Submitter : **Dr. John Lipman** **Date: 09/25/2006**

Organization : **Windy Hill Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-151-Attach-1.PDF

HHacll #
151

INTERVENTIONAL

September 13, 2006

The Honorable Mark McClellan, MD
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

As a physician with privileges at Wellstar Windy Hill Hospital, Department of Interventional Radiology I am pleased to have the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

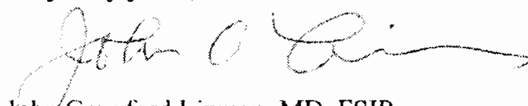
CPT codes 0071T and 0072T are currently assigned to APCs 195 and 202 with national unadjusted payment rates of $1,595 and $2,454, respectively. The procedures in the current APC assignments are less resource intensive procedures for the hospital to offer making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. The hospital charges for the MR guided focused ultrasound procedure range from $18000 to $24000. We would ask that CMS consider assignment to APC 127 which has a more appropriate clinical and resource cost assignment.

MR guided Focused Ultrasound has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients in this area. While the vast majority of women are not Medicare beneficiaries, Medicare payment is used as a benchmark for private insurers in setting payment rates for hospitals and physicians, and thus, CMS's actions are critical to helping establish appropriate payment and access. The appropriate APC assignment will be a signal to all payers that the ability to offer medical procedures that are less invasive, less traumatic and offer faster recovery should be accepted by health insurers.

I thank you for your consideration to reassign CPT codes 0071T and 0072T Magnetic Resonance Imaging Guided Focused ultrasound ablation of fibroids (leiomyomata) to an APC with a more clinical and resource cost that is appropriate. The reassignment will allow the hospital outpatient departments and women to have access to this important treatment option.

Our hospital and patients appreciate CMS's consideration of this important issue.

Very truly yours,



John Crawford Lipman, MD, FSIR
Department of Interventional Radiology, Windy Hill Hospital

2480 Windy Hill Road Suite 400 Marietta, Georgia 30067 | PHONE: 770.953.2600 | FAX: 770.953.2602

Submitter : **Dr. Gwenn Pavlovitz** **Date: 09/25/2006**

Organization : **Dr. Gwenn Pavlovitz**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-152-Attach-1.DOC

Attach# 152

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device since they rely on the use of a high cost device that is bundled into the procedure payment. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a

separate procedure.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Thank you for this opportunity to provide comment.

Sincerely,

Gwenn Pavlovitz, MD

Gwenn Pavlovitz, MD
215 W. Washington Street
Grafton, WI 53024

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A.Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Dr. James Woods** **Date: 09/25/2006**

Organization : **Dr. James Woods**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-153-Attach-1.DOC

Attach
153

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

James H. Woods, MD

James H. Woods, MD
10400 West North Avenue, Suite 480
Milwaukee, WI 53226-2425
414-778-6670

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A.Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

CMS-1506-P-154

Submitter : Dr. Neil Friedman

Date: 09/25/2006

Organization : The Hoffberger Breast Center at Mercy

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-154-Attach-1.DOC

Attach#
154

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT 19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

In excess of 200,000 women are diagnosed annually with early stage breast cancer. Many of these patients move on to lumpectomy followed by radiation therapy. A newer alternative to whole breast irradiation is Partial Breat Irradiation (PBI). This is given over 5 days rather than 7-6 weeks. The initial results show this to be equivalent. Therefore I recommend Partial Breast Irradiation (PBI) for carefully selected breast cancer patients. If the proposed reduction takes place, my hospital and I may no longer be able to provide PBI to Medicare patients, as the procedure requires a device costing $2750. As a result, Medicare will be limiting access to its beneficiaries.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Neil B. Friedman, MD

Neil B. Friedman, MD, FACS
Director, Hoffberger Breast Center at Mercy Health System
Baltimore, MD

cc. Senator Barbara Mikulski, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Jeff Bird

Organization : Xoft

Date: 09/25/2006

Category : Device Industry

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 Federal Register) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a device of brachytherapy and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive.

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical brachytherapy. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity brachytherapy. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year s proposed rule. Should you have any questions please do not hesitate to email me at jeff@shv.com.

Respectfully,
Jeff Bird, M.D. Ph.D.
Managing Director
Sutter Hill Ventures

CMS-1506-P-155-Attach-1.PDF

Attac- 155

SUTTER HILL VENTURES
755 PAGE MILL ROAD
SUITE A-200
PALO ALTO, CALIFORNIA 94304-1005

PHONE (650) 493-5600
FAX (650) 858-1854
WWW.SHV.COM

September 25, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

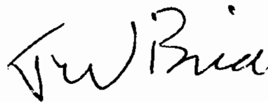
CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at jeff@shv.com.

Respectfully,



Jeff Bird, M.D., Ph.D.
Managing Director
Sutter Hill Ventures

Submitter : Dr. Jay Malmquist **Date:** 09/26/2006

Organization : AAOMS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Inpatient Only Procedures

Inpatient Only Procedures

See attachment

CMS-1506-P-156-Attach-1.DOC

Attach # 156

American Association of Oral and Maxillofacial Surgeons

9700 West Bryn Mawr Avenue • Rosemont, Illinois 60018-5701 • 847.678.6200 • 800.822.6637 • FAX 847.678.6286 • 847.678.6279

Daniel J. Daley, Jr., DDS, MS
President
Robert C. Rinaldi, PhD, CAE
Executive Director

September 22, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore MD 21244-1850

RE: August 23, 2006 Proposed Rule: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Sir/Madam:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) appreciates the opportunity to comment on the August 23, 2006 Proposed Rule for the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates. The AAOMS is specifically interested in commenting on the CPT surgical procedures proposed to be excluded from payment of an ASC facility fee.

The AAOMS represents approximately 8,000 U.S. oral and maxillofacial surgeons. The mission of the Association is to provide a means of self-governance relating to professional standards, ethical behavior and responsibilities of its fellows and members; to contribute to the public welfare; to advance the specialty; and to support its fellows and members through education, research and advocacy.

The AAOMS Committee on Healthcare and Advocacy convened a special meeting to discuss this proposed rule and reviewed each code independently to assess the merits of deleting specific codes. However, we cannot support the entire proposed rule, and we strongly urge that certain procedures be retained on the coverage list.

The Association ***does not support*** the deletion of the following codes and we hope to be able to work with CMS in reconsidering maintaining ASC coverage for:

21049 Excision of benign tumor or cyst of maxilla; requiring intra-oral osteotomy

(eg, locally aggressive or destructive lesion (s))

21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints
31040	Pterygomaxillary fossa surgery, any approach
42225	Palatoplasty for cleft palate; attachment pharyngeal flap

The Association understands and appreciates the statutory requirement that mandates review and updating of the ASC list. **Our concern with deleting the above services from the coverage list is that it will create patient hardships and impede access to care, as well as increased program expenses.** Oral and maxillofacial surgeons are the primary surgical providers of patient services associated with this subgroup of codes. As such, we know that reliance on a methodology of using solely Medicare claims data on site of service to define where a procedure is commonly performed is flawed in instances where the vast majority of these services are provided for patients who are not part of the Medicare data base. The flaw in this methodology is clearly supported by the extremely low frequency of many of these procedures in the Medicare population: The 8,000 fellows and members of the AAOMS primarily perform these procedures in younger, non-disabled patients.

In addition, failure to take into account the clinical population of patients who undergo these services, the data wholly fails to incorporate or even consider the *type of anesthesia* associated with these care scenarios. For instance, CMS is proposing the exclusion of CPT code 21195 which was performed only five times in 2004 for Medicare covered patients, according to published CMS data. Although we agree that this service may be performed in an inpatient setting, there are numerous instances when this procedure, can be performed in an ASC where it can be accomplished under conscious sedation/general anesthesia.

As a specialty society, we recognize that the CMS classification of ASC procedures dictates the pattern of coverage in the ASC industry, both for federally funded programs and the commercial carriers. The effect of arbitrarily deleting codes that require general anesthesia in a non-Medicare population has the potential of leading to industry chaos and seriously undermines standardization and quality of care. We encourage CMS to take a leadership position on this issue by recognizing the special needs of the pediatric population and the historical fact that ASCs have proven to be very cost effective in the pediatric surgery arena.

It is the firm belief of the Association that the ASC list should not restrict a practitioner from utilizing the benefits of an ASC when a patient's medical condition, age, or anesthetic requirement would best be served by performing the procedure in an ASC. Furthermore, the Association believes that, especially after reviewing the CMS frequency data for those procedures, the exclusion of these codes would not translate into significant cost savings for the

program. We also believe that removing these codes actually could increase costs by shifting those services which could be safely performed in the ASC to the more costly hospital setting.

The AAOMS appreciates your consideration of our comments. Should you have any questions, please contact Karin Wittich, Associate Executive Director, Practice Management and Governmental Affairs, at (847) 233-4334 or via e-mail at karinw@aaoms.org.

Sincerely,

President

cc: Committee on Healthcare and Advocacy
Committee on Governmental Affairs
Robert C. Rinaldi, Ph.D., CAE, executive director
Karin K. Wittich, Associate Executive Director,
Practice Management and Government affairs
Patricia Serpico, Manager, Practice Management

Submitter : Dr. Kenneth Olivier **Date:** 09/26/2006

Organization : University of Florida

Category : Physician

Issue Areas/Comments

Impact

Impact

Dear CMS,

I was contacted about the proposed changes to the reimbursement of Radioimmuotherapy (RIT) by Glaxo-Smith-Kline, so I had my office manager apply the new numbers to our patients treated in the last calendar year. By his careful calculation we would loose $65,000 over the 8 patients we treated last year (see attached file). Obviously this change, if administered as proposed, would end the delivery of RIT in the US.

RIT has an important, and unfortunately underutilized, role in the treatment of patients with relapsed low-grade lymphoma. The pivotal study for Bexxar, presented in the July 2001 Journal of Oncology, showed that patients treated with Bexxar had twice the response rate and twice the duration of response than the patient's prior chemotherapy regimen. This speaks to the important efficacy of this medication in this patient population.

Please consider revising your proposed rates. The initial proposal will effectively end the delivery of RIT in the US, which would be a severe disservice to patients with relapsed low-grade lymphoma.

Sincerely,

Kenneth R Olivier, MD
University of Florida
kolivier@ufl.edu

CMS-1506-P-157-Attach-1.PDF

Attach #
157

Radiation Oncology
CMS Proposed Rates for Radioimmunotherapy - 2007
Bexxar and Zevalin Therapy
9/26/2006

	2006 WAC	Our Current Cost	Proposed 2007 CMS Rates
Tositumomab, 450 mg.	$ 2,188.75	$ 1,775.00	$ 1,510.52
Diagnostic dose of I-131 Tositumomab	$ 2,317.50	$ 1,875.00	$ 1,368.17
Tositumomab, 450 mg	$ 2,188.75	$ 1,775.00	$ 1,510.52
Therapeutic dose of I-131 Tositumomab	$ 20,085.00	$ 16,250.00	$ 11,868.78
Compounding	$2,000-$3,000	$ 2,750.00	$ -
	$ 26,780.00	$ 24,425.00	$ 16,257.99
Projected Loss per Case		$ (8,167.01)	
Cases Done in Last 12 Months		8	
Projected Annual Loss		$ (65,336.08)	

m:\personal\ritz\CMS\2007 CMS Proposed Rates-Bexxar & Zevalin_proj impact_09-26-06.xls

Submitter : **Mr. John Millett** **Date: 09/26/2006**

Organization : **Nuclear Medicine Professionals, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

OPPS Impact

OPPS Impact

Such a drastic reduction in myocardial spect reimbursements would increase healthcare costs. As our population ages, our limited resources should be spent on early detection and prevention. We can do 100 cardiac SPECT scans for the cost of one bi-pass surgery. Cutting reimbursements would cripple our ability to provide such testing and directly hinder access to this very important imaging procedure. I urge you to reconsider these drastic cuts in reimbursements. It is unfair to ask healthcare providers to provide healthcare at a net loss. If there is no financial incentive for physician's to provide these scans, I fear most of them will discontinue doing so.

Submitter : Mrs. Traci Millett **Date:** 09/26/2006

Organization : Nuclear Medicine Professionals

Category : Other Health Care Provider

Issue Areas/Comments

Impact

Impact

Such a drastic reduction in myocardial spect reimbursements would increase healthcare costs. As our population ages, our limited resources should be spent on early detection and prevention. We can do 100 cardiac SPECT scans for the cost of one bi-pass surgery. Cutting reimbursements would cripple our ability to provide such testing and directly hinder access to this very important imaging procedure. I urge you to reconsider these drastic cuts in reimbursements. It is unfair to ask healthcare providers to provide healthcare at a net loss. If there is no financial incentive for physician's to provide these scans, I fear most of them will discontinue doing so.

Submitter : **Mrs. Melody Edgington** **Date: 09/26/2006**

Organization : **Western Washington Oncology**

Category : **Other Health Care Professional**

Issue Areas/Comments

Impact

Impact

September 20, 2006
The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT
Dear Administrator McClellan:

I am writing on behalf of Western Washington Oncology to address an issue of great importance to Medicare beneficiaries with cancer. Western Washington Oncology is a physician owned facility, which provides PET/CT, among other imaging services. We serve approximately 2500 cancer patients annually, many of whom lack ready access to a hospital. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay outpatient facilities and could compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by free standing facilities traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to $865 the same rate proposed for conventional PET from its current rate of $1,250. For outpatient facilities that represent a cut up to 60% to 70% in one year from current carrier based prices.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures such as biopsies required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Western Washington Oncology of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

The proposed payment rate reduction for PET/CT would seriously underpay imaging centers, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Melody Edgington
Chief Executive Officer
Western Washington Oncology

Cc: File

Submitter : C Van Wallendael **Date:** 09/26/2006

Organization : Xoft,Inc.

Category : Device Industry

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I would like to comment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mr. Timothy Ravenscroft** **Date: 09/26/2006**

Organization : **Bristol-Myers Squibb Medical Imaging**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-162-Attach-1.PDF

Attach# 162

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

September 26, 2006

Via FedEx and Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program HCAHPS® Survey, SCIP, and Mortality; Proposed Rule
CMS-1506-P - Comments on Drug Administration and CCI edits

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the above-captioned Proposed Rule updating the Medicare Hospital Outpatient Prospective Payment System ("HOPPS").[1] A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, including DEFINITY®, Vial for Perflutren Lipid Microsphere Injectable Suspension, a contrast imaging drug used to enhance and delineate cardiac structures during echocardiography procedures.[2]

In these comments, BMSMI would like to call to your attention a specific issue with respect to payment for the intravenous (IV) administration of echocardiography contrast imaging drugs, like DEFINITY®.**

** Please note that a separate comment letter is being submitted to Dr. McClellan/CMS by BMSMI with respect to the 2007 proposed Medicare HOPPS payment for radiopharmaceuticals

[1] 71 Fed Reg. 49506 (Aug. 23, 2006).

[2] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

As described more fully below, under current coding policies, Medicare is aggregating the payment for the IV injection of the echocardiography contrast imaging drug into the payment for the associated echocardiography procedure. This policy is impractical for two reasons:

1. It ignores the fact that the echocardiography procedure codes do not describe the use of contrast imaging drugs, and

2. There is no evidence that the costs for administration of the contrast imaging drugs are included in the claims-based cost estimates for the associated echocardiography procedures.

We request, therefore, that CMS remove any coding edits from the Outpatient Code Editor (OCE) and hospital version of the Correct Coding Initiative (CCI) that aggregate the IV administration code C8952 "Therapeutic, prophylactic or diagnostic injection; intravenous push"[3] with the associated rest echocardiography procedure codes 93307 and 93308.[4]

Background

Echocardiography procedures are used to evaluate patients with known or suspected cardiac disorders. In most cases, echocardiograms can be interpreted by physicians, and the information can be used in patient management. However, in up to 20-percent of cases[5], unenhanced echocardiograms are suboptimal and repeat studies or additional testing may be required. Echocardiography contrast imaging drugs are FDA-approved intravenously-administered drugs that can enhance images in patients with suboptimal echocardiograms. Clinical studies have shown that echocardiography contrast imaging agents can salvage up to 58-91-percent of unevaluable images.[6] Published papers have estimated that substantial cost savings can be obtained from use of contrast-enhanced echocardiography in cases with suboptimal unenhanced echocardiograms.[7]

Issue

The American Medical Association (AMA) released new Current Procedural Terminology (CPT) codes effective January 1, 2006, to report IV administration of drugs. In the notes accompanying the new codes, the AMA instructed providers not to use the new codes when an IV injection is an inherent part of a procedure. Administration of contrast imaging drugs in diagnostic imaging is given as an example of when the new codes should not be used because IV injection is considered part of the procedure.
This limitation on use of the new codes in diagnostic imaging *generally* makes sense because outside of echocardiography, there are specific codes for contrast-enhanced diagnostic imaging procedures which

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[3] Should CMS adopt all of the CPT drug administration codes for HOPPS in 2007, the relevant code would be CPT 90774 "Therapeutic, prophylactic or diagnostic injection (specify substance or drug); Intravenous push, single or initial substance/drug."
[4] 93307 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete;" 93308 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study"
[5] Waggoner AD, Ehler D, Adams D, et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: Recommendations of the American Society of Echocardiography Council on cardiac sonography. *J Am Soc Echocardiogr.* 2001;14:417-20.
[6] Package insert for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (September 2004).
[7] Shaw LJ, Gillam L, Feinstein S, et al. Use of an intravenous contrast agent (Optison™) to enhance echocardiography: efficacy and cost implications. *Am J Man Care.* 1998;4: SP169-SP176.

differentiate between procedures that do and do not involve IV administration of contrast. **However, this is not the case with echocardiography procedures. Echocardiography procedure codes were developed before echocardiography contrast imaging drugs were approved by the FDA, and the echocardiography procedure codes do not mention use of contrast imaging drugs.**

Consistent with the AMA instruction, CMS's CCI is now aggregating payment under the new IV injection codes into the payment for contrast-enhanced imaging procedures, when performed. Unfortunately, CCI has included echocardiography procedures under this aggregating policy. Although it may be reasonable to aggregate the new IV administration codes when there are specific contrast-enhanced diagnostic imaging procedure codes, there is no justification for aggregating the IV administration of contrast into the payment for echocardiography procedures.

Echocardiography procedure codes do not describe use of contrast imaging drugs because these drugs are not used in the majority of procedures. Therefore, it is unlikely that hospitals—which typically would assign a single chargemaster rate to each echocardiography procedure code—have included costs for the IV administration of contrast imaging drugs into the charge for the echocardiography procedure. As the HOPPS payment rates for the echocardiography procedures are based upon hospital charges, the HOPPS payment for these codes would not cover any expenses related to IV administration of contrast imaging drugs.

The costs for the IV administration of echocardiography contrast imaging drugs are not insubstantial relative to the costs of the associated echocardiography procedures. The IV administration of echocardiography contrast imaging drugs involves the same resources as required for other IV drug administration procedures. The claims data released to support the Proposed Rule indicate a median cost of $50.81 for IV injection procedures[8] versus median costs of $196.18 and $124.55 for the associated rest echocardiography procedures (93307 and 93308, respectively). Therefore, the cost of the IV injection procedure is approximately 25-40 percent of the cost of the associated echocardiography procedure. These amounts are too substantial to aggregate into the payment for the echocardiography procedure.

By aggregating payment for IV administration of echocardiography contrast imaging drugs into payment for echocardiography procedures, providers will not be compensated for any of the time, skills and supplies required for the IV administration of echocardiography contrast imaging drugs. Without fair reimbursement/payment for these services, providers may avoid use of echo contrast even in suboptimal echocardiography cases where use of contrast may salvage the image and may preclude the need for repeat or additional testing.

Request

We urge CMS to remove any edits from the OCE and the hospital version of the CCI that aggregate the IV drug injection code(s) C8952 (or 90774) into the codes for the associated echocardiography procedures (93307 and 93308). Deleting the OCE and CCI edits should remove financial disincentives limiting appropriate use of echocardiography contrast imaging drugs for medicare beneficiaries to help salvage images when an unenhanced echocardiography image is suboptimal.

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[8] Median costs for code 90784 (deleted code used for rate-setting) from file CMS1506P_Median_Costs_for_Hospital_Outpatient_Services_BY_HCPCS_Code.xls (accessed from http://www.cms.hhs.gov August 9, 2006).

We appreciate your consideration of our comments. Please contact Jack Slosky, Ph.D. at jack.slosky@bms.com or at 978 671-8191 if you have any questions about the comments made in this letter.

Sincerely yours,

Timothy Ravenscroft
President, Bristol-Myers Squibb Medical Imaging

Cc: American Society of Echocardiography (ASE)
American College of Cardiology (ACC)
Medical Imaging Contrast Agent Association (MICAA)
Jack Slosky, Ph.D., BMSMI

Submitter : **Mr. Timothy Ravenscroft** **Date: 09/26/2006**

Organization : **Bristol-Myers Squibb Medical Imaging**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-163-Attach-1.PDF

Attach # 163

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

September 26, 2006

Via Overnight Mail

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P Comments to the 2007 HOPPS Proposed Rule on Payment for Radiopharmaceuticals/Radionuclides, Pharmacy Handling and Overhead Costs, and Threshold for Separate Payment

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments on the Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) for Calendar Year (CY) 2007, 71 Fed. Reg. 49,506 (August 23, 2006).

A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and radionuclides (RPs) and other medical imaging drugs. Accordingly, BMSMI has a keen interest in CMS's proposed changes to HOPPS for 2007.

In brief, we support CMS's efforts to preserve Medicare beneficiary access to high quality RPs and CMS's work to recognize the complexity of RPs through appropriate Medicare payment for RPs. BMSMI urges CMS to fully integrate the unique features of RPs into workable reimbursement/payment methods, especially with respect to calculating and determining the unique RP overhead and handling costs. CMS should pay for all RPs separately and eliminate the $55 threshold for separate Medicare payment. Further refinements and alternatives are needed. Below, we summarize and then present in detail our comments and recommendations.

I. EXECUTIVE SUMMARY RECOMMENDATIONS

A. Radiopharmaceuticals and Radionuclides (RPs)

- BMSMI acknowledges that CMS's 2007 proposal for setting fixed payments for all RPs is a positive starting point to develop appropriate Medicare payments for RPs. However, the current CMS proposal needs critical refinements/adjustments to make such fixed Medicare payments appropriate and fair for many RPs, and ensure compliance with the standard of "average acquisition cost."

A Bristol-Myers Squibb Company

- Consequently, BMSMI recommends that CMS refine/adjust the current proposed 2007 fixed payments for RPs (as described below) or that CMS continues using cost-to-charge ratios (CCRs) as a methodology for payment of RPs through 2007, consistent with the APC Advisory Panel's August 24, 2006, recommendation. It is important to note that CMS advised hospitals to include overhead and handling costs together with their charges for the RPs on the claims they submitted in 2006. This process of generating new and accurate data has only started and further time is needed so that CMS may acquire and analyze at least a full year of updated 2006 claim data.
- We support CMS's decision to use the "mean" cost as the basis for payment for RPs, (if CMS would not continue CCR for one additional year), **but only if** an appropriate amount, for example, **10 to 20 percent**, can be added to reflect the unique overhead costs required for patient and hospital staff protections and regulatory compliance associated with these RPs.
- Hospital charges do not uniformly or accurately include pharmacy overhead and handling costs for RPs. RPs are unique radioactive products which require special shielding, waste disposal, and handling. In the June 2005 Report to Congress, MedPAC addressed the issue of Medicare payment for pharmacy handling costs in hospital outpatient departments and indicated that hospitals' handling costs for RPs exceed costs for all other types of drugs. The Report also recommended that CMS establish separate payments to cover the costs that hospitals incur for handling drugs and RPs. We agree with MedPAC and urge CMS to increase payment for RPs to accurately reflect these costs, and implement a mechanism to track pharmacy overhead and handling costs, which are not otherwise included in hospital charges.
- We recommend that CMS update HOPPS payment for RPs on an annual basis.
- Finally, given the unique nature of RPs, we recommend that CMS eliminate the threshold for separate payment and pay separately for all RPs to ensure that payments appropriately cover pharmacy overhead and handling costs for these unique drugs. At minimum, if CMS maintains a threshold, there should be no inflationary adjustment.

B. <u>Contrast Drugs</u>

- In the interest of parity and harmonization of payment rates across the various outpatient settings, we recommend that CMS use ASP+6% rather than ASP+5% as the basis for payment for medical contrast imaging drugs.
- In 2006 NPRM, CMS said hospital average acquisition costs for drugs including pharmacy overhead and handling costs would be covered by the average sales price plus 8 percent (ASP+8%). Subsequently, in 2006 Final Rule, CMS indicated that ASP +6% would cover the hospitals average acquisition costs for drugs. In the 2007 proposed rule, CMS is proposing that average acquisition costs for drugs and handling are equal to ASP+5%. We are concerned because CMS has never disclosed the full data on which these determinations have been made. Accordingly, BMSMI requests that CMS provide the data and rationale supporting these changes.

C. **Drug Payment Methodology / Stability**

- Stability in drug payment and drug payment methodology is needed. In addition to the HCPCS coding changes, drug payment methods have changed each year since 2002. CMS should maintain a stable method/parity with other outpatient settings until it has several years' data to suggest that a different method is warranted.

II. DETAILED COMMENTS AND RECOMMENDATIONS

A. Payment Methodology for Radiopharmaceuticals and Radionuclides (RPs)

CMS's proposal for setting fixed payments for RPs is a positive starting point to develop appropriate Medicare payments for RPs. However, we believe some additional critical refinements are needed to make such fixed Medicare payments appropriate and fair for many RPs and comply with the statutory standard for payment based on "average acquisition costs".

For this reason, BMSMI recommends (1) CMS implement much needed refinements (as described below) if the agency moves forward with fixed payments for RPs in 2007 or, (2) in the alternative, consistent with the APC Advisory Panel's August 24, 2006, recommendation, CMS continue using cost-to-charge ratios (CCRs) as a methodology for payment of RPs through 2007.

1. Use of mean costs as a basis for payment

When CMS transitions to a fixed payment methodology, BMSMI supports CMS's decision to use the mean cost as the basis for payment for RPs, but only if an appropriate amount, such as 10 - 20 percent can be added to reflect overhead, inventory, and costs associated with patient and hospital staff protections.

The use of mean cost is appropriate for several reasons. First, "mean" is defined as the arithmetic average. Therefore, mean cost rather than median cost as a basis for payment is more consistent with statutory mandate for "average hospital costs" for SCODs, which includes RPs.

Second, several detailed studies support the addition of a substantial margin for pharmacy handling and overhead costs. One study of cost report data from 55 hospitals found that labor and administrative costs (excluding acquisition costs) accounted for about one-third of the expenses in the pharmacy cost centers (Kathpal Technologies 1999). MedPAC analyzed cost report data from more than 3,300 hospitals and determined that hospital reporting of pharmacy costs varied greatly. And while the variability made it difficult to separate drug acquisition costs from pharmacy handling costs, MedPAC did find that in nearly 1,200 hospitals overhead and handling, including salaries, wages and fringe benefits, made up about 25 percent of the direct costs in pharmacy cost centers.

With regard to RPs, MedPAC determined that the overhead and handling costs were assigned to the nuclear medicine department and while MedPAC could not determine the magnitude of these costs, MedPAC did determine that RPs required far greater resources than any other category of drugs, including cytotoxic/chemotherapy agents.

In sum, "mean" is a better starting point proxy for average acquisition costs for drugs and RPs and, as such, complies better with the statutory standard for payment. However, the majority of hospitals do not yet factor in the overhead and handling costs related to RPs when they establish the charge for the RP itself. For this reason, if CMS adopts "mean" as the basis for payment of RPs, we recommend that CMS add 10 to 20 percent for overhead and handling costs.

2. Continuation of CCR for one more year

It is important to note that CMS advised hospitals to include overhead and handling costs together with their charges for the RPs on the claims they submitted in 2006. This process of generating new and accurate data has only started and further time is needed so that CMS may acquire and analyze at least a full year of updated 2006 claim data. In addition, hospitals need some stability in billing, coding, and payment mechanisms. There have been numerous, almost annual changes in coding and payment for RPs. Such changes could undermine hospitals' good faith efforts in following CMS's instructions on billing and charges. It is also important to note the APC Advisory Panel's recommendations to CMS to continue using CCR as a basis for payment for RPs.

B. Pharmacy Overhead and Handling

Hospital charges for RPs do not uniformly or accurately include pharmacy overhead and handling costs for these special products, as noted above. With respect to RPs, all the overhead and handling costs that are required for traditional drugs also apply to RPs. In addition, RPs are unique radioactive products which require special shielding, waste disposal, and handling. The additional safety and shielding requirements affect every component of handling costs. For example, because the products are radioactive, hospitals must use lead-lined storage containers. In addition, staff must wear special protection (leadlined gloves, aprons, and glasses) during preparation of the products. Likewise, hospitals' disposal of RPs must comply with the Nuclear Regulatory Commission (NRC) and state radiation safety requirements. Staff must wear special badges so their exposure to radioactivity can be measured and monitored. Finally, the hospital must establish a radiation safety office with a radiation compliance officer and obtain and comply with the NRC licensure requirements.

The June 2005 MedPAC report indicated that hospitals' handling costs for RPs exceed costs for all other types of drugs. Therefore, BMSMI urges CMS to fully integrate the unique features of RPs into a workable reimbursement method, especially with respect to calculating and determining pharmacy overhead and handling costs. Thus, whether CMS adopts "mean" + as a basis for payment of RPs or continues CCR for another year, we recommend that CMS implement a mechanism to track pharmacy overhead and handling costs, which are not otherwise included in hospital charges.

C. Annual Update of HOPPS Payment for RPs

We recommend that CMS update HOPPS payment for RPs on an annual basis. Rather than use claims data and mean costs, which may not be feasible or practical, it may be appropriate for CMS to use the Pharmacy Price Index as a basis for these annual payment updates for RPs.

D. Threshold for Separate Payment

Hospitals incur all traditional pharmacy overhead and handling costs for RPs plus the additional licensing, handling, and monitoring costs related to radioactivity discussed above. These exceptional costs are incurred for every RP, i.e., products with acquisition costs of less than $50, as well as those products with costs that exceed $50. Because the use of any RP greatly increases the resources involved in a procedure, we recommend that CMS eliminate the threshold for separate payment and pay separately for all RPs to ensure that payments appropriately cover pharmacy overhead and handling costs for these unique drugs.

At minimum, if CMS maintains a threshold, there should be no inflationary adjustment.

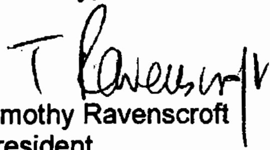
E. Payment for Cardiac Contrast Agent Drugs – Separately Payable Covered Outpatient Drugs

In the 2006 proposed rule CMS said that hospitals' average acquisition cost for drugs plus overhead and handling was covered under ASP+8%. However, in the 2006 Final Rule, CMS said average acquisition cost plus overhead and handling was covered by ASP+6%. For 2007, the agency is claiming that average acquisition cost and handling is covered by ASP-5%. Because the Kathpal and MedPAC studies suggest that pharmacy overhead and handling costs are closer to 25 percent we request CMS provide greater detail to support its assertion that average acquisition cost plus overhead/handling are covered under ASP+5%.

* * * *

We appreciate your attention to these important matters and urge CMS to make the important refinements proposed above. Please contact Jack Slosky, Ph.D., FACNP, FASNC at jack.slosky@bms.com or (978) 671-8191 for any further information regarding this BMSMI comment letter.

Sincerely,



Timothy Ravenscroft
President
Bristol-Myers Squibb Medical Imaging

cc: American Society of Nuclear Cardiology (ASNC)
Council on Radionuclides and Radiopharmaceuticals (CORAR)
Nuclear Medicine APC Task Force (NMAPCTF)

Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
Terry Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Carol Bazell, M.D., Director, Division of Outpatient Care, CMS
Ken Simon, M.D., Medical Officer, CMS

Jack Slosky, Ph.D., BMSMI

Submitter : **Dr. Alvaro Martinez** **Date: 09/26/2006**

Organization : **Dr. Alvaro Martinez**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-164-Attach-1.DOC

Attach #
164

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

There are two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and then the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment,	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

immediate						

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. This is an important option for women electing breast conservation surgery followed by radiation therapy. Traditional whole breast radiation is a 5 day a week treatment, for 6-7 weeks. Breast brachytherapy offers the option of treating the lumpectomy cavity in a much shorter 5 days (twice daily) of treatment.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate date.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ration payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.
Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Alvaro Martinez, MD

Alvaro Martinez, MD
3601 West Thirteen Mile Road
Royal Oak, MI 48073
248-551-7058

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. Frank Vicini** **Date: 09/26/2006**

Organization : **Dr. Frank Vicini**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-165-Attach-1.DOC

Attach #
165

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

There are two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and then the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	**2006 APC**	**2006 Payment**	**2007 Proposed APC**	**2007 Proposed Payment**	**Payment Change 2006-2007**	**Percent Change 2006-2007**
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These

CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate date.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ration payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Frank Vicini, MD

Frank Vicini, MD
3601 West Thirteen Mile Road
Royal Oak, MI 48073
248-551-7029

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. Aradhana Kaushal** **Date: 09/27/2006**

Organization : **Dr. Aradhana Kaushal**

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 Federal Register) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a device of brachytherapy and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive.

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical brachytherapy. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity brachytherapy. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year s proposed rule.

Submitter : **Dr. Mary Frances McAleer** **Date: 09/27/2006**

Organization : **Dr. Mary Frances McAleer**

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 Federal Register) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a 'seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive.'

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical brachytherapy. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity brachytherapy. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule.

Submitter : **Mr. Trevor M Fitzgerald** **Date: 09/27/2006**

Organization : **NW Chapter AAPM**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.
I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.
Please See Attached Document.

Trevor M Fitzgerald, MSc, DABR, CCPM
Certified Radiological Physicist
Secretary Treasurer NW Chapter American Association of Physicists I Medicine

Wenatchee Valley Medical Center, 820 N Chelan Ave, Wenatchee, WA 98801

CMS-1506-P-168-Attach-1.DOC

Attach# 168

Comment RE: Docket: CMS-1506-P - Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates

Dear Sir/Madame:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

I would like to thank you for the opportunity to comment on this year's proposed rule.

CPT 77799 ASSIGNMENT

Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule.

Trevor M Fitzgerald, MSc, DABR, CCPM
Certified Radiological Physicist
Secretary Treasurer NW Chapter American Association of Physicists I Medicine

Wenatchee Valley Medical Center, 820 N Chelan Ave, Wenatchee, WA 98801

Submitter : **Dr. Geoffrey Ibbott** **Date: 09/27/2006**

Organization : **UT M.D. Anderson Cancer Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1506-P-169-Attach-1.DOC

HHT ... FF
169

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History™

September 22, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at gibbott@mdanderson.org.

Respectfully,

Geoffrey S. Ibbott, Ph.D.
Professor and Chief, Section of Outreach Physics
Director, Radiological Physics Center

Submitter : **Hsin Lu** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-170-Attach-1.DOC

Attach #
170

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned must cover the cost of the device. The cost of the brachytherapy device is the same whether it is implanted at the time of lumpectomy or at a separate time.

This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. The hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Hsin H. Lu, MD

Hsin H. Lu, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Steven Carpenter** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-171-Attach-1.DOC

Attach# 171

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
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Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned must cover the cost of the device. The cost of the brachytherapy device is the same whether it is implanted at the time of lumpectomy or at a separate time.

This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. The hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Steven Carpenter, MD

Steven Carpenter, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Brian Butler** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-172-Attach-1.DOC

H/Hc/-FF
172

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

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Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

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This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. The hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

E. Brian Butler, MD

E. Brian Butler, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Kam Chiu** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-173-Attach-1.DOC

Attach #
173

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
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Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

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In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

J. Kam Chiu, MD

J. Kam Chiu, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Bin Sing Teh** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-174-Attach-1.DOC

Attachment 174

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned must cover the cost of the device. The cost of the brachytherapy device is the same whether it is implanted at the time of lumpectomy or at a separate time.

This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. The hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Bin Sing Teh, MD

Bin Sing Teh, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Arnold Paulino** **Date: 09/27/2006**

Organization : **Methodist Hospital Radiation Oncology Associated**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1506-P-175-Attach-1.DOC

Attach #
175

Radiation Oncology Associated

Hsin H. Lu, M.D.
L. Steven Carpenter, M.D.
E. Brian Butler, M.D.

J. Kam Chiu, M.D
Bin Sing Teh, M.D
Arnold C. Paulino, M.D

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. I have two areas of concern in the HOPPS proposed rule. The first is the proposed assignment of 19296 and 19297 to new APCs, and the second is the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, it will limit my ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

912 Heights Blvd ♦ Houston, Texas 77008 ♦ (713) 520-8860 ♦ Fax: (713) 520-8775
mhradiationoncology@hotmail.com

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned must cover the cost of the device. The cost of the brachytherapy device is the same whether it is implanted at the time of lumpectomy or at a separate time.

This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. The hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Arnold C. Paulino, MD

Arnold C. Paulino, MD
Methodist Hospital
6565 Fannin, MS 121B
Houston, TX 77030
(713) 790-2637, ext. 123

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee
Representative Joe Barton, Chairman, Energy and Commerce Committee
Representative Michael Burgess, Energy and Commerce Health Subcommittee
Representative Kay Granger, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division of Outpatient Care
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. John Anderson **Date:** 09/27/2006

Organization : Volunteer Radiation Oncology Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-176-Attach-1.DOC

Attach#
176

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. I have two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and second, the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from –22.8% to –37.0%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

In addition, our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

John Anderson, MD

John M. Anderson, MD, PhD
Baptist Regional Cancer Center
Knoxville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Marta Hayne** **Date: 09/27/2006**

Organization : **Central Baptist Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-177-Attach-1.DOC

Attach # 177

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. I have two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and second, the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from –22.8% to –37.0%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Marta Hayne, MD

Marta Hayne, MD
Central Baptist Hospital
Lexington, KY

Cc. Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Dr. Alan Beckman

Date: 09/27/2006

Organization : Central Baptist Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-178-Attach-1.DOC

Attach#
178

September 26, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. I have two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and second, the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, ranging from –22.8% to –37.0%. Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device ($2750) surpasses the proposed payment rate. These CPT codes are device-dependent and must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate time.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

As a practitioner focusing on breast cancer treatment, I am making 2 recommendations. First I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Alan Beckman, MD

Alan Beckman, MD
Central Baptist Hospital
Lexington, KY

Cc. Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, M.D., Chair, American Society of Therapeutic Radiation and Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Dr. Laura Della Vecchia**

Date: 09/27/2006

Organization : **Dr. Laura Della Vecchia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-179-Attach-1.DOC

Attach# 179

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. For those women choosing breast conservation surgery, traditional whole breast radiation is a

daily treatment (5 days/week) for 6-7 weeks. Breast brachytherapy offers the alternative of treatment to the tumor bed in a shortened course of twice daily treatments in just 5 days. This is clearly an important option for the working woman, elderly or those living some distance from a radiation facility.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.
Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

Laura Della Vecchia, MD

Laura Della Vecchia, MD
43331 Commons Drive
Clinton Twp, MI 48038
586-263-5410

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A.Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Dr. Michael Rice** **Date: 09/28/2006**

Organization : **Univ. of Louisville Hospital/Brown Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing nuclear medicine physician currently working at The University of Louisville Hospital and the James Graham Brown Cancer Center in Louisville, Kentucky. Presently, I participate in the labor intensive administration of radio-immunotherapy (RIT) agents in the treatment of certain cancers. I am both concerned and alarmed by the potential reimbursement cuts that are proposed for these types of drug treatment modalities in the 2007 HOPPS payment plan. The expertise required by many different specialists to succesfully carry out one of these treatments is extensive and it requires extreme logistical effort by many different parties. Personally, I have never been motivated to treat patients with these types of agents from a financial perspective as there is very poor professional reimbursement when taking into account the necessary labor commitment. I feel compelled to offer this service because I believe it to be a relatively non-toxic treatment option for sick individuals suffering from a horrible disease. As a teaching physician in a university based academic medical center, I believe it is our duty to provide patients with a large array of treatment options which are best suited to their lifestyles despite the expense of the chosen therapy. Admittedly, the radio-immunotherapy agents available commercially today seem extra-ordinarily expensive to produce and administer. However, when one recognizes the numerous medical experts from various specialties that are necessary to successfully complete these therapies, the expense can be validated. The successful completion of administering a radio-immunotherapy agent such as BEXXAR or ZEVALIN typically involves the expertise of radiopharmacists, radiation oncologists, medical oncologists, nuclear medicine physicians, radiologist, radiation safety officers, nuclear medicine technologists, skilled nurses, and a variety of ancillary staff. Although I am cognizant of the high cost of medical care and I recognize the need to curtail unnecessary expense, this is one area of reimbursement where we should not attempt to "cut corners." The current reimbursement for administering these drugs from a professional standpoint is pathetic at best, but that is not my concern, despite that being the component which personally affects me the most financially. Attempts at cutting the reimbursement for the technical component will significantly impair medical facilities' ability to offer this treatment option. Further cuts in technical reimbursement will not allow hospitals and various other medical facilities attempting to offer this service to even "break even." Based on the proposed cuts for 2007, many facilities would lose money offering these types of therapies, thus minimizing their incentive to treat cancer patients who are candiates for radio-immunotherapy. Further cuts in reimbusement specific to radio-immunotherapy drugs legitimately threatens both current and future sites that show a willingness to provide this highly specialized treatment. The production of other similar drugs in the future that could one day be used to treat a variety of cancers would also be slowed and jeopardized. Ultimately, such an action on your part potentially threatens the well being and treatment options of future cancer patients throughout the country. I would strongly encourage you to maintain the current reimbursement specific to radio-immunotherapy (RIT) agents and attempt to find other less vital arenas to minimize excessive cost. Thank you for your consideration.

Submitter : **Ms. Karen Linder** **Date: 09/28/2006**

Organization : **Thompson Health**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS

OPPS

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Vince Yahl** **Date: 09/28/2006**

Organization : **St. Rita's Medical Center**

Category : **Pharmacist**

Issue Areas/Comments

Medication Therapy Management Services

Medication Therapy Management Services

Though created and defined in recent years, MTMS services cannot all be viewed alike. The breadth of activity required to provide these services can vary drastically. Some MTMS is imbedded within the claims data and has been provided for years. However, MTMS was not ultimately created simply to provide nomenclature for these services or nomenclature for new services that are also be imbedded within. The scope of services provided to patients by pharmacists in recent years has escalated to emphasize patient safety, clarity of medication regimens, preventative follow up, and cost effective use of medications.
As more products become available, regimens become more complex, and more data published, the role of pharmacists is becoming more important.
Traditionally, pharmacists have been gatekeepers for accurate labeling and dispensing of medications as a response to patient needs and subsequent physician orders. This is still true today and involves a component of MTMS. However, pharmacists are also being asked to provide services that require upfront assessment of the patient, evaluation of their needs, and recommendations for medication therapy and follow up. This need for proactive rather than reactive pharmacist assessment does not appear to be imbedded in the claims data.
Medication reconciliation activities can be quite time consuming, yet necessary to assure accuracy of medication profiles as patients are enrolled and move through the health care system. This requires a more proactive approach than in the past and pharmacists are most qualified to provide such a service, but the resources cannot be devoted for this type of assessment without adequate reimbursement. Pharmacists have also carved out a role for chronic disease state management.
Further, patients requiring anticoagulation, medication titration to target doses, and vital medication alterations (including analgesics) require close, frequent, dedicated assessment of their responses to medications. These patients also have a high likelihood of having a capricious, lengthy medication profiles. Without pharmacist reimbursement, resources cannot be further dedicated to capitalize on the MTMS opportunities that have been created to assure the safe and effective use of medications in these patients. Please consider reimbursement for the new Pharmacist medication therapy management service codes (0115T, 0116T and 0117T) created by the AMA in 2006. Thank you,
Vince Yahl, Pharm D, BCPS
Pharmacy Clinical Leader, St. Rita's Medical Center
Assistant Professor, Ohio Northern University

Submitter : **Mr. Jay Schmelter** **Date: 09/28/2006**

Organization : **RiverVest Venture Partners**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-183-Attach-1.PDF

Attach #
183

RIVERVEST

7733 Forsyth Boulevard, Suite 1650
St. Louis, MO 63105

Phone: 314.726.6700
Fax: 314.726.6715

September 26, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By

excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT

Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at jschmelter@rivervest.com

Respectfully,

Jay W. Schmelter
RiverVest Venture Partners
Managing Partner

Submitter : **Mr. Kevin Pillow** **Date: 09/28/2006**

Organization : **University of Virginia Health System**

Category : **Hospital**

Issue Areas/Comments

Visits

Visits

Please see our attached suggested revisions to the clinic visit facility criteria.

CMS-1506-P-184-Attach-1.DOC

Attach
184

CMS Facility Criteria
UVA Response

Level 1 Clinic Interventions

- Suggest the addition of a non-sterile wound dressing application as an asterisk item.
- Expand the definition of "Analysis and review of lab results with patient face to face" to include new prescription review, patient education etc. < 30 minutes.
- Recommend moving to Level 3 - Physician counseling of patient requiring use of exam room/facility (> 60 minute duration).

Level 3 Clinic Interventions

- Suggest adding as a key component – Nursing face to face time with the patient for 30 minutes or greater providing patient education, counseling etc. with nurse documentation.
- Suggest adding as a key component – Sterile dressing change for wound care. (Not associated with central lines, etc.)
- Change "Assisting physician with examination(s) from an asterisk item to a key component under Level 3. Suggest adding to the definition, "or assisting with procedures under the physician global period".

Level 5 Clinic Interventions

- Would like a more clear definition of "check of integrity of blood flow to extremity".

Contributory Factors to Clinic Guidelines

- Suggest adding the use of an interpreter for the clinic visit.
- Suggest adding the use of patient movement devices for transfer to and from exam table.

Submitter : **Dr. Bruce Thomadsen** **Date: 09/28/2006**

Organization : **University of Wisconsin**

Category : **Other Practitioner**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

I am an Associate Professor of Medical Physics at the University of Wisconsin specializing in brachytherapy physics. I am also the current chair of the American Association of Physicists in Medicine's Emerging Brachytherapy Modalities Workgroup, although I am writing not in that latter capacity but as a practitioner and researcher in brachytherapy. I am writing to discuss the proposed OPPS Rule, and specifically as it relates to electron brachytherapy.

Electronic brachytherapy is brachytherapy conducted using an x-ray source for the therapeutic radiation rather than a radioactive source. The proposed rule would not classify electronic brachytherapy as 'brachytherapy' but as a different clinical entity, and supporting that decision based on section 1833(t)(2)(H) of the Social Security Code. On both clinical and physical bases, this decision seems unwarranted.

Clinically, brachytherapy simply is the treatment of disease by placement of the radiation source in close proximity, such as in the target (implants), in a body cavity near the target (intracavitary insertion) or in the body surface (surface application). The technique defines brachytherapy, and the source of the radiation is irrelevant. Physically, the important variable is that the source treats the target at very short distances. Again, the origin of the radiation makes no difference, be it a radionuclide or an x-ray generator.

The agency has said that they 'consider the definition of 'brachytherapy source' in the context of current medical practice, and in light of the language in section 1833(t)(2)(H) of the Act.' Further, they say, 'We are proposing to define a device of brachytherapy eligible for separate payment under the OPPS as a 'seed or seeds (or radioactive source)' as indicated in section 1833(t)(2)(H) of the Act, which refers to sources that are themselves radioactive, meaning that the source contains a radioactive isotope.' The agency's interpretation of this rules out electronic brachytherapy. However, section 1833(t)(2)(B) states:

'(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;'

This paragraph instructs that clinically comparable services are to be grouped together. Thus, if the clinical practice of brachytherapy using radioactive materials or electronic sources is comparable, as noted above, they both should be considered as brachytherapy and the source of the radiation a brachytherapy device.

Given that electronic brachytherapy is brachytherapy, there would certainly be no reason to classify electron brachytherapy in any other codes that provided lesser reimbursement.

Sincerely,

Bruce Thomadsen, PhD., DABR, DABHP, DABMP, FAAPM
Departments of Medical Physics, Human Oncology, Biomedical Engineering and Engineering Physics
University of Wisconsin - Madison
1530 Medical Sciences Center
1300 University Avenue
Madison, Wisconsin 53706

CMS-1506-P-186

Submitter : **Dr. Rick Clarfeld** **Date: 09/28/2006**

Organization : **Dr. Rick Clarfeld**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-186-Attach-1.DOC

Attach #
186

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates

Dear Administrator,

I first want to thank you for this medium to share my remarks on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I do have many concerns with the proposed reduction of the RVUs by 4 units when CPT code 19296 is performed by the Surgeon in the Hospital as well as the proposed reduction of the conversion factor by 5.1%. I am also concerned with the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) as this is an issue due to the cost of the device (catheter) not being considered in the new Clinical APC, which will make it impossible for the hospital to purchase.

A reduction of the RVUs will not allow me to place the catheter in the hospital and will negatively affect my ability as a Physician to treat Medicare patients with this important procedure in the hospital. The hospital will be forced to not provide the catheter for Medicare beneficiaries as the catheter will be priced higher than the clinical APC rate. Access to this important technology will be severely limited for Medicare patients who are eligible for partial breast irradiation. Availability to this technology is very important as it allows radiation treatment in only 5-7 days. CMS should preserve the RVUs and continue the assignment of the New Technology APC for an additional year until more cost data and research is done.

As a Surgeon who is concerned about this proposal, I recommend that CMS maintain the current RVUs for CPT code 19296 when done in the hospital. I recommend that if you have to have a reduction, then possibly reduce the conversion factor, but not to the current degree. In support of the hospital, I further recommend that CMS keep the designation of CPT codes 19296 and 19297 to the New Technology APC for the hospital for at least another year until further research is completed.

Once again, thank you for allowing me to share my recommendations and this important issue and please continue to do further evaluation of this topic.

Sincerely,

Rick Clarfeld, M.D.
Surgeon
Overlake HospitaL and Medical Center
1135 116th Avenue NE, Suite 180
Bellevue, WA 98004

cc: Senator Maria Cantwell WA (D)
Senator Patty Murray WA (D)

cc: Carol Bazell, MD, MPH, Director, Division Outpatient Services

cc: American Society of Breast Surgeons
Helen Pass, M.D. President American Society of Breast Surgeons

Submitter : **Dr. Paul Radensky** **Date: 09/29/2006**

Organization : **Prothrombin-time Self Testing Coalition**

Category : **Device Industry**

Issue Areas/Comments

Other New Technology Services

Other New Technology Services

See attachment

CMS-1506-P-187-Attach-1.PDF

September 29, 2006

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: **CMS-1506-P**
Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program –HCAHPS® Survey, SCIP, and Mortality; Proposed Rule
Comments on "Other New Technology Services"—Home Prothrombin/INR Monitoring (G0248 and G0249)

Dear Dr. McClellan:

On behalf of the Prothrombin-time Self Testing (PST) Coalition comprising HemoSense, Inc., International Technidyne Corporation and Roche Diagnostics Corporation, we are pleased to submit comments on the above-captioned Proposed Rule regarding Prothrombin Time (PT)/International Normalized Ratio (INR) home monitoring for anticoagulation management. Our comments in response to the Proposed Rule are substantially the same as the summary of our testimony before the Advisory Panel on Ambulatory Payment Classification Groups (APC Advisory Panel), which we submitted to the Centers for Medicare & Medicaid Services (CMS) on August 15, 2006.

The PST Companies are medical device manufacturers who have developed the technologies used in home PT/INR monitoring. Our companies have put significant resources into the clinical development of these technologies, which have been shown to reduce the incidence of serious adverse events (strokes and bleeding) among patients requiring anticoagulation with warfarin.

We appreciate Medicare's having provided coverage for home PT/INR monitoring beginning July 2002, and we were pleased to see clarifications on billing for these services published in several Program Transmittals and codified in the Medicare Claims Processing Manual, Chapter 32, Section 60.

Under the 2006 Outpatient Prospective Payment System, home PT/INR monitoring (codes G0248 and G0249) has been assigned to APC 1503 "New Technology Level III," the payment rate for which has been adequate to cover hospital costs for furnishing home PT/INR monitoring equipment and supplies and for providing clinical staff support.

By contrast, the proposal to re-assign home PT/INR monitoring from the New Technology APC to the lowest level clinic visit (APC 0604) would result in huge (67-percent) reductions in payments for the hospital facility services involved in the training and facility component services of home PT/INR monitoring. These reductions, if implemented, would result in payments well below hospital costs for furnishing home PT/INR monitoring and would likely shut down access to home PT/INR monitoring for Medicare beneficiaries who

are followed at hospital-based anticoagulation clinics. **We urge CMS to maintain home PT/INR monitoring (codes G0248 and G0249) under New Technology APC Level III for 2007. In the alternative, we would ask CMS to assign these codes to a clinical APC that more closely correlates with the clinical and economic resources involved with home PT/INR monitoring, such as APC 0421 "Prolonged Physiologic Monitoring."**

I. Background on Home PT/INR Monitoring

Home PT/INR monitoring is performed by patients receiving chronic anticoagulation therapy with warfarin to facilitate maintenance of anticoagulation within desired ranges. Home PT/INR monitoring has been shown in published clinical studies to reduce the incidence of serious adverse events (strokes and bleeding) among patients requiring anticoagulation with warfarin. Home PT/INR monitoring is covered by Medicare for patients with mechanical heart valves meeting specific coverage criteria.

Medicare coverage is provided as a diagnostic service and reported under 3 "G" codes for (1) training (G0248), (2) furnishing of the equipment and supplies (technical component service under G0249), and (3) physician review and interpretation of test results (professional component service under G0250—this latter component is not billable by hospitals nor paid under OPPS). The descriptors for the codes relevant for OPPS are:

G0248 Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing

G0249 Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per 4 tests

Medicare coverage for home PT/INR monitoring commenced in July 2002. The "G" codes were assigned to APC 0708 "New Technology—Level III ($100-$200)," which was renumbered as APC 1503 "New Technology—Level III ($100-$200) in 2004. G0248 and G0249 remained assigned to APC 1503 through 2006. Very few claims were reported under these codes and no single claims were identified in the files supporting the Outpatient PPS payments for 2003, 2004, 2005 or 2006.

II. Proposed Rule Would Result in Substantial Reduction in Payment for Home PT/INR and is Inconsistent with Clinical and Economic Resources Involved with the Home PT/INR Monitoring Service

In the Proposed Rule, CMS announced a plan to re-assign codes G0248 and G0249 from New Technology APC Level III (payment rate $150) to APC 0604—"Level I Clinic Visit" (Proposed Rule payment of $49.75) If adopted, this would result in a 67-percent reduction in payment for these services from 2006 to 2007

We understand that CMS's decision to re-assign codes G0248 and G0249 from the New Technology APC was driven by the relatively long period that these codes had remained in a new technology category. Although we understand why CMS normally would consider it appropriate to re-assign a procedure to a clinical APC after 4 or more years, in the case of home PT/INR monitoring, we believe the technology is still sufficiently new to warrant retaining the assignment under APC 1503 for at least one more year. The adoption of this benefit has been relatively slow due to the strict limitations of the coverage policy (only patients with mechanical heart valves are eligible).

Whether or not CMS decides to retain codes G0248 and G0249 under a new technology category, we respectfully submit that assignment to the lowest level clinic APC (0604) would be inappropriate both on clinical and economic grounds.

When provided in a hospital outpatient setting, home PT/INR monitoring involves:

1. Training of patients to perform home PT/INR monitoring, which includes demonstrating use and care of the PT/INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing (G0248). The practice expense database supporting the Physician Fee Schedule for code G0248 shows that this service involves 75 minutes of a nurse's or technologist's time to train patients to perform home PT/INR monitoring.[1]

2. Furnishing of a PT/INR monitor (a PT/INR test meter), test strips to run in the monitor, lancets for collecting blood samples, and alcohol swabs for preparing the skin for the self-testing of PT/INR by patients or their caregivers at home (or otherwise outside the hospital setting) on a weekly basis (code G0249)[2]. Code G0249 is an unusual service under the OPPS because it involves the hospital's furnishing equipment and supplies for use by patients in their homes. Each PT/INR monitor ($2,000 price listed in the physician fee schedule database) is dedicated for use by one patient only.

None of the other procedures in APC 0604[3] involve the furnishing of equipment and supplies to patients for use in their homes. None of the other procedures in APC 0604 involve care extended over a 4-week period.

The median cost data posted by CMS to support the 2007 Proposed Rule show median costs of $95 for G0248 and $127.88 for G0249. This median cost for G0248 is approximately twice the median cost of APC 0604 ($49.93); the median cost of G0249 is more than 2.5-fold the median cost of APC 0604.

Therefore, the proposal to assign codes G0248 and G0249 to APC 0604 appears to be neither consistent clinically with other services assigned to that APC nor economically homogeneous with those other procedures.

III. Summary and Recommendations

Codes G0248 and G0249 are neither clinically nor economically coherent with other codes in APC 0604. Home PT/INR monitoring training (G0248) is substantially more involved than the lowest level clinic visit services assigned to APC 0604. Home PT/INR monitoring 4-weekly test equipment and supply (G0249) is substantially more resource intensive than essentially all of the procedures in APC 0604.

Codes G0248 and G0249 were assigned to New Technology Level III for approximately 3 years by 2005, the year from which claims supporting the 2007 Proposed Rule are drawn. Although we understand the desire to assign codes to clinical APCs after adequate claims data become available, given the low volume of claims,

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[1] 2006 Final Rule Practice Expense Inputs.mdb

[2] The coverage policy limits coverage to testing no more than once per-week. The 4-test payment units under code G0249 may reflect weekly testing over a 4 week period or less frequent testing over a longer period. However, Medicare instructions to hospitals permit hospitals to report code G0249 as 3 units—i.e., 12 weekly tests. CMS allows hospitals to report this way because patients must be physically present at the hospital at the time these services are billed and it was assumed that patients would otherwise attend the hospital approximately every 3 months for evaluation and management of their anticoagulation and/or underlying condition.

[3] Other codes assigned to APC 0604 in the Proposed Rule are: 92012 (eye exam established pat.); G0101 (CA screen;pelvic/breast exam); G0245 (initial foot exam pt lops); G0379 (direct admit hospital observ).

we would recommend maintaining codes G0248 and G0249 under APC 1503 (New Technology—Level III) for at least one more year.

Alternatively, should CMS conclude that it is appropriate to assign these procedures to a clinical APC, we would support the recommendation of the APC Advisory Panel to assign these procedures to APC 0421 "Prolonged Physiologic Monitoring." The other code assigned to APC 0421, (glucose monitoring, cont) fits more closely with home PT/INR monitoring, and the proposed payment ($101.47) is nearer to the median claims-based costs for home PT/INR monitoring than assignment to APC 0604.

If CMS implements its proposal to move codes G0248 and G0249 from APC 1503 to APC 0604, hospitals that are offering this service will see a 67-percent drop in payments to levels well below their costs. We would anticipate that most hospitals offering this service will discontinue offering this service. We would also anticipate that hospitals considering the adoption of this service would chose not to do so.

By contrast, if CMS maintains codes G0248 and G0249 under APC 1503, hospitals who currently offer this technology for their patients on chronic anticoagulation will not suffer losses for continuing to offer this service. Those who are considering offering the service will not have a financial disincentive to turn away the service.

* * * *

We appreciate the opportunity to comment on this Proposed Rule. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., at 305.347.6557 or by e-mail at pradensky@mwe.com if you have any questions about our comments or would like to discuss these further. Thank you for your consideration of our comments.

Sincerely,

/s/ Larry Cohen

Larry Cohen
President
International Technidyne Corporation

/s/ David Phillips

David Phillips
Vice President, Marketing
HemoSense, Inc.

/s/ John Ridge

John Ridge
Director, Reimbursement Affairs
Roche Diagnostics Corporation

Cc: Denise Garris, American College of Cardiology
Paul Radensky, M.D., J.D., McDermott, Will & Emery LLP

Submitter : **Ms. TWILA MARTIN** **Date: 09/29/2006**

Organization : **FRANCES MAHON DEACONESS HOSPITAL**

Category : **Other Health Care Professional**

Issue Areas/Comments

Visits

Visits

1-FIVE POINT RATING SCALES DIFFICULT BECAUSE PEOPLE INCLINED TO PICK THE MIDDLE LEVEL
2-THIS MODEL IS NOT AS DETAILED AS THE THREE LEVEL MODEL WITH CRITICAL CARE, SO WILL BE MORE DIFFICULT TO TEACH
3-IT DOESN'T MAKE SENSE THAT THERE IS NO NURSING CREDIT FOR EMOTIONAL SUPPORT OR DISCHARGE TEACHING IN THE ER GUIDELINES

Submitter : **Mr. Bryan Newman** **Date: 09/29/2006**

Organization : **Medical Imaging of Baltimore**

Category : **Health Care Industry**

Issue Areas/Comments

Radiology Procedures

Radiology Procedures

September 29, 2006
The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT
Dear Administrator McClellan:

I am writing on behalf of Medical Imaging of Baltimore to address an issue of great importance to Medicare beneficiaries with cancer. Medical Imaging of Baltimore is an independent diagnostic testing facility (IDTF), which provides PET/CT, as well as MRI and CT services. We serve approximately 1400 cancer patients annually, many of whom lack ready access to a hospital. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay IDTFs, and could compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by free standing facilities traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to $865 the same rate proposed for conventional PET from its current rate of $1,250. For IDTFs that represents a cut up to 60% to 70% in one year from current carrier based prices.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures such as biopsies required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to MIB of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Many cancer patients live far from hospitals, and rely on IDTFs for oncologic imaging. The proposed payment rate reduction for PET/CT would seriously underpay IDTFs, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Bryan Newman, CNMT(PET), AART (N).
PET/CT Specialist
Medical Imaging of Baltimore
6715 N. Charles St.
Baltimore, MD 21204

CMS-1506-P-189-Attach-1.DOC

Attach IT
189

September 29, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Medical Imaging of Baltimore to address an issue of great importance to Medicare beneficiaries with cancer. Medical Imaging of Baltimore is an independent diagnostic testing facility (IDTF), which provides PET/CT, as well as MRI and CT services. We serve approximately 1400 cancer patients annually, many of whom lack ready access to a hospital. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay IDTFs, and could compromise beneficiary access to this vital technology.

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Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to MIB of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Many cancer patients live far from hospitals, and rely on IDTFs for oncologic imaging. The proposed payment rate reduction for PET/CT would seriously underpay IDTFs, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Bryan Newman, CNMT(PET), AART (N).
PET/CT Specialist
Medical Imaging of Baltimore
6715 N. Charles St.
Baltimore, MD 21204

Submitter : **Kerri Peterson** **Date: 09/29/2006**

Organization : **Kerri Peterson**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-190-Attach-1.DOC

Attach 190

September 18, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Hospital Outpatient Prospective Payment System

Dear Administrator:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' proposed rule, as published in the Federal Register on August 23, 2006. This letter is written in order to express concern regarding the proposed RVU reduction for CPT 19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Our facility opposes this proposal and requests CMS reconsider maintaining assignment of the New Technology APC for an additional year. We are concerned that because these codes are fairly new (1-1-2005), that enough data may not have been collected to provide for APC re-assignment. As currently proposed, the reduction and reassignment will impact our Medicare patients diagnosed with breast cancer. Partial breast irradiation (PBI) allows the radiation process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, our facility may not be able to cover the cost of the procedure, which requires a device with a cost of $2750. Our procedure costs are more than the proposed Clinical APC is reimbursing.

We urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. Thank you for your careful consideration and review in this important matter.

Sincerely,

Kerri Peterson

Kerri Peterson
Manager of Radiation Oncology
Research Medical Center
2316 E. Meyer Road
Kansas City, MO 64132

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care

f

CMS-1506-P-191

Submitter : **Dr. Michael DeHaan** **Date: 09/29/2006**

Organization : **Dr. Michael DeHaan**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-191-Attach-1.DOC

Attach #
191

MICHAEL R. DEHAAN, M.D.

Board Certified General Surgeon

1 Erie Court Suite # 6010
Oak Park, IL 60302

(708)383-4300/4350
Fax (708)763-1219

September 29, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

Michael DeHaan, MD

Michael DeHaan, MD

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Mark A.Malangoni, MD, FACS, Chair, American College of Surgeons
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Dr. Darius Francescatti** **Date: 09/29/2006**

Organization : **Dr. Darius Francescatti**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-192-Attach-1.DOC

Attach #
192

September 14, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System

Dear Administrator:

I am writing to you today, regarding the proposed RVU reduction for CPT19296 and CPT 19297, as well as the APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate. The proposed reductions and reassignment will significantly impact my ability to care for Medicare patients with breast cancer. Access to partial breast irradiation (PBI) is a valued option for my patient population. With a breast cancer diagnosis, it is important that the tumor is removed and radiation therapy start as quickly as possible.

Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital may no longer be willing to offer this service. The catheter itself costs $2750 and is priced higher than the proposed clinical APC payment rate. As a result, we will be limiting Medicare patients' access to treatments for those patients who are clinically eligible for breast conservation surgery and PBI. I am certain that is not Medicare's intent.

As a surgeon focused on offering the best care to my Medicare patients, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter.

Sincerely,

Darius S. Francescatti, MD, JD

Darius S. Francescatti, MD, JD

cc. Senator Dick Durbin, Senate Appropriations Labor HHS Sub-Committee
Carol M. Bazell, MD, MPH Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American College of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Eric Sutphen** **Date: 09/29/2006**

Organization : **Dr. Eric Sutphen**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-193-Attach-1.DOC

HTMoCH ##
193

September 25, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

There are two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and then the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

HCPCS Code	**2006 APC**	**2006 Payment**	**2007 Proposed APC**	**2007 Proposed Payment**	**Payment Change 2006-2007**	**Percent Change 2006-2007**
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment,	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

immediate							

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. This is an important option for women electing breast conservation surgery followed by radiation therapy. Traditional whole breast radiation is a 5 day a week treatment, for 6-7 weeks. Breast brachytherapy offers the option of treating the lumpectomy cavity in a much shorter 5 days (twice daily) of treatment.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate date.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ration payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.
Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Eric Sutphen, MD

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St Louis, MO 63128

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. G. Paul Yazdi** **Date: 09/29/2006**

Organization : **Dr. G. Paul Yazdi**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-194-Attach-1.DOC

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1911

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates;

Dear Administrator:

Thank you for this opportunity to provide comment on the proposed 2007 payment rates and specifically to comment on the impact the proposed APCs for breast brachytherapy will have on breast conservation therapy for those patients with breast cancer.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. For those women choosing breast conservation surgery, traditional whole breast radiation is a daily treatment (5 days/week) for 6-7 weeks. Breast brachytherapy offers the alternative of treatment to the tumor bed in a shortened course of twice daily treatments in just 5 days. This is clearly an important option for the working woman, elderly or those living some distance from a radiation facility.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These

CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures since they are reliant on the use of a high cost device that is bundled into the procedure payment. APC 648 Breast Reconstruction with Prosthesis includes other similar procedures to those of 19296 and 19297. The similarities not only are clinical but also in the cost of the device. Should CMS discontinue the assignment of 19296 and 19297 in new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Alternatively, I recommend that CPT codes 19296 and 19297 be assigned to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the group title from Breast Reconstruction with Prosthesis to Level IV Breast Surgery. Thank you for this opportunity to provide comment.

Sincerely,

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cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
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