelay
Rebecca Kane
Joan Sanson
Jim Hart
Carol Burrell

8. 30 05 42

08/22/2005

Joseph P. Hallet
2714 Cypress Avenue
Norman, OK. 73072-6850

Dear Dr. McClellan:

1. The intent of this letter is to advise you of my interest in the prostate Cryosurgery procedures.
2. On 22 July 2004 Cryosurgery was performed on my prostate gland with absolute results. Should any further be required, Cryosurgery would definitely be my choice.
3. I am responding to a notice in the July Federal Register in which the present hospital out patient rates would have great difficulty in meeting the new proposed rates.
4. I feel that Cryosurgery is a great surgical program and should continue its existence without financial burdens imposed by higher rates. I would surely recommend that Cryosurgery be practiced in many, many other hospitals.
5. An adjustment to the proposed payment rate for APC674 should be in an upward direction.
6. I was advised prior to surgery that Cryosurgery would be my best choice, I am so glad to have made that choice. I am 88 years of age and have participated in athletics for many, many years. I might add that swimming has been my favorite. I find that swimming affords the greatest body movements. In addition I might add that Cryosurgery did not harm my sexual activities

Sincerely,


Joseph P. Hallet
405 321 2099

Cryo

Dana Burley
Rebecca Kane
Joan Simon
Jim Hartz
Carol Bazell

P. 30-05

43

3980 Ferguson Road
Indianapolis, IN 46239-1528

August 20, 2005
In regards to: CMS-1501-P

Mark B. McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan,

Subject: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate.

First of all I wish to inform you that I am a recipient of Cryosurgery of the Prostate. My Outpatient Surgery was conducted on October 28, 2004, and the Surgeon was Dr. Chris A. Magee, M.D., Urology of Indiana, 1270 N. Post Road, Suite A, Indianapolis, IN.

I was fortunate that I had Blue Cross Blue Shield Medical Insurance along with a secondary Insurance which was Tricare (Military Medical Program). I could have postponed my surgery date to November 1, 2004 as I would have been insured by Medicare and Medicaid as my Primary Medical Insurance Carrier.

I know the high cost of Cryosurgery and that I had adequate insurance coverage to have the surgery performed. I have been informed that in the July Federal Register that the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006 will not cover what the hospital costs are. Inadequate payment rate for 2006 will mean fewer hospitals will offer this treatment.

Further, I know the effectiveness of this surgery and if it was not available, I would have had to undergo major surgical removal of the prostate, thereby requiring a longer recovery time and longer hospital inpatient stay. All in all, I was in the hospital less than 20 hours and recovered at home.

I feel that anyone on Medicare/Medicaid would be unjustly penalized if the costs for Hospital Outpatient Prostate Cryosurgery payments were reduced as proposed by CMS-1501-P for APC674: Cryosurgery of the Prostate.

Sincerely yours,


Richard D. Champion, Sr.

Cc: James L. Hart, CMS, Mary Syiek, Endocare

Cryo Dara Burley
Rebecca Kune
Joan Sanson
Jim Hartz
Carol Bazell

Rec'd 44
8-30-05

August 18, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan,

This letter is in regard to the proposed reduction in the hospital outpatient payment rates for prostate cryosurgery. A procedure that I underwent recently and want to keep available for everyone facing prostate cancer.

I understand the new rates will not cover hospital costs on a procedure that is minimally invasive, extremely efficient, and cost effective, according to the July Federal Register. This reduction will result in fewer hospitals offering the procedure and, therefore less access to a cutting edge technology that kills all the cancer cells.

Furthermore, my recovery was free of complications and extremely fast. My priorities were: 1.) Rid my body of the cancer, 2.) retain control of my bladder, and 3.) not have to go through a surgery. Cryosurgery allowed me to accomplish all of these goals. I would recommend Cryosurgery for all men that are diagnosed with prostate cancer.

Please consider adjusting the payment rate for APC 674 up, not down, for all the thousands of men out there suffering from prostate cancer.

Thank you listening to me.

Leonel F. Bourdeau, PC survivor



Cryo
Comment on NT

Diana Burley ✓
Barry Levi ✓
Rebecca Karl ✓
Joan Sano ✓
Jim Hart ✓
Carol Bazell ✓

Rec'd 8-30-05 45

20 August 2005

Mark B McClellan, M.D., PH.D.

Administrator, Center for Medicare and Medicaid

I am writing to ask you to increase MEDICARE support for Cryo surgery and to inform you of the success I personally experienced through Cryo.

I was diagnosed with prostate cancer with an aggressive Gleason Scale rating of eight. I elected cryo surgery after examining other alternatives. My Cryo surgery took place on 11 August 05, the prostate was removed, and four important results occurred:

1. I experienced little or no pain through-out the convalescence.
2. Should further Cryo surgery be necessary because of cancer's return, it is still available as a course of treatment, unlike some other treatments.
3. I have been cancer free for one full year with zero P.S. A.
4. I was never incontinent and quality of my life was unaffected.

The July Federal Register proposed that hospital payment rates be reduced in 2006 for Cryo prostate surgery. This will discourage medical professionals from utilizing this marvelous new technique. Further, degrading this financing can set-back Cryo's advancement against other forms of cancer, such as breast, lung, stomach, pancreas, etc..

Because my cryo surgery has been so successful, quick healing, and relatively painless, I pray MEDICARE not only abandon its proposal to cut cryo financing, but that MEDICARE set even higher rates to Hospitals and Doctors to encourage and expand this progressive cancer treatment.

Edwin T. Lynch
2982 N. Ocean Shore Blvd, #48,
Flagler Beach, FL 32136

Cryo

Dana Burley
Rebecca Kane
Joan Sammy
Sam Hart
Carol Bazell

Rec'd
8-30-05

46

Dear Dr. McClellan,

I am writing to you in regard to Medicare reimbursement for Cryosurgery of the prostate. As a recipient of Cryosurgery of the prostate in June 2004, I would like to see it available to all men who are candidates at more hospitals.

The cryosurgery is a minimally invasive procedure with short hospital stay and quick recovery. In my case, it was an alternative to six weeks of radiation therapy at a clinic sixty miles from my home. I am happy to tell you that I recovered with no permanent side effects and after sixteen months my PSA is still well below the cancer range.

I understand from the notice in the July Federal Register that the proposed payment rate for APC 674 will not cover hospital cost for the procedure. Again, I urge you to continue payment for Cryosurgery of the prostate and to increase the payment rate to hospitals to keep it available for men like myself.

Thank you for your time and any assistance you can give to this manner.

Dolph Dugally
2102 Soapstone Road
Pittkin, Pa. 70656

Cryo

Dana Burley
Rebecca Kuma
Joan Sanson
Jim Hartz
Carol Bazell

Rec'd 47

8.30.05

August 22, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Attention: Cms-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Cryosurgery of the Prostate
CMS-1501-P: Medicare Program; Proposed Changes to the Hospital Outpatient
Payment System and Calendar Year 2006 Payment Rates for APC 674.

This letter is written to let you know of my concern regarding the proposed payment rates for Cryosurgery of the Prostate. I recently was diagnosed with prostate cancer and studied all the options available. I chose Cryosurgery for many reasons. I'm also writing because during my counseling sessions with the Surgeon who performed the Cryosurgery for me he indicated that due to new Medicare rates his nor the hospitals costs would be covered in the future and that he would have to reconsider performing this operation.

My Brother and I have both been diagnosed with prostate cancer in the last few years. Cryosurgery was not available to my Brother but it was to me. I believe the differences in our experience would be representative of most. My Brother had a radical prostatectomy and I had the Cryo.

My Brother was is the hospital three (3) full days, I was there over night.

My Brother had a complete abdominal incision and an in-dwelling catheter for two weeks. I had a small incision below the scrotum and a subtomic catheter for one week.

My Brother was told he could not return to work for four weeks. I was told to resume normal routine after a week or sooner if I felt like it.

My Brother procedure cost in excess of \$28,000. My Cryosurgery will be about half of that.

After a few weeks I have very few problems with incontinence or anything else. After two years my Brother still has problems and frequently has to wear depends or some other absorbent. The radical for my Brother didn't work so he has also now had to

undergo radiation which has created even more problems for him, including self catheterization from time to time.

From our experiences it would seem that Cryosurgery should receive full support of Medicare. My Brother sure wishes that Cryosurgery was an option open to him from his Physician at the time. I hope that Cryosurgery is an option for the many hundreds of thousands of men who will be faced with prostate cancer in the future. The side effects that my Brother has gone through or those of seed implants or other methods are frightening compared to those of Cryo.

I therefor urge you to provide increase payment rates for Cryosurgery so that more hospitals and more surgeons will offer it. Cryo is minimally invasive, recovery is quick, and many individuals will be able to return to work within a few days thus also saving employers lost time (Money).

Thank you for you time and consideration.

Sincerely

A handwritten signature in black ink that reads "Fred Jansen". The signature is written in a cursive style with a large, sweeping initial "F".

*Fred Jansen
P.O. Box 91
Anderson MO. 64831*

*Cc James L Hart CMS
Mary Syiek. Endocare*



Banner Health

Centers for Medicare & Medicaid Services
Dept of Health and Human Services
Attn. CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

APC/Gen

Dana Buzley
Rebecca Kanne
Joan Sano
Jim Hart
Carol Bazell

48
1441 North 12th Street, Phoenix, AZ 85006
602-495-4000
BannerHealth.com

RE: "DRUG ADMINISTRATION"

To Whom It May Concern:

This letter is in regards to the 2006 OPSS proposed drug administration changes noted in the Federal Register/Volume 70, No. 141 dated 7/25/05. The required method of reporting these services for outpatient hospitals changed from reporting Q codes in 2004 to CPT codes in January, 2005. The concern with the 2006 OPSS lies in the method for reporting these services is proposed to change again in January, 2006. I understand from reading the proposed changes that the existing CPT codes for reporting IV and chemo administration will be deleted and new CPT codes will be issued that correspond with the HCPCS G codes physician offices are using to report these services in 2005. It can be cumbersome and difficult for hospital providers to identify, get clear direction on the application of CPT reporting changes (for example, it took several months to get clarification to round up the number of units for the additional hours for the IV and chemo infusion > 30 minutes in 2005) and implement the required hospital changes associated with CMS changes that are so substantial. Since the loss of the three month grace period for implementing the annual CPT code changes and the timing of the OPSS final rule it can be difficult for providers to be ready by the first of the year.

Within the Banner Health system of hospitals, CPT codes for IV hydration and chemo administration are hard-coded in the Charge Description Master (CDM) which in all probability is typical of hospitals around the country that provide outpatient IV and chemo administration services. While the proposed changes may offer CMS more "clinical" information such as the "reason" for the IV infusion; hydration vs. therapeutic/diagnostic reasons, it potentially may add confusion, frustration and an additional administrative burden for clinical staff who are focusing on caring for many patients who now must decide among many new charge codes which are the most appropriate to bill.

Regarding reimbursement, these proposed changes will not change the mapping of these APC groups as noted in the 2006 OPSS proposal. Hospitals will be burdened with "breaking out" the reporting of these services without any change to the APC mapping in 2006. The APC groupings will still be collapsed by the OCE into per visit APC payments as they are in 2005.

If the existing CPT codes that describe drug administration services are deleted in 2006, I'd like to see CMS develop HCPCS codes that more closely match the existing CPT code descriptions for hospitals to use for reporting these services.

Sincerely,

Pam Sticklen B.S., R.N., CPC-H
CDM Analyst, Banner Health

PBT

Debbie Hunter
Rebecca Kwan
Joan Sanow
Jim Hart
Carol Bazell

49

AUG 24 2005

**MD ANDERSON
CANCER CENTER**
PROTON THERAPY CENTER

August 8, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2006 Payment Rates (CMS-1501-P)), we note the following proposed changes as they relate to proton beam therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

We agree with the proposed rule for the following reasons:

1. Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.
2. The proposed rates more accurately reflect the significant capital demands associated with developing, and the high costs of operating, a proton therapy center.

We also note that proton therapy technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully by CMS, as it is expected to be modest for the next two to three years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPTS rule. We urge CMS to make the proposed rule its final rule for CY 2006. This will ensure that the nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires approximately \$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of development and construction.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce R. McMaken". The signature is fluid and cursive, with a prominent flourish at the end.

Bruce R. McMaken
Managing Director
The Proton Therapy Center-Houston, Ltd., LLP

DHPPC

(reimbursement)

50

F4I-Reg Staff

568903

(X-Reg: 015 # 114490)

VARIAN

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PBT Debbie Hundy
Kane
Sanow
Hart
Buzell

August 11, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPSS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining

2005 AUG 23 PM 2:22

adequate Medicare payment for the technology. It is critical that CMS HOPPS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marcel R. Marc".

Marcel R. Marc

Cryo

September 2, 2005

Kane
Sanow
Hart
Bazell
Burley

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: Comments on *CMS-1501-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*

Specific Comments on *Device-Dependent APC 0674: Cryosurgery of the Prostate*

Dear Dr. McClellan:

On behalf of Endocare, Inc., I offer the following comments on the proposed rule for the Medicare hospital outpatient prospective payment system that was published in the *Federal Register* on July 25, 2005, and in particular the proposed payment rate for APC 0674, *Cryosurgery of the Prostate*.

In this letter, I will discuss the impact of the proposed 2006 payment rate for APC 0674, note methodological problems with the hospital claims data used by CMS in setting this proposed rate, and suggest an alternative approach CMS can use with this data to set a fair 2006 price for prostate cryosurgery procedures.

Endocare is a medical device company focused on the development and distribution of minimally invasive technologies for tissue and tumor ablation for cancer patients. Our primary area of focus has been on prostate cancer with the objective to dramatically improve men's health and quality of life. Endocare manufactures a total system required to perform cryosurgery and manufactures the CryoProbes (identified by HCPCS Code C2618) used in the cryosurgery of the prostate procedure. Prostate cryosurgery is the only procedure included in APC 0674.

In support of Endocare's comments, I have enclosed two (2) items with this letter that I will reference:

Dr. Mark B. McClellan
September 2, 2005
Page 2 of 6

- **Enclosure 1:** The first enclosure is a document containing briefing material prepared for an August 24, 2005 meeting of the *Coalition to Preserve Cryosurgery* with Center for Medicare Management Director Herb Kuhn (and other CMS payment policy staff via video-conference) on the subject of prostate cryosurgery. This document contains information on the clinical and patient impact of further reducing the payment to hospitals for performing prostate cryosurgery procedures. Additionally, in this Enclosure 1 is an explanation (from a hospital billing consultant) of why hospitals have not properly captured all charges for this procedure and the findings of an analysis performed by The Moran Company, of hospital outpatient claims from 2004.
- **Enclosure 2:** The second enclosure is a document we prepared and delivered at a May 18, 2005 meeting with CMS staff responsible for setting payment rates for the Medicare hospital outpatient prospective payment system. This document contains background material on prostate cryosurgery, as well as “external data” (Attachment B) relevant to pricing prostate cryosurgery procedures for 2006.

Having provided comments on the enclosure documents, I will now offer four (4) specific points:

1. The proposed 2006 APC payment rate to hospitals for outpatient cryosurgery of the prostate procedures is not sufficient to cover the cost of the procedure.

As we have documented through “external data” in previous submissions to CMS, a hospital incurs costs of more than \$9,000 to provide the prostate cyroablation procedure. The external data we have presented in prior years—and, again in May and June of this year¹—to CMS staff underscores this point.

- **Copies of UB92s.** These documents illustrate the hospital’s charges for all the individual components of the procedure, including CryoProbes. The hospital data we have collected for 2004 shows that our hospital customers have charges that average just under \$23,000—and that these charges adjusted to costs (using a cost-to-charge ratio of 0.42) are over \$9,560.
- **Copies of invoices and cancelled checks written by hospitals to Endocare.** These documents illustrate that hospitals pay on the average more than \$4,500 per case for CryoProbes and other cryoablation supplies.

Unfortunately, the 2005 Medicare hospital outpatient payment rate for the procedure is approximately \$6,300, and the rate proposed for 2006 is even less—just over \$5,600. The average shortfall between hospital costs and payment by Medicare is over \$3,000 per case.

¹ See Enclosure 2—The 2004 external data can be found in Attachment 2 of this document.

Dr. Mark B. McClellan
September 2, 2005
Page 3 of 6

2. *The proposed 2006 APC payment rate to hospitals for outpatient prostate cryosurgery procedures will mean reduced access or no access for Medicare beneficiaries to a minimally invasive treatment in a less intensive setting.*

In the early years of the hospital outpatient prospective payment system, hospitals absorbed the costs resulting from a shortfall in Medicare payment due to low case volume. However, hospitals now tell us that they can no longer absorb these losses. In the past two years a total of 29 hospitals have ceased performing or elected not to initiate a cryosurgery program due to inadequate Medicare payment.² While on the surface this number appears to be low, it represents 21% of the total number of hospitals that Endocare knows have provided more than five (5) prostate cryosurgery procedures per year in 2004.³

These points were underscored by hospital administrators in the August 24, 2005 *Coalition to Preserve Cryosurgery* meeting with Center for Medicare Management Director Herb Kuhn and his staff.⁴ A Medicare payment rate for cryosurgery that is set too low would be a severe blow to the adoption of this technology at a time when it is just beginning to grow in acceptance as a minimally invasive treatment option with clinicians and patients.⁵

- According to Anna Shields, a leading hospital billing consultant, who participated in the August 24, 2005 *Coalition to Preserve Cryosurgery* meeting, hospitals have a difficult time correctly billing for higher-priced medical devices—and these problems undermine the validity of the claims data CMS uses to set hospital outpatient payment rates.
- With respect to prostate surgery programs in particular, Ms. Shields stated that the “newness” of the cryosurgery programs and the fact that hospitals’ charge-masters have not yet been aligned to the time and materials that are actually utilized, lead hospitals to underreport their true costs for prostate cryosurgery procedures. In fact, a review of the 2004 OPPS claims data illustrates that approximately eighty percent (80%) of the hospitals reporting claims for cryosurgery of the prostate submitted less than ten (10) claims each in 2004.
- Further, she stated there are incentives that exist for hospitals to resist billing changes—incentives that range from fear of CMS and HHS OIG audits to the negative impact a change in billing practice may have with internal hospital management and external audiences.

² See Enclosure 1—Tab D lists these hospitals.

³ See Enclosure 2—Attachment 1 of Appendix B contains a listing of all hospitals in the U.S. performing 5 or more prostate cryosurgery procedures using Endocare products in 2004.

⁴ See Enclosure 1—Tab F contains the views of hospital administrators on the proposed Medicare payment rate for APC 0674.

⁵ According to the American Urological Association patient website: “...results place cryoablation therapy between radical prostatectomy and radiotherapy in effectiveness....equivalent to other therapies for low-risk disease and possibly superior for moderate and high-risk prostate cancer.” See the American Urological Association patient website at: <http://urologyhealth.org/adult/index.cfm?cat=09&topic=42>

Dr. Mark B. McClellan
September 2, 2005
Page 4 of 6

- Physicians and hospital administrators in attendance at the August 24, 2005 *Coalition to Preserve Cryosurgery* meeting confirmed the points made by Ms. Shields.⁶

3. *There will be treatment consequences if an adjustment is not made to the 2006 payment rate proposed for outpatient cryosurgery of the prostate procedures.*

Incentive for more expensive inpatient hospital admissions. CMS covers cryosurgery of the prostate in both the inpatient and outpatient settings through national coverage decisions⁷. Many physicians initially select the patients who have high-risk disease, who are older, and who are often not surgical candidates. These older, sicker patients routinely have other co-morbid conditions. This initial cryosurgery patient population often requires an overnight stay for monitoring and to deal with the patients' other co-morbidities. However, as a cryosurgeon adds volume to his practice, he begins to offer cryosurgery to patients with no other co-morbidities—and these patients are often suitable for treatment in an outpatient setting. However, if an appropriate reimbursement rate is not established for the outpatient setting, hospitals may encourage physicians to admit patients for more expensive inpatient care under the DRG 335 (patient without complications).

Incentive to perform more expensive prostate treatments in place of outpatient prostate cryosurgery. In addition to being clinically equal (or even superior in certain cases) to current treatment alternatives, the cost to the Medicare program to treat prostate cancer patients with cryosurgery can be much less than for most other prostate cancer treatment alternatives. These alternative treatments for prostate cancer are up to three (3) times more costly to the Medicare program.⁸

4. *Given the Reference Point Provided by the External Data Submitted by Endocare, and in Light of the Analysis of Medicare Data Performed by The Moran Company, CMS Should Re-Examine its Hospital Claims Data and Calculate a New Payment Rate for APC 0674.*

The external data submitted by Endocare (contained in Enclosure 2) indicates that there is a significant difference between the costs hospitals actually incur in performing prostate cryosurgery and the payment rate that results from the methodology used by CMS in the July 25, 2005 proposed regulation. Because of the clinical impact of this proposed reduction, as well as the reasons cited in the discussion above for hospitals under billing their actual costs for this procedure, we suggest that CMS consider an alternative methodology in using available claims to set a more appropriate payment rate for APC 0674.

⁶ See Enclosure 1—Tab D contains the key points made by Anna Shields.

⁷ Prostate cryosurgery was covered by Medicare in 1999 (for primary disease) and 2001 (for salvage treatment for radiation failure patients).

⁸ See Enclosure 2—Page 5 of the presentation provides a chart listing the cost per case for a variety of prostate cancer treatment alternatives.

Dr. Mark B. McClellan
September 2, 2005
Page 5 of 6

The Moran Company's analysis of Medicare claims data (contained in Enclosure 1, at Tab V) offers several alternative scenarios in this regard. *Based on Endocare external data which provides information on hospital acquisition costs for the probes used in this procedure, we urge you to refrain from using any claim in the 2004 hospital outpatient data set for which the total hospital charges for the device portion of the procedure are not at least \$6,000.*

- This suggested threshold of \$6,000 in the device portion of the procedure is based on the following calculation: \$4,000 for CryoProbe acquisition cost, multiplied by a very conservative hospital mark-up factor of 1.5.
- The \$4,000 CryoProbe acquisition cost is an extremely conservative threshold, given the fact that external data submitted by Endocare in prior years—and again this year—documents average hospital payment for CryoProbes and temperature probes used in the procedure, to be more than \$4,500.

Because the Moran analysis shows that this device charge can be found in a significant number of hospital claims in hospital revenue codes, as well as the HCPCS C-code (C2618), Endocare suggests that CMS use this method to identify claims for use in calculating a median cost for APC 0674. This approach would result in a median cost of \$6,892.⁹

In closing, we request that CMS take the following specific actions with respect to setting an appropriate payment rate for APC 0674, *Cryosurgery of the Prostate*:

- Consider the external data submitted by Endocare concerning hospital acquisition costs of the various probes used in prostate cryosurgery procedures to re-calculate hospital median costs for this procedure. In particular, CMS should eliminate or adjust claims for prostate cryosurgery procedures in the 2004 Medicare data base in which charges for the CryoProbes are less than \$6,000.
- Consider the claims analysis prepared by The Moran Company using this methodology. According to Moran, including only claims with HCPCS Code C2618 and/or revenue codes with charges of \$6,000 or greater would still result in a representative set of single claims and providers. The resulting median cost in this approach would be \$6,892 per procedure, instead of just over \$5,600, the payment rate set forth in the proposed rule.

⁹ See page 11 of The Moran Company presentation, at Tab E of Enclosure 1.

Dr. Mark B. McClellan
September 2, 2005
Page 6 of 6

- We believe that, at a minimum, the 2006 payment rate for APC 0674, Cryosurgery of the Prostate should not be set below the 2005 rate, plus inflation.

We are optimistic and hopeful that 2006 will serve as a "transition year" as hospitals learn to do a better job in correctly capturing their charges for prostate cryosurgery procedures. We know that some hospitals have made changes in 2005--but, unfortunately, these improvements in billing will not have an impact until 2007, given the two-year lag in claims data available for rate setting.

Thank you for allowing us the opportunity to comment on this proposed rule. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,



Craig T. Davenport
Chief Executive Officer
Chairman of the Board

Enclosures

Enclosure 1: Briefing Documents for Coalition to Preserve Cryosurgery Meeting with CMS (August 24, 2005)

Enclosure 2: Briefing Documents for Endocare 2006 Payment Rate Discussion with CMS (May 18, 2005)

c: Dr. Herb Kuhn, Director, Medicare Program



Prostate Cancer Advocates

August 30, 2005

Center for Medicare and Medicaid Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Sir/Madam,

I have worked with prostate cancer patients, survivors and family members for four years. As a former educator and family therapist, I know that patients feel in control and do best when they are educated about this disease and treatment options, and when they have access to all options. Thanks to Medicare National Coverage decisions (1999, 2001) these options, including cryotherapy, are indeed available to patients.

The appeal of cryotherapy is growing, not only for its minimal invasiveness, clinical success, and low rate of incontinence, but also because it can be done on an outpatient basis. I have spoken with literally hundreds of former patients, and their reports are consistent. They chose it because there is no major surgery or radiation, there is very little risk of incontinence, they are rapidly back to work/normal activity, and it's repeatable if necessary.

Sadly, some 30 hospitals have cancelled their cryosurgery programs due to their costs not being adequately met by Medicare reimbursement. That Medicare might deny access to a minimally invasive treatment alternative with clinical success at least as high as others seems unconscionable. It further defies logic in the face of data that cryotherapy is less costly to the Government. I realize that CMS is not directly blocking treatment access. The problem seems to lie in the use of a claims-based methodology that poses a learning curve with some bugs yet to be worked out, resulting in hospital claims that do not fully capture costs and thus posing an indirect obstacle.

I have faith in the intent and ability of CMS to do what is right for patients, and to make sure that hospitals receive adequate coverage of their costs for providing prostate cryotherapy on an outpatient basis. Such a decision not only saves Government money both short and long term, but more importantly guarantees patients easy access to this life-saving and lifestyle-preserving treatment.

Sincerely,

Karen M. Barrie, M.S.
Director, CryocarePCA (Prostate Cancer Advocates)
cc: Mary Syiek

Toll-Free Patient Support Line

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(877-722-2796)

CRYO

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Kane
Sarnow
Nant
Burley

August 22nd, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services

Attention: CMS-1501-P
P. O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P Medicare Program, Changes to the hospital outpatient prospective payment System and calendar year 2006 payment rates for APC674: *Cryosurgery of the Prostate*

Dear Dr. McClellan:

No therapy is 100% effective and unfortunately no therapy can guarantee zero impact on a patients quality of life.

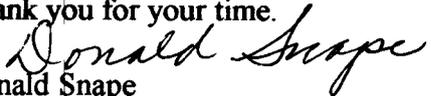
My Doctor sent me to a urologist who ordered a biopsy. The result was a Gleason Score of 6.

I put all of my efforts into the discovery and began collecting a variety of reports and resources for and about prostate treatment. Our selection of the cryo process was based on two primary issues. First it was the least invasive procedure and offered the quickest recovery. I feel at this point that medicare should continue to cover the cryoablation procedure. These procedures may change and they could improve over time. I had cryo process done 6 months ago and have had some side effects. I still feel that this procedure was my best choice to have done.

This procedure that I had, was performed a Froedtert Medical Center in Milwaukee, Wisconsin by Dr. Robert Donnell.

I hope that you will consider this plea to change the payment rates for the above procedures.

Thank you for your time.



Donald Snape
337 Oak Ridge Drive
Darien, Wisconsin 53114
261-882-6514 Home Phone

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August 29, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 21244-8018
Baltimore, MD 21244-8018

7/15/05
Surge
Jard
Bartel
Baltimore

Dear Dr. McClellan,

I am writing in regard to CMS-1501-P Medicare Program; Changes to hospital Outpatient Prospective Payment System and Calendar Year Rates for APC 674: Cryosurgery of the Prostate.

Seven years ago, I had Prostate Cancer and my treatment was Radiation. I stayed free of Cancer for seven years. It re-occurred and I was told by a major medical facility that they had no treatment to offer me.

I learned about Cryosurgery through a newspaper report. It was hope and an answer. I had Cryosurgery four years ago. It has been successful and I have had the assurance if my Prostate Cancer re-occurred, I could have the surgery again. There is no other Prostate Cancer treatment with this assurance. If Medicare had not covered this procedure, I would not have been able to have the surgery. I am Cancer free thanks to the Cryosurgery I received. It is less invasive than any other Prostate Cancer treatment.

I am responding to a notice in the July Federal Registry that contained the proposal outpatient payment rates for Prostate Cryosurgery in 2006 and that you have been informed the new rate will not cover what hospital costs are. This will cause many men to not be able to have the benefit of this treatment. A treatment that is less invasive and will give them life.

I am requesting that Medicare would give patients more access to this treatment. That more hospitals would be able to offer this treatment. I urge Medicare to adjust the proposed payment rate for APC 674 upward to reflect the actual cost to perform this procedure.

Thanks to this treatment, I have had the privilege to enjoy life and my family. Being able to be a part of my family's life today.

Sincerely,

Geoff Kee

Coalition For The Advancement Of Brachytherapy

660 Pennsylvania Avenue, S.E.

Suite 201

Washington, D.C. 20003

(202) 548-2307

Fax: (202) 547-4658

B-Therapy

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Kane
Sarnow
Hart
Bazell
Levi

September 7, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Dr. McClellan:

The Coalition for the Advancement of Brachytherapy (CAB)¹ is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule (see attachment 1).

Executive Summary and Recommendations

We would like to thank CMS for the opportunity to meet with staff during the past several years to explore how refinements can be made for brachytherapy payment under HOPPS. Although CMS has made significant changes in brachytherapy payment policy, the recent proposed rule highlights that further refinements are essential to ensure appropriate payment to hospitals and meaningful access to high quality cancer treatment for Medicare patients.

Given the proposed reduction in 2006 payments for all brachytherapy APCs (312, 313 and 651), CAB strongly recommends that CMS reestablish its efforts to use only "correctly coded" claims for rate-setting purposes. We urge CMS to use the most accurate and representative data possible to establish these rates by only using claims data where each brachytherapy procedure claim contains an appropriate brachytherapy source device "C" code(s). It appears that non-representative and erroneous claims are having disproportionate impacts on the rates for these codes that CMS has proposed in the recent notice.

¹ The Coalition for the Advancement of Brachytherapy was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer.

The fact that CMS is using such a small percentage of total claims to establish brachytherapy rates (for example, CMS used less than 3 percent of all claims for APC 0651) heightens the need for CMS to ensure that non-representative claims do not distort the payment rates. Claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were 9 percent to 34 percent higher than the average all single-procedure claims for the APC. This suggests that a "correct coding" screen, similar in concept to the screens CMS applied in the past to "device-dependent" APCs, is necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs.

Nonetheless, CAB continues to have significant concerns regarding the accuracy of hospital reported brachytherapy data on which CMS relies, and engaged Christopher Hogan, Ph.D. of Direct Research LLC to perform an independent analysis of the 2004 claims data that formed the basis for the 2006 payment rates. Dr. Hogan's analysis of the claims data appears throughout our correspondence and is presented in Tables 2 through 4.

CAB appreciates the agency's efforts to include multiple procedure claims data to calculate relative payment weights by using the "same date of service" and an expanded list of "bypass" codes to provide more "pseudo" single claims. However, additional revisions to the current methodology must be explored to ensure that CMS does not rely on severely flawed data to establish reimbursement levels.

We commend CMS's stated commitment to ensure that Medicare beneficiaries have timely access to new technologies in the 2006 proposed rule. Specifically, we are encouraged by CMS's willingness to create new pass-through device categories where an existing or previously existing category descriptor does not appropriately describe the new type of device.

We recognize that a system as complex as HOPPS will continue to encounter challenges for specific types of services, including brachytherapy. Our recommendations to CMS regarding brachytherapy are summarized below:

- Use only "correctly coded" claims to adjust the final 2006 relative weights for brachytherapy APCs 312, 313 and 651.
- Apply a "dampening" adjustment to all device-related APCs to limit the reduction in payment from 2005 to 2006 rates, including APCs 312, 313 and 651.
- Require mandatory hospital coding of appropriate brachytherapy source "C" codes for brachytherapy procedure APCs 312, 313 and 651.
- Increase efforts to educate hospitals on the importance of accurate coding of devices, including brachytherapy sources.
- Develop alternative methodologies to utilize single and multiple-procedure claims for determining median costs and setting HOPPS payment rates.
- Utilize the best external data available to qualify hospital reported data and correct brachytherapy APC rates, including proprietary or confidential data, to determine median cost calculations.
- Maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further, we request that all changes to APC assignments be listed in the preamble of future proposed and final rulemaking.

- Eliminate the proposal to require the submission of a CPT code application as a condition for a New Technology APC.
- Implement the APC Advisory Panel's recommendation to delay the multiple diagnostic imaging procedure reduction for one year and to further study the issue.

These recommendations are also intended to assist CMS in meeting its obligations for payment of brachytherapy under the Medicare Modernization Act.

I. APC Relative Weights

All radiation oncology procedure codes (CPT codes 77xxx) have proposed increases in 2006 under HOPPS except brachytherapy codes in APCs 312, 313 and 651 (see table 1). CAB believes that the reductions are based on several factors, including: inaccurate hospital coding of brachytherapy source device "C" codes; elimination of multiple-procedure claims used to determine relative weights; and utilization of "incorrectly" coded brachytherapy claims to determine payment rates.

Table 1 Comparison of 2005 vs. Proposed 2006 HOPPS Payment Rates for Brachytherapy APCs

| APC | CPT Codes | 2005 Payment | 2006 Proposed Payment | Percentage Change from 2005 to 2006 |
|---|-----------------------------------|--------------|-----------------------|-------------------------------------|
| 312 Radioelement Applications | 77761, 77762, 77763, 77776, 77777 | \$317.87 | \$296.90 | -6.6% |
| 313 Brachytherapy | 77781, 77782, 77783, 77784, 77779 | \$790.75 | \$763.48 | -3.4% |
| 651 Complex Interstitial Radiation Source Application | 77778 | \$1,248.93 | \$720.71 | -42.3% |

Multiple Procedure Claims

CAB appreciates CMS's continued efforts to include multiple procedure claims data in order to calculate relative payment weights and we support the "date of service" and expanded list of "bypassed" codes to create more "pseudo" single claims. However, the continued reliance on single procedure claims fails to produce a statistically valid number and sample of brachytherapy procedure claims used for rate-setting.

CMS continues to rely exclusively on single procedure claims to establish payment rates for the hospital outpatient APCs. This approach excludes more than 97 percent of the complex interstitial brachytherapy claims from the calculation of the proposed payment rates for APC 651 (see table 2).

Table 2 Comparison of All Claims vs. Single Procedure Brachytherapy Claims

| APC | Total Number of All Claims | Total Number of Single Claims | Percentage of Claims Used for Rate-Setting |
|---|----------------------------|-------------------------------|--|
| 651 Complex Interstitial Radiation Source Application | 11,963 | 342 | 2.8% |
| 312 Radioelement Applications | 882 | 363 | 41.2% |

Because the typical radiation oncology encounter involves multiple services, it is safe to say that CMS has based its payment rates on atypical encounters. We believe that the data from single encounter claims is so low that it must represent services performed in small, relatively non-busy centers with low technological complexity and similarly inappropriately low costs and charges. The overwhelming majority of brachytherapy procedures are done with other procedures as evidenced by the number of single claims captured in CMS's updated data.

Significant reductions in proposed 2006 payment rates for a number of device-related APCs, including APC 651, are a direct result of the inaccurate capture of costs estimated from CMS' single and "pseudo" single procedure claim rate-setting methodology. This is particularly problematic for procedures routinely performed in conjunction with other procedures (e.g., radiation oncology and brachytherapy) whose costs, by definition, would always be reported on multiple procedure claims, but under single claims methodology are not being captured.

These typical reports are disregarded by CMS in its use of single claims data. The data used by CMS is not only too limited, but it represents a small segment of procedures that undervalue brachytherapy procedures. It is unfair to the majority of hospitals to base payment rates for any APC on a few hundred claims when more than thousands of claims exist that are more representative. **We urge CMS to create new APC payment rates using both single and multiple procedure claims.** We believe that additional data will increase the likelihood of accurate APC payments in the future. CAB would be happy to assist CMS in analyzing this data and would hope that it could be completed as soon as possible so that we can be prepared to discuss this issue with the APC Advisory Panel at their next meeting in 2006.

Further, CAB recommends that CMS consider the best external data available in constructing APC rates, including proprietary or confidential data, to determine median cost calculations, whenever the single claims methodology yields an insignificant number of claims to set payment rates and to avoid over-reliance on skewed data.

CAB urges CMS to consider and accept external data in constructing the APC rates. We continue to agree with the February 2005 APC Advisory Panel's recommendation that CMS proceed with caution in using existing data on devices submitted with "C" codes to set reimbursement rates and that CMS consider using external data in setting such rates. We remain concerned, however, at CMS's stringent criteria and parameters for submitting external data and request that CMS consider all external data based on its merits, including confidential proprietary data. CMS should expand the use of confidential, proprietary external data to calculate future payment rates whenever such data is needed and proven reliable.

Correctly Coded Claims

The 2006 HOPPS proposed payment rates are based on hospital outpatient claims from January 1 – December 31, 2004. CAB undertook an analysis of the 2004 claims to determine what percentage of all brachytherapy claims and single procedure brachytherapy claims were "correctly coded," which included both a brachytherapy procedure code and a brachytherapy source device "C" code (see table 3) For this analysis, a single-procedure claim was "correctly coded" if the original claim from which it was created had the proper brachytherapy source "C" code on the claim.

Table 3 Percentage of "Correctly Coded" Brachytherapy Claims

| APC | Total Number of All Claims | Percentage of "Correctly Coded" Claims | Total Number of Single Claims | Total Number of "Correctly Coded" Single Claims | Percentage of "Correctly Coded" Single Claims |
|---|----------------------------|--|-------------------------------|---|---|
| 312 Radioelement Applications* | 882 | 38% | 363 | 46 | 12.7% |
| 313 Brachytherapy | 7,156 | 34% | 8,625 | 3,442 | 39.9% |
| 651 Complex Interstitial Radiation Source Application | 11,963 | 86% | 342 | 181 | 52.9% |

*The Total Number of "Correctly Coded" Single Claims for APC 312 is based on data from 18 hospitals

We then examined the median costs of all single procedure claims compared to the median costs of "correctly coded" single procedure claims (see table 4)

Table 4 Comparison of Median Cost of Single Claims vs. "Correctly Coded" Single Claims

| APC | Median Cost of Single Claims | Median Cost of "Correctly Coded" Single Claims | Percentage Difference of Median Cost |
|---|------------------------------|--|--------------------------------------|
| 312 Radioelement Applications* | \$301.91 | \$403 | 33.5% |
| 313 Brachytherapy | \$776.35 | \$849.39 | 9.4% |
| 651 Complex Interstitial Radiation Source Application | \$732.86 | \$864.54 | 18.0% |

*The Median Cost of "Correctly Coded" Single Claims for APC 312 is based on data from 18 hospitals

Claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were 9 percent to 34 percent higher than the average all single-procedure claims for the APC. CMS's coding screen for "device-dependent" APCs provides a model for examining these brachytherapy claims. CMS found that claims without the device coded tended to underreport charges and costs when compared to claims with the device reported. CMS then screened out these unrepresentative claims for "device-dependent" APCs prior to calculating the rates. This suggests that a coding screen, similar in concept to the screens CMS applied in the past to "device-dependent" APCs, is necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs. In past years, CMS has used only "correctly coded" claims to determine brachytherapy payment rates and we recommend that they do so for 2006.

We point out here that our analysis properly removed the costs of the brachytherapy source ("C" code) line items before calculating the total packaged costs of APC. This should be clear, as our median costs for all claims is quite close to the median as published by CMS. So, the higher costs of the correctly-coded claims is not due to the (improper) inclusion of the source costs in the median calculation, but reflects the impact of selecting claims from hospitals who carefully and fully code the charge data.

CAB recommends that CMS use only "correctly coded" claims for brachytherapy APCs 312, 313, and 651 to determine the final 2006 HOPPS payment rates. "Correctly coded" claims are defined as an outpatient claim that contains a brachytherapy procedure code and at least one brachytherapy source device "C" code (see table 5).

Table 5 “Correctly Coded” Brachytherapy Claims (Based on 2004 Outpatient Claims Data)

| APC | CPT Codes | Brachytherapy Device “C” Codes |
|---|--------------------------------------|---|
| 312 Radioelement Applications | 77761, 77762, 77763, 77776, or 77777 | C1716, C1718, C1719, C1720, C2616, C2632, or C 2633 |
| 313 Brachytherapy | 77781, 77782, 77783, 77784, or 77779 | C1717 only |
| 651 Complex Interstitial Radiation Source Application | 77778 | C1716, C1718, C1719, C1720, C2616, C2632, or C 2633 |

CAB recommends that CMS review the 2004 claims data used to package appropriate costs into Brachytherapy APCs 312, 313 and 651 to ensure that the brachytherapy source(s) was included on each hospital claim. We request that CMS select the claims that accurately reflect the procedure, source and device coding and delete the claims that do not, and revise the final payment rate for 2006 to reflect the appropriate cost of the brachytherapy procedure(s).

Further, CAB recommends that CMS issue a Medicare Program Transmittal instructing providers to report the appropriate “C” code and charge of the brachytherapy source(s) on all brachytherapy procedure claims. We request that CMS also instruct providers to report all brachytherapy procedures by date of service.

We urge CMS to make these changes not only to achieve more accurate and appropriate payment, but also because such changes will more properly reflect CMS’ implementation of the brachytherapy specific requirements in the Medicare Modernization Act, which stated in part:

The payment basis for the (brachytherapy) device under this section shall be equal to the hospital’s charges for each device furnished, adjusted to cost (Medicare Modernization Act section 621(b), Social Security Act section 1833(t) (16)(C).

II. Device-Dependent APCs

CAB is very concerned that CMS did not continue its policy of stabilizing all device-related APC rates by protecting against significant cuts to APCs. For the last several years, CMS established a “dampening” adjustment to virtually all APCs (except “New Technology” APCs). These adjustments were created to limit the impact of payment reductions from year to year.

In the 2006 proposed rule, CMS acknowledged that a payment reduction of more than 15% from the 2005 HOPPS payment rate might be problematic for hospitals that provide these services. As mentioned previously, Brachytherapy APC 651 has a proposed reduction of 42.3%.

To address the lack of C-code data and the significant reductions for several APCs, CMS is proposing to adjust the median costs for the “device-dependent” APCs in Table 15 to 1) the higher of the 2006 unadjusted median or; 2) 85% of the adjusted median on which payment was based for 2005 HOPPS. The “device-dependent” adjustment factor proposed for 2006 was not applied to APC 651 for Complex Interstitial Brachytherapy.

CAB recommends that CMS apply the “dampening” adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

III. Brachytherapy

APC 651 Complex Interstitial Radiation Source Application

APC 651 includes one CPT code 77778 *Interstitial Radiation Source Application; Complex*. This interstitial brachytherapy procedure is used to code for prostate brachytherapy, a high volume cancer therapy, as well as other complex interstitial brachytherapy procedures that utilize more than 10 brachytherapy sources per procedure. The 2006 proposed payment for APC 651 is \$720.71, which is a 42.3% reduction from the current payment of \$1,248.93.

Since the inception of HOPPS in 2000, the payment policy and coding for important components of prostate brachytherapy have changed numerous times and the payment rates have been very unstable. The hospital claims data for prostate brachytherapy has fluctuated dramatically and not stabilized since 2000. The legislative provision that Congress enacted in 2003 concerning brachytherapy reflects longstanding concerns regarding the hospital data used by CMS to establish payment rates for brachytherapy.

The proposed fluctuation in payment for APC 651 is dramatic, and this is part of an ongoing concern that significant problems exist with the accuracy and/or interpretation of CMS's data for brachytherapy procedures. These issues could result in part from the challenges faced by hospitals in learning new codes and policies, given that significant changes have occurred on nearly an annual basis since 2000 in the coding of prostate brachytherapy services, devices and supplies. We also believe that the problem is compounded by Medicare's single claim methodology.

In 2004, there were 11,963 claims that contained CPT code 77778, however, CMS based the 2006 proposed payment on just 342 claims or approximately only 2.8% of outpatient claims. The extremely low volume of claims used for rate-setting is troubling. Based upon our analysis, CMS did not use "correctly coded" claims to set the 2006 proposed rates for 77778. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device "C" code, the median cost increases by approximately 18% to \$864.54. In past years, CMS has used only "correctly coded" claims to determine payment rates for certain services and we recommend that they do so for 2006 for this service.

Given these ongoing concerns and the significant change in payment that is proposed for APC 651, CAB recommends that CMS review the 2004 claims data for APC 651 *Complex Interstitial Radiation Source Application* to ensure that the brachytherapy sources are included on each hospital claim that contains CPT procedure code 77778. This will ensure the use of the more accurate claims data for establishing the rate for APC 651. We request that CMS select the claims data that accurately reflect the device coding and not use the claims that do not. CMS should revise the final payment rate for 2006 to reflect more appropriately the cost of the complex interstitial brachytherapy procedure.

Further, if after using only "correctly coded" claims to determine the 2006 median for APC 651 results in a 15% or greater reduction than the current 2005 payment, CAB requests that CMS apply the "device-dependent" or similar adjustment factor to APC 651 to adjust the median cost to 85 percent of the CY 2005 median used to set the payment rate in 2005. Complex interstitial brachytherapy always requires the use of 10 or more brachytherapy sources, which are defined as medical devices.

Payment rates for brachytherapy must be stabilized. A 42.3% payment reduction is very significant, and as CMS notes in the proposed rule, reductions in excess of 15% "may be problematic for hospitals that provide the services contained in this APC," and may affect beneficiary access to this important treatment for prostate cancer.

If hospital outpatient departments do not provide brachytherapy as a treatment option for prostate cancer, Medicare beneficiaries may be forced to choose a more costly and invasive alternative treatment option. Prostate brachytherapy is often preferable to other clinical therapies due to its lower incidence of serious complications (such as impotence and urinary incontinence).

Utilizing only "correctly coded" claims and applying the "device-dependent" adjustment factor to APC 651 will help address these concerns and will limit the proposed reduction in 2006 payment for complex interstitial brachytherapy.

Brachytherapy Sources

CAB appreciates CMS's continued recognition that brachytherapy sources vary based on the type, number and radioactive intensity of the sources, however, CAB believes that the irregular reporting of medical device "C" codes by hospitals is only one factor contributing toward the inaccurate data on which CMS is setting payment rates (see table 3).

CAB continues to support mandatory reporting of all medical device "C" codes and related incentives to encourage hospitals to be more vigilant in reporting the total costs of performing device-related services. We recommend that CMS consider expanding their proposal to implement device code edits for all device-related and "device-dependent" APCs. Furthermore, we encourage CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies.

Brachytherapy requires the use of medical devices and we suggest that brachytherapy source "C" codes be required for APCs 312, 313, and 651. We believe that limited mandatory "C" coding will be more of an administrative burden to hospitals and may cause confusion. We support expanding the 2005 policy to all device-related and "device-dependent" APCs to promote "correct coding" and improve the quality of the claims data. In addition to using device "C" codes, hospitals should be educated on how to report charges for brachytherapy source devices utilized in the outpatient department.

IV. CPT 57155 Insertion of Uterine Tandems and/or Vaginal Ovoids for Brachytherapy

CMS proposes to move CPT 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 193 *Level V Female Reproductive Procedures* to APC 192 *Level IV Female Reproductive Procedures*. The current payment for CPT 57155 is \$758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of \$255.66. We note that some CPT codes were moved to different APCs without a discussion in the preamble providing the rationale for the changes. For example, there was no discussion in the proposed rule regarding the proposed assignment of CPT 57155 to APC 192 and we are concerned that a reduction of 66% could have a negative impact on Medicare beneficiaries' access to this important treatment for vaginal and/or uterine cancer. CMS acknowledges in the proposed rule that payment reductions greater than 15 percent from the CY 2005 HOPPS to the CY 2006 OPSS may be problematic for hospitals that provide the services contained in these APCs (see July 25, 2005 *Federal Register*, page 42714).

CAB recommends that CMS maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further, we request that all changes to APC assignments be listed in the preamble of future proposed and final rulemaking.

V. New Technology APCs

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application (for either a Category I or III CPT code) be filed with CMS as a part of the application for a New Technology APC, along with CPT's letter acknowledging or accepting the CPT code application.

CAB is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated decision, and may add undue delay to decisions, preventing rapid recognition of new technologies for Medicare beneficiaries.

The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections, necessary for public policy making. AMA meetings are closed to the public. The bases for decisions are not available to the public. There are no voting representatives on the AMA CPT Editorial Panel from the medical technology industry and medical technology manufacturers. The AMA CPT Editorial Panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act. Thus, requiring the submission to the AMA CPT Editorial Panel risks the involvement of an organization that may not be accountable as are all other agencies that are responsible for federal public policy decisions. Even the requirement that AMA only acknowledge receipt of the application suggests that the AMA has some potential "veto" power over a decision that arises uniquely within CMS' authority.

Further, Category I CPT codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Editorial Panel would assign a Category III "emerging technology" code that often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries, as well as commercial payers.

CAB suggests that delegating even this modest function to the AMA may be an unlawful delegation of federal decision making to a private organization.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives of manufacturers on the decision making panel, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients.

The Coalition for the Advancement of Brachytherapy recommends that CMS eliminate the proposed requirement to submit a CPT application to the AMA prior to submitting a New Technology APC application.

VI. Transitional Pass-Through Payments for Devices

CAB supports the CMS proposal to create new pass-through device categories where an existing or previously existing category descriptor does not appropriately describe the new type of device. Congress intended to provide access through transitional pass-through payments to new and beneficial medical devices, including brachytherapy sources. We believe CMS has sufficient documentation on devices in expired categories to differentiate them from new devices, and authority to clarify the definitions of previous categories to distinguish them from appropriate new categories. We further recommend that CMS continue to consider the need for pass-through status when the costs of a new device are not reflected in existing APCs.

VII. Multiple Diagnostic Imaging Procedures

Currently under HOPPS, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50%.

The Coalition for the Advancement of Brachytherapy agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However, CAB has serious concerns that CMS has used external data rather than HOPPS data and methodology to analyze this position. CMS utilized the Medicare Physician Fee Schedule methodology and data, rather than that of the HOPPS process in developing this policy. Further, we believe that the hospital's cost-to-charge ratios and related cost reporting methodology already takes into account reductions for multiple imaging procedures. Since the HOPPS methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in the proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities.

CAB supports the American College of Radiology's comments and the APC Advisory Panel's recommendation that CMS delay implementation of the multiple diagnostic imaging procedure reduction for one year because further study is necessary.

Conclusion

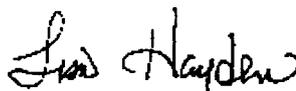
Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy procedures and sources is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in the hospital outpatient setting.

We hope that CMS will take these issues under consideration during the development of the 2006 Hospital Outpatient Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,



Raymond Horn
Chair



Lisa Hayden
Vice-Chair

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytoc Corporation
MDS Nordion
Mentor Corporation
Nucletron Corporation
Oncura
Pro-Qura
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
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American Brachytherapy Society
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2005
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1501-P
HOPPS
2006
Proposed Rule

September 1, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Dr. McClellan:

Sanarus Medical, Inc. is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

Sanarus Medical is dedicated to providing truly minimally invasive solutions for the detection, diagnosis, treatment and follow-up of breast disease. The Sanarus technology will transform the way breast disease is managed and treated; from an operating room-based, surgically intensive approach to a more comfortable, cost-effective, outpatient-based, care pathway.

Recommendation

Sanarus Medical requests that Medicare provide coverage and reimbursement for cryoablation of benign breast fibroadenoma in the hospital outpatient setting in 2006 by assigning payment to new category III CPT code 0120T. **Sanarus recommends that 0120T be placed in New Technology—Level XXIV APC 1524 and assigned a status indicator of “S.”**

0120T Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

Background

In the United States, it is estimated that as many as 700,000 patients per year are diagnosed with breast fibroadenoma, which is the most common benign finding on breast biopsy. Approximately 30% - 50% of patients seek treatment. A review of the hospital outpatient claims data indicates that 37,558 procedures (CPT 19120, Excision of cyst, fibroadenoma, other) were performed on Medicare beneficiaries in 2004 (Source: 2004 Hospital OPSS Proposed Rule File with analysis conducted by The Moran Company). Although all of these potential patients may be candidates for cryoablation of a fibroadenoma, it is not expected that all of them will receive this treatment as alternative treatments are also available.

The fibroadenoma cryoablation procedure is a reasonably simple and minimally invasive procedure. The first step in the treatment of the fibroadenoma is to localize the fibroadenoma with the cryoprobe (cryolocalization), much like needle wire localization is used with malignant lesions, followed by a freeze cycle. The cryoprobe is inserted into the center of the lesion through a 3 mm skin incision using local anesthesia and under continuous ultrasound monitoring. The fibroadenoma is ablated in situ through exposure to a second freeze-thaw cycle. Based upon research data on cryoablation, two freeze-thaw cycles with freeze time algorithms tailored to the fibroadenoma size are used. Temperature is monitored with a thermocouple in the cryoprobe tip. Ultrasound is used to monitor the growth of the ice ball as it engulfs the fibroadenoma.

In cryoablation of fibroadenomas, treatment typically ranges from 15 – 60 minutes. The extent of freezing is tailored to the size of the fibroadenoma using a time-based algorithm. Sterile saline or local anesthetic is injected between the skin and growing ice ball if the distance between them becomes less than 5 mm. Following the second freeze-thaw cycle, the cryoprobe is removed, pressure is applied over the ice ball site for 20 minutes to decrease the risk of hematoma formation, and then the patient is discharged with advice to take an over-the-counter analgesic, if necessary, for localized breast discomfort.

Cryoablation is performed by a radiologist or surgeon with the assistance of a nurse and/or ultrasound technician. The procedure may take place in a hospital outpatient department or physician office and requires the VISICA™ Treatment System, a single-use disposable cryoprobe, and ultrasound equipment for image guidance to place the cryoprobe. Several studies have demonstrated the safety, efficacy, durability and reproducibility of cryoablation as a primary therapy for fibroadenomas.

Historically, the treatment of choice for fibroadenomas has been surgical resection. The advantage of this approach is that it provides definitive diagnosis while removing the lesion and lessening the need for follow-up monitoring. However, surgical removal of fibroadenoma has its disadvantages, including the use of general anesthesia, skin incisions resulting in scarring and patient discomfort, and operating room costs. In the past decade, there has been a movement toward less invasive surgery for these lesions, such as cryoablation. Cryoablation has become an important, less-invasive treatment option for women who have been diagnosed with fibroadenomas and want definitive therapy, but who would prefer not to undergo surgical resection.

Rationale for Coverage and Payment

Cryoablation of breast fibroadenomas is both minimally invasive and cost-effective. This technology could provide savings to the Medicare program since it may be performed under a local anesthetic in the outpatient department or physician office. Studies have shown high levels of patient satisfaction due to minimal discomfort and fewer side-effects compared to invasive surgery. This new technology should be available to Medicare beneficiaries treated in the hospital outpatient setting. We believe that providing coverage and payment for this technology will have a minimal impact on the Medicare payment system because the incidence of fibroadenomas is typically in the non-Medicare aged population.

The American Medical Association established a new category III CPT code for cryoablation of breast fibroadenomas (0120T), which was released July 1, 2005 and will be implemented on January 1, 2006 (see below). As you know, the AMA does not assign relative weights or relative value units (RVUs) to category III CPT codes. Medicare has the authority to determine national payment rates for category III CPT codes.

0120T Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

In addition, Sanarus Medical recently submitted a New Technology APC application for "placement of cryoprobe for localization" of benign or malignant breast tumors. Cryoablation of fibroadenomas requires an additional step beyond cryolocalization, which is a second freeze-thaw cycle to destroy the tumor that is reabsorbed by the body over time.

Sanarus Medical recommends that 0120T Cryoablation of breast fibroadenoma be assigned to New Technology Level XXIV, APC 1524 with a payment rate of \$3,250 (see itemized procedure costs below). This new technology should be appropriately placed into a New Technology APC with a significant status indicator ("S").

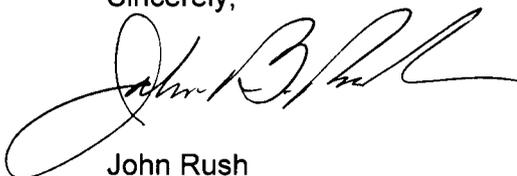
| Item | Cost |
|--|---------|
| Administrative cost | \$240 |
| Operating Room (60 minutes) | \$350 |
| Ultrasound Technician (60 minutes) | \$250 |
| Nurse (60 minutes) | \$370 |
| VISICA 2mm Single-use Disposable Cryoprobe | \$1,485 |
| VISICA Treatment System | \$351 |
| Argon & Helium Gas | \$98 |
| General supplies (topical anesthetic, drapes, dressings, etc.) | \$85 |

Conclusion

Cryoablation of breast fibroadenoma is a remarkably effective, reasonably simple alternative to the surgical excision of breast fibroadenomas. Cryoablation of fibroadenoma has been associated with high levels of physician and patient satisfaction. We request that Medicare provide coverage and reimbursement for cryoablation of benign breast fibroadenoma in the hospital outpatient setting in 2006 by assigning payment to new category III CPT code 0120T. Sanarus recommends that 0120T be placed in New Technology—Level XXIV APC 1524 and assigned a status indicator of "S."

We commend CMS and its staff in providing reimbursement for multiple category III CPT codes under HOPPS. Your previous policy decisions have provided for high-quality, cost-effective treatments for Medicare beneficiaries. We appreciate your consideration of our recommendation to provide payment for cryoablation of breast fibroadenomas (0120T). Should CMS staff have additional questions, please contact Michael Mydra, Vice President of Reimbursement at (952) 934-3655.

Sincerely,



John Rush
President & CEO



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Hart
Baker
Burley
Ritter

August 29, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Dr. McClellan:

.decimal, Inc. is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

.decimal, Inc. is a manufacturer of customer filters for solid compensator-based intensity modulated radiation therapy (IMRT). .decimal is dedicated, through the delivery of our products, to providing our customers and their patients with better cancer treatment solutions. Our mission is to exceed our customers' expectations for superior quality, responsiveness to their needs and professionalism in the delivery of our products in the fight against cancer.

We would like to thank CMS for the significant changes in IMRT payment policy implemented in 2004, 2005 and continued in 2006 under HOPPS. Your decision to provide coverage and reimbursement for compensator-based IMRT has ensured appropriate payment to hospitals and meaningful access to high-quality cancer treatment care for Medicare patients.

Recommendation

.decimal requests that CMS either update the December 19, 2003 Medicare Program Transmittal 32 (Change Request 3007) or issue a new Medicare Program Transmittal to include compensator-based IMRT delivery code 0073T (see Attachment 1). Program Transmittal 32 is now out of date and the information is incorrect as compensator-based IMRT delivery may no longer be coded with CPT 77418, but must utilize category III code 0073T effective January 1, 2005.

0073T Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session.

A One-Time Notification that includes clarification of billing for IMRT under HOPPS in 2006 will ensure that hospitals properly code for compensator-based IMRT when treatment is delivered. We suggest the following edits to section “5. Billing for Intensity Modulated Radiation Therapy” in order to comply with CPT coding guidelines (suggested text in bold and strikeout):

5. Billing for Intensity Modulated Radiation Therapy Intensity modulated radiation therapy (IMRT), also known as conformal radiation, delivers radiation with adjusted intensity to preserve adjoining normal tissue. IMRT has the ability to deliver a higher dose of radiation within the tumor and a lower dose of radiation to surrounding healthy tissue. Two types of IMRT are multi-leaf collimator-based IMRT and compensator-based IMRT. IMRT is provided in two treatment phases, planning and delivery. Effective January 1, ~~2004~~ **2006**, when IMRT is furnished to beneficiaries in a hospital outpatient department that is paid under the hospital outpatient prospective payment system (OPPS), hospitals are to bill according to the following guidelines:

- a. When billing for the planning of IMRT treatment services CPT codes 77280-77295, 77300, 77305-77321, 77336, and 77370 are not to be billed in addition to 77301; however charges for those services should be included in the charge associated with CPT code 77301.
- b. Hospitals are not prohibited from using existing IMRT CPT codes 77301 and ~~77418~~ to bill for compensator-based IMRT ~~technology~~ **planning** in the hospital outpatient setting. **However, hospitals should use CPT 77418 for multi-leaf collimator-based IMRT delivery and 0073T for compensator-based IMRT delivery.**
- c. Payment for IMRT planning does not include payment for CPT codes 77332-77334 when furnished on the same day. When provided, these services are to be billed in addition to the IMRT planning code 77301.
- d. Providers billing for both CPT codes 77301 (IMRT treatment planning) and 77334 (design and construction of complex treatment devices) on the same day should append a modifier -59.

CMS will need to make further revisions to the “Flowchart for Understanding Intensity-Modulated Radiation Therapy” to include:

- Changing the dates from 2004 to 2006; and
- Clarifying which codes to use for multi-leaf collimator-based IMRT delivery (77418) and compensator-based IMRT delivery (0073T).

Background

In 2004, Medicare allowed all hospital outpatient departments to bill the existing IMRT procedure codes, CPT 77301 IMRT planning and CPT 77418 IMRT delivery, for compensator-based technology. This payment policy decision was clarified in the December 19, 2003 Medicare Program Transmittal 32 (Change Request 3007).

Effective January 1, 2005, the CPT descriptor for CPT 77418 was changed to explicitly exclude compensator-based technology and a new category III code 0073T was created to describe compensator-based IMRT delivery.

In 2005, CMS established a national payment policy for compensator-based IMRT delivery 0073T performed in hospital outpatient departments and freestanding radiation oncology centers. For payment purposes, Medicare cross-walked compensator-based IMRT delivery (0073T) to CPT code 77418 (multi-leaf collimator-based IMRT delivery) in APC 412. A Medicare Program Transmittal was not issued to provide revised coding guidance to hospitals that offer IMRT services.

For 2006, CMS proposes to maintain compensator-based IMRT delivery (0073T) in APC 412. **We support Medicare's decision to assign 0073T to APC 412.** As mentioned previously, the December 19, 2003 Program Transmittal 32 (Change Request 3007) is outdated and incorrect.

.decimal requests that CMS either update the December 19, 2003 Medicare Program Transmittal 32 (Change Request 3007) or issue a new Medicare Program Transmittal to include compensator-based IMRT delivery code 0073T and coding guidance for IMRT planning and delivery.

Impact of Medicare's Payment Policy

In the year 2005, .decimal has added 25 new hospital system and freestanding cancer clinics to its customer ranks. Solid filters for IMRT are now in use in 32 states and more than 100 hospitals and freestanding clinics – numbers that are growing each month. These customers represent the widespread, practical application of solid filters for superior IMRT treatment delivery. Equivalent reimbursement to other established, proven radiation treatment delivery methods has enabled hospitals and clinics in large metropolitan areas like Detroit and Las Vegas, and rural areas like Plymouth, Indiana and the Appalachian foothills in North Carolina, to effectively treat cancer patients where they live with unparalleled accuracy. In places like Jacksonville, Illinois and rural South Dakota, Nebraska and West Virginia, physicians have now been able to treat patients where they live instead of having no choice but to have their patients endure uncomfortable travel and long periods away from home to receive treatment at distant hospitals. The accessibility to quality cancer care via solid, compensator-based IMRT that CMS continues to protect and provide for has made a substantial, positive impact to many cancer patients.

For example, in the Appalachian foothills extending from Asheville, North Carolina, the availability of solid IMRT now enables several clinics to provide quality radiation treatment where patients live. These clinics do not have the budget to purchase expensive equipment and their associated maintenance packages. Fortunately, CMS' continued support of equivalent reimbursement for solid, compensator-based IMRT has enabled these clinics to deliver superior treatment to their patients where the physician deems it medically appropriate. These patients no longer need to travel away from home to larger metropolitan areas for treatment, creating a significantly more comfortable treatment situation for patients and their families.

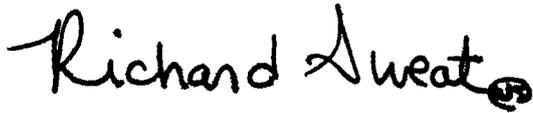
The clinical impact of compensator-based IMRT is also significant. Palm Tumor Clinic in California and many others have contacted .decimal to talk about the real, tangible patient benefits. For example, users report that the lower monitor units required for compensator-based IMRT has led to patients having far fewer and less severe side effects than other forms of radiation treatment. This has caused fewer missed treatments by patients who had previously been too ill from radiation side effects to maintain a regular treatment schedule.

Conclusion

We commend CMS and its staff in providing coverage and reimbursement for compensator-based IMRT. Your policy decisions have provided for a high-quality, cost-effective cancer treatment for Medicare beneficiaries and we thank you.

We appreciate your consideration of our recommendation to issue a Medicare Program Transmittal that includes coding guidance for compensator-based IMRT. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

A handwritten signature in black ink that reads "Richard Sweat" with a small circular mark at the end of the name.

Richard Sweat
President & CEO

CMS Manual System
Pub. 100-20 One-Time Notification

**Department of Health &
 Human Services (DHHS)
 Centers for Medicare &
 Medicaid Services (CMS)**
Transmittal 32
Date: DECEMBER 19, 2003
CHANGE REQUEST 3007

I. SUMMARY OF CHANGES: This One-Time Notification outlines changes in the OPPS for calendar year 2004. These changes were discussed in the OPPS final rule for 2004, which was published in the **Federal Register** on November 7, 2003. Unless otherwise noted, all changes are effective for services furnished on or after January 1, 2004. The changes will be implemented through revisions to the Outpatient Code Editor and the OPPS Pricer, which will be in effect for services furnished on or after January 1, 2004. Enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (DIMA) of 2003 does not affect the information in this One-Time Notification. Changes in the OPPS for calendar year 2004 resulting from the DIMA will be addressed separately.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004

***IMPLEMENTATION DATE: January 5, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|-------|----------------------------------|
| N/A | |
| | |
| | |

***III. FUNDING:**

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

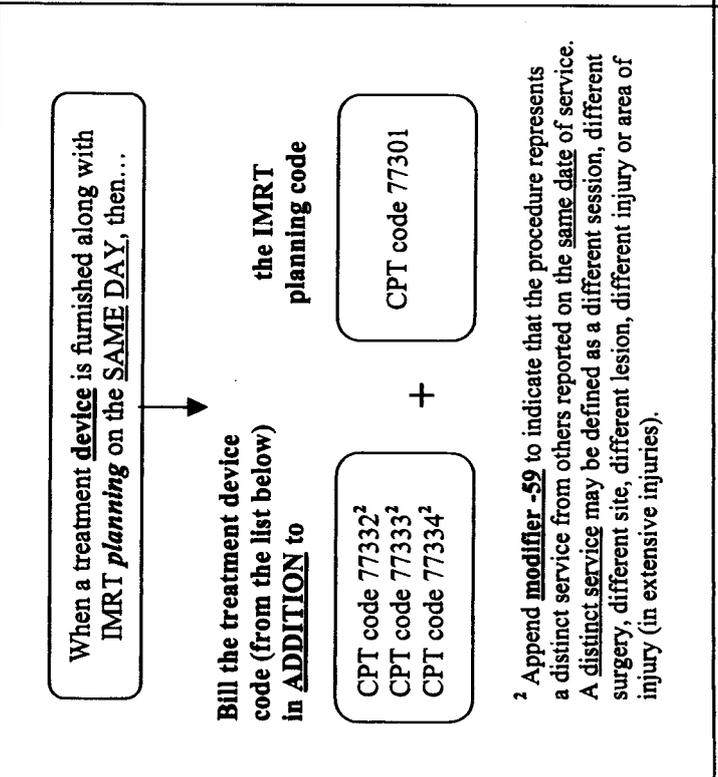
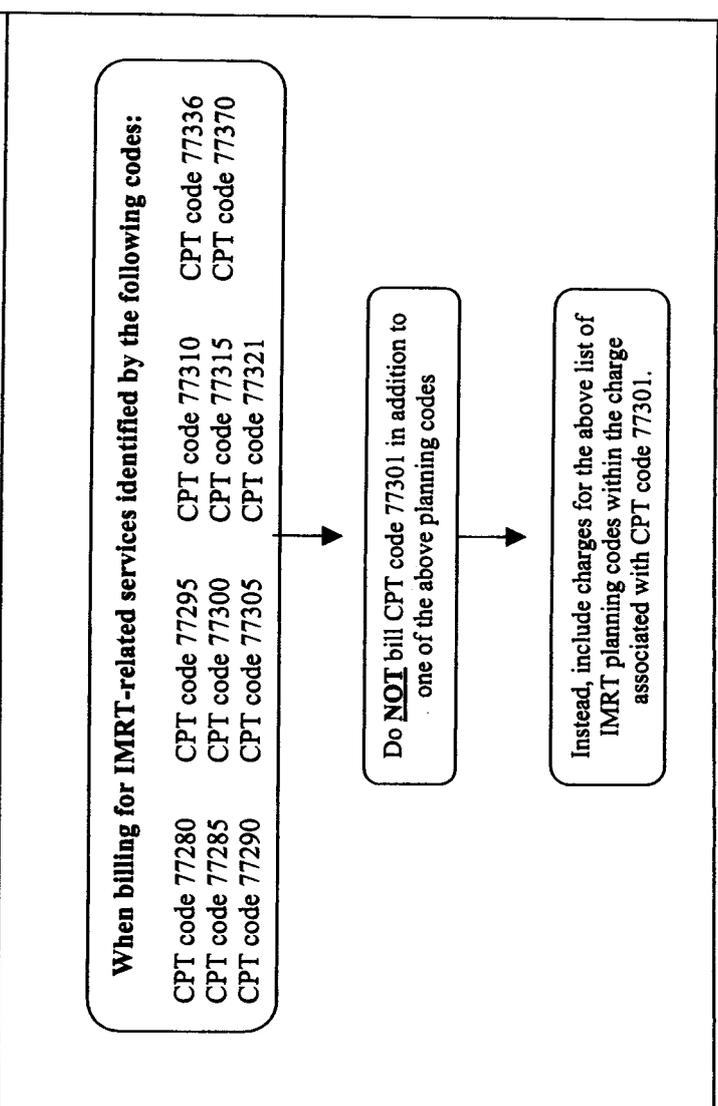
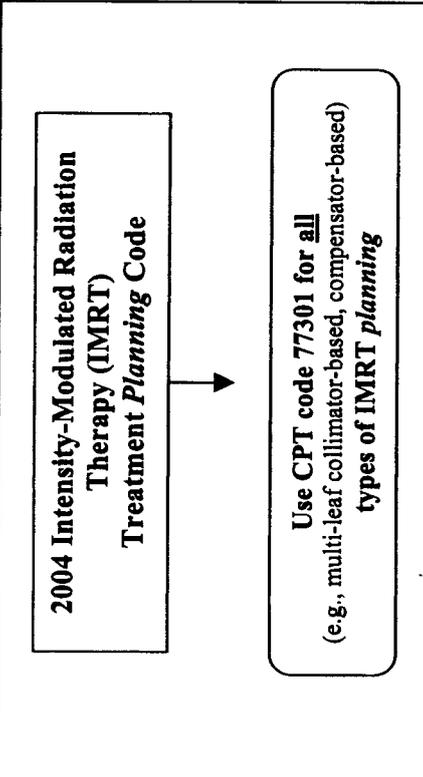
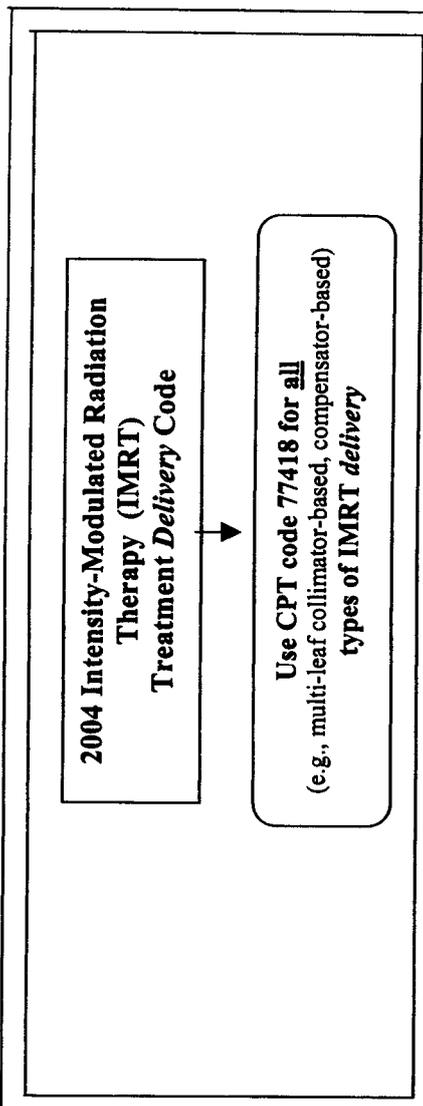
| | |
|----------|--------------------------------------|
| | Business Requirements |
| | Manual Instruction |
| | Confidential Requirements |
| X | One-Time Notification |
| | Recurring Change Notification |

***Medicare contractors only**

5. **Billing for Intensity Modulated Radiation Therapy** Intensity modulated radiation therapy (IMRT), also known as conformal radiation, delivers radiation with adjusted intensity to preserve adjoining normal tissue. IMRT has the ability to deliver a higher dose of radiation within the tumor and a lower dose of radiation to surrounding healthy tissue. Two types of IMRT are multi-leaf collimator-based IMRT and compensator-based IMRT. IMRT is provided in two treatment phases, planning and delivery. Effective January 1, 2004, when IMRT is furnished to beneficiaries in a hospital outpatient department that is paid under the hospital outpatient prospective payment system (OPPS), hospitals are to bill according to the following guidelines:
- a. When billing for the planning of IMRT treatment services CPT codes 77280- 77295, 77300, 77305 -77321, 77336, and 77370 are not to be billed in addition to 77301; however charges for those services should be included in the charge associated with CPT code 77301.
 - b. Hospitals are not prohibited from using existing IMRT CPT codes 77301 and 77418 to bill for compensator-based IMRT technology in the hospital outpatient setting.
 - c. Payment for IMRT planning does not include payment for CPT codes 77332 - 77334 when furnished on the same day. When provided, these services are to be billed in addition to the IMRT planning code 77301.
 - d. Providers billing for both CPT codes 77301 (IMRT treatment planning) and 77334 (design and construction of complex treatment devices) on the same day should append a modifier -59.

Flowchart for Understanding Intensity-Modulated Radiation Therapy¹

¹Note that the coding guidance reflected in this flowchart are for Medicare reporting purposes only. Medicare coding guidelines may differ from third party payer policies; therefore, hospitals may wish to contact their local third party payers for specific reporting guidelines related to billing for IMRT services.



² Append **modifier -59** to indicate that the procedure represents a distinct service from others reported on the same date of service. A distinct service may be defined as a different session, different surgery, different site, different lesion, different injury or area of injury (in extensive injuries).



Correlated Audioelectric Cardiography

September 6, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Management
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule", July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan;

Inovise Medical is a medical diagnostic company located in Portland, OR. Inovise manufactures AUDICOR (correlated audioelectric cardiography) which is currently in use in Emergency Departments around the country as a front line diagnostic to improve the diagnostic accuracy and reduce the time required to diagnose heart failure patients. AUDICOR technology enables physicians to provide earlier treatment for these patients resulting in better clinical outcomes.

The issue that is of concern to Inovise, and the hospitals utilizing the technology, is the current outpatient reimbursement for the technical component of correlated audioelectric cardiography (HCPCS 0069T). In the 2005 Outpatient Final Rule AUDICOR, described as "Acoustic Heart Sound Services," was incorrectly assumed to add minimal additional cost above the cost of an ECG test (HCPCS 93005) which is performed at the same time. As a result, HCPCS 0069T, the technical component of the AUDICOR procedure, was assigned a status code of "N - Items and Services packaged into APC Rates" and was bundled into the payment for ECG (APC 99 with a proposed 2006 national payment of \$22.58).

In actuality, the cost to a hospital to perform correlated audioelectric cardiography (AUDICOR) is significantly greater than even the cost of performing the ECG itself. In order to quantify the cost differential, Inovise worked closely with several hospitals to calculate their cost to perform an AUDICOR test as compared to an ECG test (please refer to attached cost analysis for details). Based upon the analysis, it was determined that the cost for performing an ECG test is estimated to be \$31.23. The analysis determined that a hospital's cost of performing an AUDICOR test is \$54.95. As the data indicates, the cost for performing AUDICOR exceeds the cost for ECG by \$23.72 per procedure.

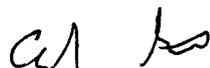
Inovise Medical, Inc.
10565 SW Nimbus Avenue, Suite 100
Portland, Oregon 97223-4311
p: 503.431.3800
f: 503.431.3801
w: www.audicor.com

Furthermore, we reviewed the median cost data used to establish the proposed 2006 APC payments (spreadsheet file "median_apc_1501p.xls" obtained from CMS website). The spreadsheet identifies the "True Median Cost" for APC 99 (the APC for ECG, HCPCS 93005) as \$23.06. When we compared the estimated cost of an AUDICOR test, it exceeded the median cost by approximately 2.4 times. We also compared the cost of an AUDICOR test to the lowest median cost service within APC 99 (HCPCS code 93041 as defined in hcpcs_medians_1501p.xls obtained from CMS website) in accordance with section 1833(t)(2) of the Act and found that the cost of AUDICOR exceeded the "True Median Cost" of HCPCS 93041 by 4.09 times (please see enclosed analysis for details).

Inovise respectfully requests, that in order to establish equitable reimbursement for hospitals, that CMS modify the status code for 0069T from "N - Items and Services packaged into APC Rates" to status "S - Significant Procedure, Not Discounted when Multiple" to allow the HCPCS code to be mapped directly to APC 99. In doing so, hospitals would be able to receive a separate APC payment for the performance of a correlated audioelectric cardiography procedure.

Thank you for your attention to this matter. Should you have any questions, please feel free to contact me at 503-431-3853.

Sincerely,



David Starr
Director of Marketing

Enclosure

CC: Director Herb Kuhn, Center for Medicare Management
Deputy Director Tom Gustafson, Center for Medicare Management
Director Elizabeth Richter, Hospital and Ambulatory Policy Group

COST ANALYSIS

EKG and AUDICOR Combined

| DISPOSABLES | Category | Units | Unit Cost | Extended Cost |
|---------------------------|----------|-------|-----------|-----------------|
| gauze, 2x2 | item | 2 | \$ 0.12 | \$ 0.24 |
| EKG paper | sheet | 5 | \$ 0.08 | \$ 0.40 |
| ECG Electrodes Disposable | lead | 15 | \$ 0.08 | \$ 1.20 |
| Audicor Electrodes | lead | 2 | \$ 12.50 | \$ 25.00 |
| AUDICOR Paper | sheet | 5 | \$ 0.15 | \$ 0.75 |
| AUDICOR Ink | item | 5 | \$ 0.05 | \$ 0.25 |
| Total | | | | \$ 27.59 |

SOURCE

CPEP
CPEP
CPEP
INOVISE
INOVISE
INOVISE

| LABOR EXPENSE | Minutes* | Hourly Rate | Extended Cost |
|-------------------------|-----------|-------------|-----------------|
| EKG Technician | 19 | \$ 17.80 | \$ 5.64 |
| Insurance Billing Staff | 20 | \$ 12.70 | \$ 4.23 |
| Medical Records | 8 | \$ 13.40 | \$ 1.79 |
| Scheduling Secretary | 5 | \$ 12.70 | \$ 1.06 |
| Transcriptionist | 5 | \$ 12.70 | \$ 1.06 |
| EKG Technician | 5 | \$ 17.80 | \$ 1.48 |
| Total | 62 | | \$ 15.26 |

*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP
INOVISE

| | |
|--------------------------|-----------------|
| FACILITY OVERHEAD | \$ 42.85 |
|--------------------------|-----------------|

Overhead calculated as equivalent to variable costs

| | |
|--------------------|-----------------|
| GRAND TOTAL | \$ 85.69 |
|--------------------|-----------------|

AUDICOR Alone

| DISPOSABLES | Category | Units | Unit Cost | Extended Cost |
|--------------------|----------|-------|-----------|-----------------|
| gauze, 2x2 | item | 2 | \$ 0.12 | \$ 0.24 |
| Audicor Electrodes | lead | 2 | \$ 12.50 | \$ 25.00 |
| AUDICOR Paper | sheet | 5 | \$ 0.15 | \$ 0.75 |
| AUDICOR Ink | item | 5 | \$ 0.05 | \$ 0.25 |
| Total | | | | \$ 25.99 |

CPEP
INOVISE
INOVISE
INOVISE

| LABOR EXPENSE | Minutes* | Hourly Rate | Extended Cost |
|----------------|----------|-------------|----------------|
| EKG Technician | 5 | \$ 17.80 | \$ 1.48 |
| Total | 5 | | \$ 1.48 |

INOVISE

| | |
|--------------------------|-----------------|
| FACILITY OVERHEAD | \$ 27.47 |
|--------------------------|-----------------|

Overhead calculated as equivalent to variable costs

| | |
|--------------------|-----------------|
| GRAND TOTAL | \$ 54.95 |
|--------------------|-----------------|

93005 EKG Alone

| DISPOSABLES | Category | Units | Unit Cost | Extended Cost |
|---------------------------|----------|-------|-----------|----------------|
| gauze, 2x2 | item | 2 | \$ 0.12 | \$ 0.24 |
| EKG paper | sheet | 5 | \$ 0.08 | \$ 0.40 |
| ECG Electrodes Disposable | lead | 15 | \$ 0.08 | \$ 1.20 |
| Total | | | | \$ 1.84 |

CPEP
CPEP
CPEP

| LABOR EXPENSE | Minutes* | Hourly Rate | Extended Cost |
|-------------------------|-----------|-------------|-----------------|
| EKG Technician | 19 | \$ 17.80 | \$ 5.64 |
| Insurance Billing Staff | 20 | \$ 12.70 | \$ 4.23 |
| Medical Records | 8 | \$ 13.40 | \$ 1.79 |
| Scheduling Secretary | 5 | \$ 12.70 | \$ 1.06 |
| Transcriptionist | 5 | \$ 12.70 | \$ 1.06 |
| Total | 57 | | \$ 13.77 |

*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP
*Minutes: CPEP

| | |
|--------------------------|-----------------|
| FACILITY OVERHEAD | \$ 15.61 |
|--------------------------|-----------------|

Overhead calculated as double variable costs

| | |
|--------------------|-----------------|
| GRAND TOTAL | \$ 31.23 |
|--------------------|-----------------|

APC Median Comparison

| | |
|--------------------------------|--------------------|
| APC 99 "True Median Cost" | \$ 23.06 |
| AUDICOR Cost vs. APC 99 | \$ 54.95 |
| AUDICOR Cost vs. APC 99 | 2.382769587 |

2 Times Rule Test for APC 99

| HCPCS Code | "True Median" |
|------------------------|-----------------|
| 93005 | \$ 23.14 |
| 93041 | \$ 13.42 |
| 93278 | \$ 33.85 |
| 93701 | \$ 23.33 |
| AUDICOR Cost | \$ 54.95 |
| AUDICOR Cost vs. 93041 | 4.09 |

DAVID WU
1ST DISTRICT, OREGON



1023 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3702
TELEPHONE: (202) 225-0855

620 SOUTHWEST MAIN STREET
SUITE 606
PORTLAND, OR 97205
TELEPHONE: (503) 326-2901
(800) 422-4003

<http://www.house.gov/wu>

Congress of the United States
House of Representatives

Washington, DC 20515-3701
August 29, 2005

COMMITTEES:

EDUCATION AND THE WORKFORCE

21ST CENTURY COMPETITIVENESS
EMPLOYER-EMPLOYEE RELATIONS

SCIENCE

RANKING MEMBER
ENVIRONMENT, TECHNOLOGY AND STANDARDS
SPACE AND AERONAUTICS

Mark B. McClellan, M.D., Ph.D.
Administrator Centers for Medicare and Medicaid Management
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing on behalf of Inovise Medical, Inc. of Oregon. Inovise is an innovative company in Congressional District One, and I am very concerned that its request for the proper billing code for its product be given all due consideration.

Representatives from Inovise would like to meet with you to discuss the current code being considered by CMS for their medical device, Audicor. I am confident that a meeting would clear up any misunderstandings of the product and provide the opportunity for CMS to understand how the product works and why the current code under consideration does not reflect the true nature of the product or how it is used.

Thank you for taking the time to consider this request. I look forward to a positive partnership between CMS and Inovise. Should you have questions or if I can be of assistance, please call me at 503-326-2901.

With warm regards,

David Wu
Member of Congress

DW:rp
CC: Director Herb Kuhn, Center for Medicare Management
Deputy Director Tom Gustafson, Center for Medicare Management
Director Elizabeth Richter, Hospital and Ambulatory Policy Group
David Starr, Director of Strategic and Product Marketing, Inovise, Inc.

United States Senate

WASHINGTON, DC 20510-3704

August 30, 2005

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan:

It is my pleasure to support Inovise Medical, Inc. of Oregon. Representatives from Inovise will be meeting with your staff on September 13, 2005 to discuss the current APC coding that has been assigned by the Centers for Medicare and Medicaid Services (CMS) for the medical device Audicor. I am hopeful that this meeting will clear up any misunderstandings of the product and provide an opportunity for CMS to understand why the current APC coding does not reflect the true nature of the product or how it is used.

Thank you for your prompt attention to this request. If you have any questions, please do not hesitate to contact Gary Schmidt of my staff at 503-326-2910.

Sincerely,



Gordon H. Smith
United States Senator

GHS:gs

cc: Ms. Patti White, Chief Executive Officer, Inovise Medical, Inc.

SEP - 2 2005

5-1
Josh Ofman, MD, MSHS
Vice President
Reimbursement and Payment Policy
Global Government Affairs

AMGEN

555 Thirteenth Street, NW
Suite 600 West
Washington, DC 20004
202.585.9663
Fax 202.289.9730
Email jofman@amgen.com
www.amgen.com

September 1, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Handwritten notes:
Date
SP
H...
P...
A... d

Re: CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule; Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status (Non Pass-Throughs)

Dear Administrator McClellan:

Amgen is writing to comment on the calendar year 2006 Medicare hospital outpatient prospective payment system (OPPS) proposed rule (Proposed Rule), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on July 25, 2005.¹ As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, our comments address the "Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status" section of the Proposed Rule as it applies to all separately payable drugs and to our innovative biological product, Aranesp[®] (darbepoetin alfa), in particular.²

Amgen commends the agency on its proposal to use a free market-based approach to set the OPPS payment rates for separately payable drugs, including Aranesp[®]. The proposed payment methodology for all separately payable drugs would allow the payment rates for these products to reflect market dynamics and would encourage the desired market adaptations that manufacturers and hospitals make to remain competitive. Regarding Aranesp[®] in particular, CMS accurately notes in the Proposed Rule that "the ASP [average sales price] data represents market prices for this biological" and that using the ASP methodology to establish the 2006 OPPS payment rate for Aranesp[®] "will permit market forces to determine the appropriate payment for this biological."³ For these reasons, CMS

¹ 70 Fed. Reg. 42674.

² Aranesp[®] is indicated for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies and for the treatment of anemia associated with chronic renal failure, including patients either on dialysis or not on dialysis.

³ 70 Fed. Reg. 42727.

has proposed not to apply an "equitable adjustment" under Section 1833(t)(2)(E) of the Social Security Act to the payment rate of Aranesp[®] in 2006. We recommend that CMS finalize these proposals as they appear in the Proposed Rule.

Below, we provide our comments on the proposed payment methodology for separately payable drugs. Additionally, we present further evidence to support the treatment of Aranesp[®] under the Proposed Rule.

We support the proposed payment of ASP+6 percent for separately payable outpatient drugs and encourage CMS to finalize this proposal.

We are pleased that CMS is attempting to pay hospitals at rates reflective of the costs that they incur to purchase drugs and biologicals. Because reported ASP data are based on the prices paid in the market for drugs and biologicals, we support the CMS proposal to set payment at ASP+6 percent and to add an additional percentage to reflect pharmacy handling costs. Section 1847A of the Social Security Act mandated the implementation in 2005 of the ASP+6 percent methodology for drugs and biologicals covered in the physician office setting, and CMS has recently proposed paying for all separately payable drugs administered in dialysis facilities at ASP+6 percent.⁴ By expanding this payment methodology to separately payable drugs covered under OPPI in 2006, payment rates would be made consistent across these three primary settings of outpatient care. For these reasons, Amgen encourages CMS to finalize this proposal as it appears in the Proposed Rule.

We also support additional payments for pharmacy overhead costs.

As the Medicare Payment Advisory Commission (MedPAC) recommended in its June 2005 report to the U.S. Congress, separate payment for pharmacy costs is needed because these costs would not be accounted for in acquisition-based payment for drugs under OPPI in 2006. The Commission correctly concluded that hospital handling costs for drugs, biologicals, and radiopharmaceuticals are "not insignificant."⁵ Therefore, the CMS proposal is a positive step towards providing more appropriate payment for the costs associated with providing drugs in the hospital outpatient setting, and we urge the agency to implement the proposal to pay hospitals separately for pharmacy overhead costs.

By implementing market-based pricing and eliminating the "equitable adjustment" for Aranesp[®], as CMS proposes, Medicare and its beneficiaries will pay less for comparable clinical outcomes.

In past years, OPPI payments for separately payable drugs have been determined under different methodologies, and CMS has applied an "equitable adjustment" using a dose conversion ratio despite extensive submissions showing the clinical comparability of Aranesp[®] and Procrit[®] as well as lower costs of Aranesp[®]. With the implementation of the proposed market-based payment rates for all separately payable drugs, including Aranesp[®], it is clear that an "equitable adjustment" is not needed in 2006. CMS correctly notes this fact in the Proposed Rule.⁶

⁴ 70 Fed. Reg. 45846.

⁵ MedPAC (2005). *Report to the Congress: Issues in a Modernized Medicare Program*. http://www.medpac.gov/publications/congressional_reports/June05_Entire_report.pdf.

⁶ 70 Fed. Reg. 42727.

By setting payment rates using market-based prices that reflect the value that other payers, physicians, and, in other settings, even the Medicare program ascribe to products, there is no need for CMS to impose its regulatory authority to adjust pricing in the case of Aranesp[®] and Procrit[®] in 2006. In fact, such a measure merely would create distortions in the market, which are not needed given the agency's clearly stated position that the ASP+6 payment system reflects market-based pricing. Furthermore, as we will demonstrate below, there are clear and compelling clinical and economic data to support the agency's proposal not to apply an "equitable adjustment" in 2006.

Clinical practice guidelines support the clinical comparability of Aranesp[®] and Procrit[®] at commonly administered doses.

The treatment of Aranesp[®] under the Proposed Rule is fully consistent with well-established clinical practice guidelines, which have been validated by randomized, comparative clinical trials. Most notably, the National Comprehensive Cancer Network (NCCN) *Clinical Practice Guidelines in Oncology™: Cancer and Treatment-Related Anemia* and the U.S. Pharmacopeia Drug Information (USP DI[®]) monograph list the commonly used initial dose of Aranesp[®] at approximately 200 micrograms (mcg) every other week (Q2W).⁷ Amgen's clinical submissions to CMS in 2003 and 2004 demonstrated that Aranesp[®] under these guidelines achieve comparable clinical outcomes to commonly administered doses of Procrit[®].^{8,9}

Definitive head-to-head, randomized controlled trials of Aranesp[®] and Procrit[®] confirm the validity of the clinical practice guidelines.

CMS should also be aware that Amgen's 2003 and 2004 submissions have now been validated by randomized, head-to-head clinical trials, which represent the highest standard of evidence to evaluate comparative effectiveness.^{10,11} These new trials have been added to the established evidence base regarding the comparability of clinical outcomes of Aranesp[®] 200 mcg Q2W and Procrit[®] 40,000 international units (IUs) every week (QW) for chemotherapy-induced anemia patients. Among these studies is a properly powered, 1,200-person, non-inferiority trial that represents the optimal methodology to address the question of clinical comparability. These studies demonstrated the following key points:

- Comparable clinical outcomes between Aranesp[®] and Procrit[®] were observed in clinically relevant, well-established endpoints, indicating that the products are comparable at 200 mcg Q2W and 40,000 IUs QW, respectively;

⁷ Sabbatini (2004). *Clinical Practice Guidelines in Oncology™: Cancer and Treatment-related Anemia*. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp; Klasco, R, Ed. (2004). Darbepoetin alfa (systemic). *USP DI[®] Drug Information for the Healthcare Professional*. Greenwood Village, Colorado, Thomson Micromedex. Note that the USP DI[®] monograph references weight-based dosing.

⁸ "Darbepoetin Alfa Briefing Document" prepared for the meeting between Amgen and CMS on April 28, 2003.

⁹ Data from Amgen Inc., submission on the 2005 OPPS proposed rule, dated October 7, 2004.

¹⁰ Glaspy, J., R. Berg, et al. (2005). Final results of a phase 3, randomized, open-label study of darbepoetin alfa 200 mcg Q2W versus epoetin alfa 40,000 IUs QW in patients with chemotherapy-induced anemia. *41st Annual Meeting*. Orlando, FL, American Society of Clinical Oncology: Presented at the 41st Annual Meeting of the American Society of Clinical Oncology.

¹¹ Schwartzberg, L., L. Yee, et al. (2004). "A randomized comparison of every-2-week darbepoetin alfa and weekly epoetin alfa for the treatment of chemotherapy-induced anemia in patients with breast, lung, or gynecologic cancer." *Oncologist* 9(6): 696-707.

- Aranesp[®] was also shown to be clinically comparable (as defined by the pre-specified non-inferiority margin) to Procrit[®] with respect to transfusion requirements, the sole clinical factor recognized by the U.S. Food and Drug Administration, as well as other standard, validated clinical factors, including hemoglobin outcomes; and
- Patients and the Medicare program receive substantial economic and other benefits from the convenient once every-2-week dosing schedule with Aranesp[®], which requires half the number of injections than Procrit[®].

Amgen will continue to share new clinical developments regarding Aranesp[®] with CMS.

Aranesp[®] costs Medicare and beneficiaries less than Procrit[®].

Aranesp[®] is less expensive than Procrit[®] at the payment rates that CMS published in the Proposed Rule, as noted in Table 1. By applying the proposed payment rates for doses based on the aforementioned clinical guidelines and validated in randomized controlled trials, the Medicare program will pay less for Aranesp[®] than Procrit[®] and achieve the same clinical outcomes.

Table 1: Comparison of Proposed Weekly OPPS Payments for Aranesp[®] and Procrit[®]

| | Procrit[®] | Aranesp[®] |
|---------------------------------|--|---|
| Weekly Dose | 40,000 IUs (40,000 IUs QW) | 100 mcg (200 mcg Q2W) |
| Dosing Assumption Source | Clinical Guidelines and Head-to-Head, Randomized Controlled Trials | Clinical Guidelines and Head-to-Head, Randomized Controlled Trials |
| Proposed OPPS Payment | <u>\$9.99</u> per 1,000 IUs (Proposed Rate for Q0136 ¹²) | <u>\$3.28</u> per 1 mcg (Proposed Rate for Q0137 ¹²) |
| Total Weekly Payment | <u>\$399.60</u> ($\9.99×40) | <u>\$328.00</u> ($\3.28×100) |
| Payment Comparison | Medicare and Beneficiary Payments are <u>\$71.60 Less</u> per Week, per Patient with Aranesp[®] on Average | |

Based on dosing referenced in clinical guidelines, the Medicare payment would be, on average, \$71.60 less per week, per patient for Aranesp[®] than Procrit[®]. Of that total amount, beneficiaries would be responsible for \$14.32 less per week in Part B copayments. Additionally, due to the less frequent dosing pattern of Aranesp[®], Medicare and its beneficiaries would also pay less for drug administration and related hospital outpatient services for Aranesp[®] than for Procrit[®], as shown in Table 2.

¹² 70 Fed. Reg. 50880.

Table 2: Comparison Including the Proposed Weekly OPPS Payment Amounts for Services Related to Aranesp® and Procrit®

| Assumptions¹³ | Procrit® | Aranesp® |
|---|--|-----------------|
| Drug Administration Services | CPT® code 90782 (injection SC/IM) | |
| <i>Injections (APC 0353) per 2 weeks¹⁴</i> | 2 at \$23.46 | 1 at \$23.46 |
| <i>Total Medicare payment</i> | \$46.92 | \$23.46 |
| Hospital Outpatient Visits | CPT® code 99211/2 (outpatient visit, established) | |
| <i>Visits (APC 0600) per 2 weeks¹⁵</i> | 2 at \$51.56 | 1 at \$51.56 |
| <i>Total Medicare payment</i> | \$103.12 | \$51.56 |
| Total 2-Week Service Payments | \$150.04 | \$75.02 |
| Total 2-Week Payment Comparison Including Services and Product Doses | Medicare and Beneficiary Payments are \$218.22 Less per Patient, per 2 Weeks with Aranesp® on Average | |
| Weekly Payment Comparison Including Product Doses | Medicare and Beneficiary Payments are \$109.11 Less per Patient, per Week with Aranesp® on Average | |

Based on the lower costs of Aranesp® as outlined in Table 2, the Medicare program and its beneficiaries would pay about an estimated \$15.3 million less for Aranesp® vs. Procrit® in 2006.¹⁶ In light on the clearly demonstrated lower costs of Aranesp®, CMS should finalize the proposed payment rate for the product.

In summary, we agree with the agency's proposal for Aranesp® and other separately payable drugs.

As CMS prepares to finalize changes to OPPS for 2006, we recommend the following:

- adopt the market-based ASP+6 percent methodology to set payment rates for separately payable drugs,
- implement the proposal to pay hospitals separately for pharmacy overhead costs, and
- finalize the proposed market-based treatment of Aranesp® in order to achieve significant Medicare payment reductions and savings for beneficiaries.

¹³ This comparison assumes the provision of one administration service and one hospital outpatient visit on the date that the drug is delivered. Because actual services rendered depend on the needs of specific patients, patients may receive an administration service, an outpatient visit, both services, or some other combination of services on a particular date of service.

¹⁴ The amount used in this analysis represents the 2006 proposed national average Medicare payment allowable, including the beneficiary copayment, for APC 0353. 70 Fed. Reg. 50811.

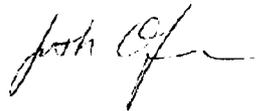
¹⁵ The amount used in this analysis represents the 2006 proposed national average Medicare payment allowable, including the beneficiary copayment, for APC 0600. The most commonly billed levels of outpatient visits on the same dates of service with Procrit® injections are CPT® 99211 and 99212, which both map to APC 0600. 70 Fed. Reg. 50822.

¹⁶ Estimate based on data from an independent analysis of 2004 OPPS claims conducted by The Moran Company. Data on file.

* * * * *

Amgen appreciates this opportunity to comment on the important issues raised in the Proposed Rule and looks forward to working with you to ensure that Medicare beneficiaries treated in the hospital outpatient setting continue to have access to new and important biological therapies. Please contact Chris Mancill by phone at (202) 585-9618 or by email at cmancill@amgen.com to arrange a meeting or if you have any questions regarding our comments. Thank you for your attention to this important matter.

Regards,

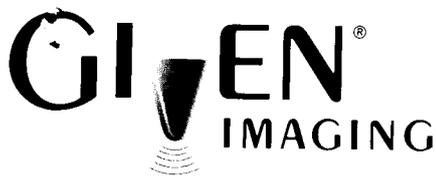


Joshua J. Ofman, MD, MSHS
Vice President,
Reimbursement and Payment Policy



David Beier
Senior Vice President,
Global Government Affairs

cc: Ms. Leslie Norwalk, Deputy Administrator, CMS
Mr. Herbert Kuhn, Director, Center for Medicare Management, CMS
Ms. Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
Dr. Barry Straube, Acting Chief Medical Officer, Acting Director of the Office of Clinical Standards and Quality, CMS
Dr. Peter Bach, Senior Advisor, Office of the Administrator, CMS
Dr. Steve Phurrough, Director, Coverage and Analysis Group, CMS
Mr. Jim Hart, Director, Division of Outpatient Care, CMS
Ms. Joan Sanow, Deputy Director, Division of Outpatient Care, CMS
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Expanding the scope of GI

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August 31, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention:
CMS-1501-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Handwritten notes:
Baltimore
Baltimore
Baltimore

Subject: Interrupted Procedures / Modifier -52 - Partial reduction or discontinuation of services that do not require anesthesia

Dear Sirs:

We wish to comment on the application of the proposed 50 percent reduction in payment for procedures reported with a -52 modifier. Our concern relates to the capsule endoscopy of the esophagus (PillCam ESO). As background, our request for a new technology APC for this procedure was denied on the grounds that the procedure could be adequately described by an existing code, namely, CPT Code 91110 with a -52 modifier.

Code 91110 is defined as follows:

Gastrointestinal tract imaging, intraluminal (eg. capsule endoscopy), esophagus through ileum, with physician interpretation and report.
(Append modifier 52 if the ileum is not visualized).

As we understand the proposal, the rationale for a reduction for a discontinued or reduced service is the assumption that the resource costs of a procedure reported with modifier -52 are substantially diminished. We are not really in a position to comment on the reasonableness of the proposed reduction in payment for a discontinued radiological service. However, the reduction in payment for a capsule endoscopy of the esophagus is totally inappropriate and inconsistent with the HOPPS objective to pay appropriately based on the resources required to produce a service.

We do not disagree that consistent with the definition and the parenthetical of code 91110 that there is a substantial reduction in the **professional component** associated with the interpretation of the images from the procedure as compared to the number of images obtained when the complete GI tract, including the ileum is visualized. That was certainly the intent of adding the parenthetical statement in the CPT definition of appending a -52 modifier. However, there is absolutely **no** reduction in the resources

required for the technical component or the facility costs covered by the APC rate for Code 91110 whether or not the ileum is visualized. This is because the staff, equipment, overhead and, most importantly, supply costs associated with the disposable capsule camera are identical for capsule endoscopy of the esophagus and for capsule endoscopy of the entire GI tract. In fact, the capsule camera which costs \$450 represents about 90 percent of the overall APC rate and is identical for both types of capsule procedures. The only difference in the two procedures is the portion of the GI tract that is imaged and the number of images that are captured for the physician to interpret in order to obtain a diagnosis. Thus, this does not represent a "reduced service" from the standpoint of hospital resource costs.

Although our immediate concern is with the capsule endoscopy of the esophagus, we would note that the same concern and rationale would apply in any situation where the ileum is not visualized whether in a capsule endoscopy of the complete GI tract or in a capsule endoscopy of the esophagus.

If CMS decides to finalize the proposed policy and provide for a 50 percent reduction in payment for services for which a -52 modifier is appended, we urge CMS not to apply this reduction to the capsule endoscopy of the esophagus for the reasons described above.

This could be accomplished by a variety of actions including the following:

- Authorize hospitals to report Code 91110 without a -52 modifier for capsule endoscopy of the esophagus or other situations when the ileum is not visualized.
- If the decision is to require the use of the modifier, establish an administrative exception so that intermediaries would not reduce payment under HOPPS in any situation where Code 91110-52 is reported. A reduction in payment would of course still be applicable for the professional component.
- Establish a temporary code to be used by hospitals to report the TC or technical component of the capsule endoscopy of the esophagus procedure. The payment should be equal to the APC rate for Code 91110.

Thank you for the opportunity to offer these comments.

Sincerely,


Cheryl Soderholm

Director of Reimbursement

Given Imaging, Inc

404-992-7891

ENCLOSURE

| Resources Used by the Facility and Physician Wireless Capsule Endoscopy | | | |
|--|-----------------|------------|----------------|
| | Minutes | Nurse Time | Physician Time |
| Equipment Preparation | | | |
| Disinfect capule endoscope | single use | | |
| Charge batteries (8 hours) | not included | | |
| Disinfect equipment & sensor array | 30 | 30 | |
| Setup sensor array in sleeves | 10 | 10 | |
| Patient Preparation | | | |
| Explain procedure guidelines | 5 | 5 | |
| Clean and shavethorax | 15 | 15 | |
| Attach sensor array | 10 | 10 | |
| Setup DataRecorder with SensorArray | 5 | 5 | |
| Activate and test capsule endoscope | 5 | 5 | |
| Adjust and attach belt | 5 | 5 | |
| Endoscopy Procedure | | | |
| Discuss ingestion technique | 5 | | 5 |
| Introduce capsule endoscope | 20 | | 20 |
| Observe patient | 15 | 15 | |
| Endoscope advance, patient waiting | 0 | | |
| Patient sedation & monitoring | n/a | | |
| Complete Procedure & Download | | | |
| Disconnect belt and equipment | 5 | 5 | |
| Remove sensor array from thorax | 5 | 5 | |
| Discuss patient feedback | 10 | | |
| Patient discharge | 10 | 10 | 10 |
| DataRecorder download | 45 | | |
| Physician Procedure Review | | | |
| Patient discharge | 10 | | 10 |
| Capsule endoscopy review (2,600 images) | 20 | | 20 |
| Burn CD at workstation, manage images and data | 20 | | 20 |
| Prepare report | 20 | | 20 |
| Total time allocation (minutes) | 270 | 120 | 105 |
| Total time allocation (hours) | 4.5 | 2 | 1.75 |
| Hourly Rates (including benefits) | | | |
| Labor Costs (including benefits) | | \$45.00 | \$175.00 |
| Endoscopy Workstation Capital Cost (3 yr. depreciation) | \$25,850.00 | \$90.00 | \$306.25 |
| Annual Maintenance Fee for Workstation | \$2,500.00 | | |
| Workstation cost (allocated per use) | \$214.24 | | |
| Capsule Endoscope Disposable Cost | \$450.00 | | |
| Miscellaneous Supplies (razors, shaving cream, towels, CDs, disinfectant, etc.) | \$15.00 | | |
| Required procedure room & clean room | | | |
| Adjustable Examination Table | | | |
| Required waiting area | | | |
| Standard overhead rate (estimated) | \$212.00 | | |
| Estimated Procedure Cost (excluding physician time) | \$981.24 | | |