Submitter : Dr. John Shook **Date:** 09/18/2006

Organization : Saint Luke's Cancer Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-75-Attach-1.DOC

Attachment 75

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

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

Dear Administrator:

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

The proposed reductions and reassignment will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial 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 decide to decline to offer this service. The catheter itself (at $2750) 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 physician 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 and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

John W. Shook, MD
4323 Wornall Road
Kansas City, MO 64111
816-932-2836

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

Submitter : Mr. Chris Giacomino **Date:** 09/19/2006

Organization : Strategic Outpatient Services, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-76-Attach-1.PDF

Attach #
76

SOS

70 Grand Avenue • Suite 101
River Edge, NJ 07661
Phone 201 488 1996 • Fax 201 488 1919
www.sosinc.biz

September 18, 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 Strategic Outpatient Services, Inc. (SOS) to address an issue of great importance to Medicare beneficiaries with cancer. SOS operates six (6) outpatient diagnostic imaging centers, which provide PET/CT imaging services to over 10,000 cancer patients annually. 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 imaging centers, and will compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by doctors offices 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 imaging centers that represents a cut of up to 60% to 70% in one year from current carrier based prices. More shocking however, is that the proposed combined reimbursement for PET/CT's technical component, professional component and allowable reimbursement for FDG will be almost 20% below SOS's cost of providing these services *excluding* an allowance for a return on invested capital. How can this

possibly be? Especially given that in today's managed care environment, what CMS does, Aetna, United Healthcare, Blue Cross Blue Shield, Cigna, etc. are all sure to follow.

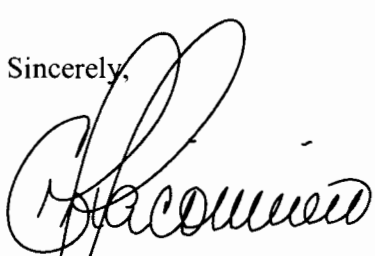
Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits 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 SOS 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 outpatient imaging centers for oncologic imaging. The proposed payment rate reduction for PET/CT would seriously underpay outpatient diagnostic 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. Furthermore, since the vast majority of PET/CT scans are presently performed in outpatient imaging centers, CMS should rapidly work to develop a payment methodology that takes the costs of operating in this very different environment into account and factor that into its "hospital" outpatient rates. It makes no sense to have a cost-based reimbursement methodology based on the costs of less than half of the entities providing a given service.

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

Sincerely,



Chris Giacomino
Vice President / Operations
Strategic Outpatient Services, Inc.
Office: 201-488-7996
Cell: 201-362-6910
www.sosinc.biz

Submitter : Ms. Bobbie McAdams **Date:** 09/19/2006

Organization : University Health Care System

Category : Hospital

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

Separate payment should be made for multiple IV injections of the same substance/drug. Providers expend the same amount of resources when a second IV injection is given to a patient even though it is the same drug. You still have to obtair the drug, prepare it for administration, go to the patient location, perform the safety checks, administer the drug and monitor the patient outcome and document the procedure. In 2005 there was separate payment for IV injections cpt 90784 and there continues to be a separate payment for IM/SQ injections, cpt code 90772 so it does not make sense to have a separate payment for one and not the other. The same amount of resources are needed for each.

We have patients that are in observation status for pain control or other conditions that may receive several IV injections of the same drug/substance and it is given around the clock. These injections should have a payment for each of the injections administered.

The cost for administering the first does of a medication is the same as administering subsequesnt doses of the same medication. For ER and Observation patients (which can be up to 24/48 hour stay), it is common practice to administer multiple doses of a single drug.

CMS continues to instruct us to code and bill for all medically necessary services that are provided to our patients. With so many services being provided on an outpatient basis, it becomes even more important to capture and charge for these servcies and to receive APC payments from Medicare.

I have attached a previous letter written to CMS related to the IV injection regulations containing several examples of the impact this regulation has on hospitals. This letter was written in conjunction with two other hospitals.

Submitter : Mrs. Denise Merlino **Date:** 09/19/2006

Organization : Society of Nuclear Medicine

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-78-Attach-1.PDF

Attach #
78

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

September 19, 2006

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

Administrator Mark McClellan M.D. PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the proposed 2007 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 71 Fed. Reg. 163, August 23, 2006. The Society of Nuclear Medicine (SNM) representing more than 16,000 physicians, scientists, pharmacists and nuclear medicine technologists appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. The SNM is committed to carefully reviewing and providing manageable options for all stakeholders. We appreciate CMS willingness to understand and account for the unique and varying attributes of radiopharmaceuticals and processes used in Nuclear Medicine (NM) procedures provided to Medicare beneficiaries. We look forward to working with the CMS collaboratively as you respond to our concerns and recommendations herein.

Our comments on the Proposed Rule will address:

1. New status indicator Q for CPT 38792;
2. Proposed CMS reassignment of procedures to new or different APCs
    a. CPT 78811- 13 PET to APC 0308
    b. Proposal to lump all non-myocardial PET studies into one non-homogeneous APC
    c. CPT 78814-16 PET/CT tumor procedures from New Technology APCs 1513-4 to APC 0308

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

d. CPT 78608 Brain Metabolic PET procedure from New Technology APC 1513 to APC 0308

e. CPT 78491 and CPT 78459 Cardiac Procedures from APC 0306 to 0307

f. CPT 78804 from APC 1513 to 0408, and CPT 78806 from APC 0406 to 0408, the procedures differ only that one is a multi-day study and the other a single day study;

3. The continued assignment of the NM procedure, CPT 78730, bladder residual volume, in the non-NM APC 0304

4. Reimbursement for Radiopharmaceuticals and Drugs

   a. The proposed increase of a threshold for payment to $55

   b. Packaging of New Drugs and Radiopharmaceuticals

   c. The proposed payment for radiopharmaceuticals based on 2005 mean cost data.

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

1. CPT 38792 New Status Indicator Assignment Q

CMS created a New Status Indicator "Q" for 2007, and plans to apply this to AMA CPT 38792 *Injection procedure; for identification of sentinel node* "special" Packaged Services Subject to Separate Payment Under Certain OPPS Payment Criteria. **The SNM appreciates CMS willingness and efforts in creating the new status indicator and applauds this decision to apply status Q to CPT 38792.** The SNM and other professional societies and stakeholders have previously commented that status N is not appropriate for all hospitals. The new CMS status indicator "Q" definition states "Packaged Service Subject to Separate Payment Under OPPS Payment Criteria." The assignment of "Q" to CPT 38792 will allow hospitals to bill and receive payment when CPT 38792 is provided alone and is the only NM service billed on a particular date of service. We understand that CPT 38792 will be packaged if it appears on the same DOS as other procedures, such as a surgical procedure.

New Technology & Two Times Rule
APC Assignment for Nuclear Medicine Procedure CPT Codes

It is our understanding that CMS retains a procedure in a New Technology APC until sufficient claims data has been collected in order to assign it to a clinical APC (November 30, 2001 final rule (66 FR 59897). We also understand that in cases where CMS believes the original New Technology APC assignment was based on inaccurate or inadequate information, or when the New Technology APCs are restructured, CMS may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC bands, reassign the procedure or service to a different appropriate New Technology APC.

2a. Tumor PET CPT codes 78811, 78812 and 78813

CMS is proposing assignment of non-myocardial PET procedures to a clinical APC based on what CMS believes are several years of robust and stable data.

The proposal is to assign tumor PET scans, **CPT codes 78811, 78812, and 78813**, to new APC 0308 (Non-myocardial PET Imaging) with a median cost of $865.30 for CY 2007.

We have found in both working and educating hospitals that they are slow in changing their charge masters, including changes in codes and in setting charges that reflect actual costs. We remain concerned by the potential for charge compression for higher cost procedures. The SNM and other professional societies are committed to a continued effort to educate hospitals regarding charge compression, and charge master management reflective of actual hospital costs for nuclear medicine procedures.

Nonetheless, in spite of the difficulties hospitals seem to have in updating their charge masters, the SNM agrees with CMS that claims data acquired over the past several years using G

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

codes crosswalked to the current PET Tumor codes, plus the 9 months of experience with the current CPT codes, is adequate to move CPT 78811-13 from a new technology APC to a homogeneous clinical APC with a reimbursement such as APC 0308.

2b. The **SNM does not agree with the proposal to lump several organ and disease categories into the same NM APC,** such as the proposal for APC 0308, where all "non-myocardial" PET procedures are proposed to be placed. During the initial years of the HOPPS, the nuclear medicine community developed with CMS a process for categorizing clinically homogeneous APCs. For example, we agree that Cardiac PET procedures should be placed in an APC separate from Tumor PET studies.

Specifically, the SNM requests that the Tumor PET procedures be placed in an APC separate from Brain PET to maintain clinical homogeneity.

2c. Tumor PET/CT CPT codes 78814, 78815 and 78816

For CY 2007, CMS is proposing the assignment of concurrent PET/CT scans, specifically, CPT codes 78814, 78815, and 78816, to a clinical APC because it believes it has adequate claims data from CY 2005 upon which to determine the median cost of performing these procedures.

This decision appears to be based on a full year or less of claims data, since the new PET/CT technology codes were introduced in January of 2005. The **SNM does not support CMS' decision to move Tumor PET/CT codes out of the New Technology APC and into a clinical APC at this time.** As stated earlier, hospitals' management of charge description masters and cost reporting are slow to adopt new CPT codes, let alone actual acquisition cost changes. The Academy of Molecular Imaging (AMI) recently met with CMS to outline significantly different costs for PET versus PET/CT. We believe that CMS' data does not support the notion that PET and PET/CT costs are similar, rather that the data supports our contention of the very slow updating of hospitals charges reflective of actual costs. The SNM believes CMS reassignment of PET/CT is premature and not consistent with the published policy for moving a procedure out of a new technology APC. **Consistent with the APC panel recommendation numbers 7 and 17 at the August 2006 Panel meeting, the SNM strongly recommends that CMS keep CPT codes 78814, 78815 and 78816 in the New Technology APC 1514 at a rate of $1,250.**

Further, the SNM strongly disagrees with the proposal to lump Tumor PET/CT procedures into the same APC as Tumor PET studies. Performing PET/CT scans requires different and more expensive resources than pure PET scans (e.g. specially trained and licensed technologists, higher maintence costs, and higher equipment costs), and the reimbursement should reflect the additional costs. As with our comments about maintaining clinical homogeneity for all PET studies, we see no justification for lumping PET and PET/CT, which are imaging procedures requiring different human and equipment resources, into the same APC.

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

2d. Brain PET CPT Code 78608

Of all the transitions for PET procedures from the G to CPT codes, the transition from use of G0229 *PET imaging metabolic brain evaluation of refractory seizures* and G0336 *PET imaging, brain for differential diagnosis of Alzheimer's disease with aberrant features vs fronto-temporal dementia* have the closest direct relationship to the CPT 78608. **The SNM, therefore, agrees with the proposal that this procedure be moved from APC 1513 to a clinical APC. As stated previously, the SNM recommends that Brain PET be placed in its own APC and not lumped with other PET studies. Based on the published CMS claims data, the payment for this brain PET procedure-APC should be greater than that proposed for APC 0308.**

2e. Myocardial PET CPT Codes 78491, 78492 and 78459

CMS proposes to move all myocardial PET studies into one APC 0307. This includes lumping single and multiple studies based on CMS' claim that "our data do not support a resource differential that would necessitate the placement of these single and multiple scan procedures into two separate APCs. As myocardial PET scans are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly." **The SNM strongly disagrees with this conclusion.** Additionally, CMS own 2005 claims data breaks the "two times rule" for this revised APC. "First, CMS has recognized, and its claims data supports, separating other cardiac NM studies that require multiple imaging sessions (CPT 78460-1, 78464-5, 78472-3, 78481-3). Second, the conclusion that "it is possible that" hospitals performing multiple studies are more efficient (and, therefore, less costly) assumes that single studies are done primarily in hospitals that do not do multiple studies. We are unaware of any data to substantiate that conclusion or that, if true, would mitigate the doubling of time and effort to acquire multiple studies over single studies. We note that CMS' claims data has remarkably less single frequency claims data for single versus multiple studies, and thus suggest that the cost conclusions are statistical in nature and not reflective of true costs. We also note that the mean claims cost of multiple studies 78492 is $1422 (872 single frequency claims), where as the mean cost of the single PET myocardial study 78491 is $927 (single frequency only 44). (We recognize that the "true" median costs are $660 and $1014, respectively.)

The SNM is additionally concerned with the CMS' use of claims data for cardiac PET in general. We have noted that myocardial PET rates have varied widely over the past few years. In prior comments to CMS, the SNM and other professional societies noted that rates for myocardial PET did not appear to be representative of the actual costs of myocardial PET and, therefore, we recommended splitting the APC into single versus multiple studies. We are greatly concerned with providing appropriate placement and **stability for hospitals** regarding reimbursement for these procedures.

The SNM disagrees with the proposal to lump both the single and multiple PET myocardial studies into one APC and recommends that there be Level I and Level II Cardiac PET APCs. Level I for CPT 78459 and 78491, and Level II for CPT 78492. Further CMS should

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

consider dampening options similar to previous device APC for ICD and blood products to ensure adequate rate setting absent good CMS claims data. The SNM and other professional societies will work to assist CMS in identifying external or alternate CMS claims analysis to set 2007 rates for myocardial PET APCs.

2f. APC Reassignment of Procedures CPT 78804 (multiple days whole body) and CPT 78806 (single day whole body study) from APC 1513 to 0408

The proposed rule reassigns CPT 78804 (a multi-day study for tumor or radiopharmaceutical distribution) from a new technology APC to a clinical APC 0408, which will include one other NM procedure, CPT 78806, a single day study. Although 78804 is described for different indications than 78806, the procedures use the same resources but differ on the number of times the procedures are done. As stated previously, t**he SNM does not agree with CMS' decision to combine single and multiple studies in the same APC.** This decision violates resource homogeneity for these otherwise clinically similar studies. This is evidenced by CMS' claims data of a mean cost for the multi-day CPT 78804 at $507.61 and true median cost $370.68 and CPT 78806 with a mean $342.17 and true median of $289.59 for single study whole body. **Multiple studies take more time and work than single studies. The SNM requests that reimbursement and APC placement reflect that added cost. Placing these two procedures in the same APC would be an aberration for the NM APC structure.**

The SNM does agree with the creation of a new APC 408 to accommodate movement of CPT 78804 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s) whole body requiring two or more days imaging.* **Therefore, the SNM strongly urges CMS to maintain the single day study CPT 78806 in APC 406 and to create a new APC for the multiple day study CPT code 78804. We recommend that the reimbursement for CPT 78804/APC 0408 be based on the current claims data for the procedure.**

3. CPT 78730 Urinary Bladder Residual

In 2005, CMS moved CPT 78730 into a non-nuclear medicine APC 0340, based purely on hospital claims data. The SNM disagreed with that placement in 2005, as we believed the high utilization represented incorrectly coded claims. As recommended by CMS the SNM did work with the AMA CPT editorial panel, and when the AMA releases CPT 2007 later this year, there will be a new status and description for CPT 78730. In view of this new information release, **the SNM requests that CMS move the redefined CPT 78730 into the nuclear medicine add-on APC 0399 to maintain clinical and resource homogeneity for this redefined code.**

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

Reimbursement for Radiopharmaceuticals

4a. CMS threshold for drugs and radiopharmaceuticals changed from $50 to $55

The threshold for establishing separate APCs for drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. Because this packaging threshold will expire at the end of CY 2006, CMS evaluated four options for packaging levels so that they could determine what the appropriate packaging threshold proposal for drugs, biologicals, and radiopharmaceuticals would be for the CY 2007 OPPS update.

For CY 2007, CMS is proposing to update the packaging threshold using an inflation adjustment factor based on the Producer Price Index (PPI) for prescription preparations. For each year beginning with CY 2007, CMS is proposing to adjust the packaging threshold by the PPI for prescription drugs and to round the adjusted dollar amount to the nearest $5 increment in order to determine the new threshold. The adjusted amount for CY 2007 was calculated to be $55.99, which was rounded to $55.

During its March 2006 meeting the APC Panel recommended that CMS maintain the $50 packaging threshold or, if the threshold is revalued, that CMS provide the Panel with data that indicate that the costs of packaged drugs are incorporated into drug administration payment rates. The Panel has not received this data from CMS. At the recent August 2006 APC Panel meeting, the Panel recommended (No. 19) that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with specific HCPCS codes. **The SNM supports this August Panel recommendation.** The Panel also recommended (No. 28) and reaffirmed their request for CMS to provide claims analyses of the contributions of packaged costs (considering packaged drugs and other packaging) into the median cost of each drug administration service. Similarly, radiopharmaceutical administration (not radiopharmaceutical handling costs) is part of procedure rates. ***We respectfully request CMS provide analysis of the contributions of each packaged radiopharmaceutical into the median cost of each nuclear medicine APC.***

As stated in previous comments, the SNM does not agree with packaging any radiopharmaceuticals into procedures. The SNM is concerned that hospitals do not adequately bill separately for radiopharmaceuticals once they are bundled into the procedure. The SNM is further concerned that, by bundling radiopharmaceuticals into the procedure reimbursement, hospitals are unable to capture true cost changes of both radiopharmaceuticals and drugs. **Therefore, the SNM strongly recommends that CMS eliminate the $55 threshold for all drugs and radiopharmaceuticals.** A uniform policy allowing separate payment for all drugs will contribute to more homogeneous APC payment groupings and promote selection of the drugs most appropriate for the patient's needs.

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

4b. Radiopharmaceutical and Drug Packaging Issues

The SNM disagrees with the CMS decision to set status indicators for one new nuclear medicine HCPCS drug code and one new radiopharmaceutical HCPCS code at bundled status "N". Absent data, CMS should NOT simply default to applying a packaging status indicator for *new* drugs and radiopharmaceuticals just because they do not have claims data. **Consistent with our request to separately pay for all drugs and radiopharmaceuticals, the SNM requests CMS pay separately for HCPCS codes J2805 *Sincalide injection, 5mcg* with a status K and use ASP plus 6% to set pricing for at least through FY2007; the SNM also requests that CMS pay separately for HCPCS radiopharmaceutical code A9567 *Technetium Tc-99m Pentetate, diagnostic, Aerosol, per study dose up to 75 millicuries* set to status H using the 2006 radiopharmaceutical payment methodology of hospital cost times overall hospital cost to charge ratio for at least one more year.**

4c. Radiopharmaceutical Payment Methodology change from CCR to mean hospital data

For CY 2007 CMS is proposing to establish prospective payment rates for separately payable radiopharmaceuticals using mean costs derived from the CY 2005 claims data, where the costs are determined using CMS' standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

The SNM is concerned that the current method that CMS has chosen to establish payments is **inconsistent** with CMS 2006 clarification to hospitals. CMS was clear that hospitals would be paid based on the *hospital overall hospital CCR* times the *hospital charge in 2006*. Therefore, hospitals in 2006 began to develop charge description master rates for radiopharmaceuticals consistent with setting their charges high enough to be adjusted by the overall *hospital* CCR and NOT the *department* CCR. Historically, a nuclear medicine department CCR is lower than an overall hospital CCR. Consequently CMS' decision to use the same methodology for drugs to set mean and median costs is flawed, as it is likely not to capture hospital actual costs appropriately. If CMS **must** implement a payment system for radiopharmaceuticals based on hospital claims data, they **must** use the same policy instructed to the hospitals, during the year of the claims, to establish those payment rates.

There were significant changes in HCPCS Level II descriptors for radiopharmaceuticals effective January 1, 2006. CMS clarified their intentions for radiopharmaceutical payments by specifically directing hospitals to adjust charges to ensure that overhead and handling costs were included in the charge for the radiopharmaceuticals only in 2006. Therefore, this data is not yet available in CMS 2005 claims data. Hospitals are traditionally slow in adopting changes, and we believe this policy is no exception. Some hospitals appear to be making changes, but it is clear that all the necessary adjustments have not been made.

The SNM agrees with the APC Panel (recommendations Nos. 18 and 20) that CMS is premature in moving to a new payment methodology for radiopharmaceuticals for FY2007. While the SNM

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

understands that CMS only intended to have the cost-to-charge (CCR) payment methodology in place for CY 2006, **the SNM, like the APC panel, urges CMS to continue with the current invoice CCR payment methodology for one more year (CY 2007) in order to establish good data, and also to explore alternative methods for capturing hospital costs for radiopharmaceuticals**.

Like CMS, the SNM believes that it is critical to come forth with an equitable solution for **all** radiopharmaceuticals based on acquisition and handling costs. ***The proposed CMS 2007 radiopharmaceutical payment policy does not work for all radiopharmaceuticals especially those with higher acquisition costs because of cost compression.*** The claims data begins to seriously underestimate the actual cost of radiopharmaceuticals for those products that cost more than $200 **(Undervalued Radiopharmaceuticals, Table 1)**. This under-estimation ranges from 1X to 10X. It is especially egregious for the more complex monoclonal antibody diagnostics and for therapeutic radiopharmaceuticals. Implementing a new payment system that does not account and accommodate all outstanding issues is premature. Hospitals need stability; moving to a system that does not adequately cover the costs could jeopardize access and patient care.

Further, the SNM is extremely concerned that continued underpayment by CMS for these "state of the art" products will not only result in patients not receiving their benefits now, but will shortly dissuade radiopharmaceutical manufacturers from investing in new and potentially even more useful radiopharmaceuticals. The current cost to charge method for determining radiopharmaceutical hospital acquisition costs does not work for a large number of radiopharmaceuticals and must be replaced.

We recognize that there are many factors that complicate an easy solution, but the SNM's desire is to develop a payment system similar to that of the ASP model used for other drugs. The SNM recommends that CMS work collaboratively with the SNM as we explore the potential for a national rate setting that is established at the HCPCS code description level (as opposed to NDC level), using a modified average pricing model obtained directly from central radiopharmacies (distributors as opposed to manufacturers of radiopharmaceuticals). We also recommend that CMS work with hospitals to consider other alternatives and contributing factors, such as distance for transportation fees and other factors such as the half-life of radiopharmaceuticals, into the formula and rate calculation. MedPAC and other agencies have acknowledged that handling costs for radiopharmaceuticals is higher than those of traditional drugs and chemotherapy drugs. As with our concern that cost compression has resulted in incorrect cost data for many radiopharmaceuticals, we believe that the true handling costs are not reflected in the current charge data being acquired by CMS. Further, it is not apparent to us that there is any fixed or sliding dollar amount or percentage that would accurately account for handling costs for each and every radiopharmaceutical. We believe that hospitals could accurately determine radiopharmaceutical handling costs on average for each individual procedure, and that they would include them in charges for all nuclear medicine procedures. This would be consistent with policies under the RBRVS. **The SNM would support CMS directing hospitals to include the handling costs of radiopharmaceuticals in their charges for nuclear medicine procedures.**

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

The SNM recognizes that acquiring such data from hospitals and central radiopharmacies is not an easy task; therefore, we are more than willing to assist CMS in this endeavor in order to ensure a reliable process for rate setting in the future.

We thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the Nuclear Medicine Procedure and Radiopharmaceutical APCs. If you need additional information, please contact the SNM staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Respectfully Submitted,

Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Coding Advisor

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Carol Bazell, MD, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

Undervalued Radiopharmaceuticals

Table 1

1	2	3	4	5	6	7	8	9	10	11
HCPCS 2006 & other years for comparison	**Description**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**CMS Mean Unit Cost 2005 Data**	**AVG**	**CMS Mean 2005 Data vs Hospital Avg**
A9545 was C1081	I131 tositumomab, rx IODINE I-131 TOSITUMOMAB, THERAPEUTIC, PER TREATMENT DOSE	H	K	C1081 $19,422.00	$11,868.78	N/A	n/a	$11,868.78	$22,460.00	($10,591.22)
A9543 was C1083	Y90 ibritumomab, rx YTTRIUM Y-90 IBRITUMOMAB TIUXETAN, THERAPEUTIC, PER TREATMENT DOSE, UP TO 40 MILLICURIES	H	K	C1083 $20,948.20	$12,130.20	N/A	$19,614.96	$12,130.20	**$19,987.50**	($7,857.30)
A9544 was C1080	I131 tositumomab, dx IODINE I-131 TOSITUMOMAB, DIAGNOSTIC, PER STUDY DOSE	H	K	C1080 $2,241.00	$1,368.17	N/A	n/a	$1,368.17	$3,320.00	($1,951.83)
A4642 and C1066	In111 satumomab INDIUM IN-111 SATUMOMAB PENDETIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 6 MILLICURIES	H	K	$1,390.25	$192.12	$1,470.45 $1,494.41	n/a	$192.12	**$1,915.05**	($1,722.93)
A9508	I131 iodobenguate, dx IODINE I-131 IOBENGUANE SULFATE, DIAGNOSTIC, PER 0.5 MILLICURIE	H	K	$996.00	$429.55	N/A	n/a	$429.55	**$2,131.33**	($1,701.78)

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

1	2	3	4	5	6	7	8	9	10	11
HCPCS 2006 & other years for comparison	**Description**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**CMS Mean Unit Cost 2005 Data**	**AVG**	**CMS Mean 2005 Data vs Hospital Avg**
A9549 was C1122	Tc99m arcitumomab TECHNETIUM TC-99M ARCITUMOMAB, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	H	K	C1122 $1079.00 per vial	$255.95	$1,494.53	n/a	$255.95	**$1,661.35**	($1,405.40)
A9542 C1082	In111 ibritumomab, dx INDIUM IN-111 IBRITUMOMAB TIUXETAN, DIAGNOSTIC, PER STUDY DOSE, UP TO 5 MILLICURIES	H	K	C1082 $2,419.78	$1,344.34	N/A	n/a	$1,344.34	**$2,330.00**	($985.66)
A9507	In111 capromab INDIUM IN-111 CAPROMAB PENDETIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES	H	K	$1,915.23	$928.19	$1,774.30	$1,801.12	$928.19	**$1,861.31**	($933.12)
A9504	Tc99m apcitide TECHNETIUM TC-99M APCITIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 20 MILLICURIES	H	N	$415.00	Packaged into APC rate	$350.46	n/a	$51.16	**$437.12**	($385.96)
A9548 & C1092	In111 pentetate INDIUM IN-111 PENTETATE, DIAGNOSTIC, PER 0.5 MILLICURIE	H	K	$224.10	$262.81	$590.28	n/a	$262.81	$637.21	($374.40)
A9600	Sr89 strontium STRONTIUM SR-89 CHLORIDE, THERAPEUTIC, PER MILLICURIE	H	K	$406.16	$533.58	$1,416.60	n/a	$533.58	$787.00	($253.42)

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

1	2	3	4	5	6	7	8	9	10	11
HCPCS 2006 & other years for comparison	**Description**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**CMS Mean Unit Cost 2005 Data**	**AVG**	**CMS Mean 2005 Data vs Hospital Avg**
A9521 & C1096	Tc99m exametazime TECHNETIUM TC-99M EXAMETAZIME, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	H	K	$778.13	$317.07	$435.23	$455.59	$317.07	**$559.85**	($242.78)
A9547 was C1091	In111 oxyquinoline INDIUM IN-111 OXYQUINOLINE, DIAGNOSTIC, PER 0.5 MILLICURIE	H	K	$373.50	$306.51	N/A	n/a	$306.51	**$532.55**	($226.04)
A9557 was Q3003	Tc99m bicisate TECHNETIUM TC-99M BICISATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	H	K	$370.60	$254.46	$344.78	n/a	$254.46	$407.87	($153.41)
A9551 was C1201	Tc99m succimer TECHNETIUM TC-99M SUCCIMER, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES	H	K	$118.52 per vial	$84.79	$203.00	n/a	$84.79	**$160.89**	($76.10)
A9559 was Q3012 CMS C9013	Co57 cyano COBALT CO-57 CYANOCOBALAMIN, ORAL, DIAGNOSTIC, PER STUDY DOSE, UP TO 1 MICROCURIE	N	K	$85.49	$63.74	N/A	n/a	$101.39	$153.48	($52.09)
A9531	I131 max 100uCi IODINE I-131 SODIUM IODIDE, DIAGNOSTIC, PER MICROCURIE (UP TO 100 MICROCURIES)	H	N	Packaged	Packaged into APC rate	product on survey but not comparable descriptions	n/a	$2.83	**$32.50**	($29.67)

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

1	2	3	4	5	6	7	8	9	10	11
HCPCS 2006 & other years for comparison	**Description**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**CMS Mean Unit Cost 2005 Data**	**AVG**	**CMS Mean 2005 Data vs Hospital Avg**
A9537 was A9513 per mCi & C1097 per dose	Tc99m mebrofenin TECHNETIUM TC-99M MEBROFENIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 15 MILLICURIES	N	N	Packaged per mCi	Packaged into APC rate	$32.94 per dose	n/a	$15.46	**$40.99**	($25.53)
A9563 was Q3007	P32 Na phosphate SODIUM PHOSPHATE P-32, THERAPEUTIC, PER MILLICURIE	H	K	$94.98	$117.11	$281.40	n/a	$117.11	$142.50	($25.39)
A9561 was Q3009 per mCi & C1058 per vial	Tc99m oxidronate TECHNETIUM TC-99M OXIDRONATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLICURIES	N	N	Packaged per mCi	Packaged into APC rate	$22.87 & $19.68	n/a	$3.24	$24.75	($21.51)
A9539 was A9515 per mCi & C1098	Tc99m pentetate TECHNETIUM TC-99M PENTETATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	N	K	Packaged per mCi	$56.77	$24.74 per dose	n/a	$4.97	**$25.68**	($20.71)
A9529 combined generic code yes	I131 iodide sol, dx IODINE I-131 SODIUM IODIDE SOLUTION, DIAGNOSTIC, PER MILLICURIE	H	N	$9.73	Packaged into APC rate	product on survey but not comparable descriptions	n/a	$16.11	**$35.00**	($18.89)
A9538 was A9514 per mCi	Tc99m pyrophosphate TECHNETIUM TC-99M PYROPHOSPHATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	N	N	Packaged per mCi	Packaged into APC rate	N/A	n/a	$8.07	**$21.54**	($13.47)

The above table shows the following:

Column 1: 2006 HCPCS code and previous years code (if applicable) for comparison
Column 2: Radiopharmaceutical description
Column 3: 2006 Status Indicator
Column 4: 2007 Proposed Status Indicator
Column 5: CMS CY 2005 Final Payment Rate
Column 6: CMS CY 2007 Proposed Payment Rate
Column 7: Mean hospital acquisition cost based on 2002 SNM survey data
Column 8: GAO Acquisition Cost Survey 2004 Average Purchase Price
Column 9: CMS 2005 Mean Unit Cost Data
Column 10: SNM Current Mean Unit Cost Data based on a limited survey performed recently of primarily academic hospitals of SNM members of the SNM coding & reimbursement workgroup members
Column 11: SNM Mean Unit Cost Data versus CMS 2005

Submitter : Ms. Bobbie McAdams **Date:** 09/19/2006

Organization : University Health Care System

Category : Hospital

Issue Areas/Comments

Inpatient Only Procedures

Inpatient Only Procedures

Inpatient Only Procedures:

We recommend removing cpt codes 60520 & 60502 from the Inpatient only list as these can be safely performed in the outpatient setting. In addition they are frequently performed in conjunction with cpt code 60500 which is NOT on the inpatient list.

Submitter : **Rebecca Knight** **Date: 09/19/2006**

Organization : **Foothills Surgical Associates, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Rebecca Knight, MD

Rebecca Knight, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Cheryl Stanski **Date:** 09/19/2006

Organization : Holston Medical Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-81-Attach-1.DOC

Attach #
61

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; 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 CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. 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 and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

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,

Cheryl A. Stanski, MD

Cheryl A. Stanski, MD
Holston Medical Group
2204 Pavilion Drive
Kingsport, 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. Michael Berry **Date:** 09/19/2006

Organization : The Breast Clinic of Memphis

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-82-Attach-1.DOC

Attach 82

September 19, 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 CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. 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 and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

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,

Michael P. Berry, MD

Michael P. Berry, MD, FACS
The Breast Clinic of Memphis
6215 Humphrey's Boulevard
Memphis, 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. Russell Patterson, III **Date:** 09/19/2006

Organization : Surgery, Diseases of the Breast

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-83-Attach-1.DOC

Attach H
83

September 19, 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 these codes from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. 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 and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting treatment access to Medicare patients.

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,

Russell H. Patterson, MD

Russell H. Patterson, MD, FACS
Surgery Diseases of the Breast
6215 Humphrey's Boulevard
Memphis, 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. Edibaldo Silva **Date:** 09/19/2006

Organization : Creighton University Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-84-Attach-1.DOC

Attach #84

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
Federal Register publication – August 23, 2006

Dear Administrator:

I write to you today, to voice my concerns regarding the proposed RVU reduction for CPT 19296 and CPT 19297 as well as the APC reassignment of CPT 19296 from the "New Technology" to the "Clinical payment" rate. I do appreciate this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule.

The proposed reductions and reassignment will unfortunately impact my ability to care for Medicare patients with a diagnosis of breast cancer. Access to partial breast irradiation (PBI) is crucial for my patient population. 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 decide to decline to offer this service. The catheter used in delivery of the radiation is itself (at $2750) 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 do not believe that is what Medicare intended by making these proposed adjustments.

As a physician 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 and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Edibaldo Silva, MD, PhD, FACS

Edibaldo Silva, MD, PhD, FACS
Division of Surgical Oncology
Creighton University Medical Center
601 North 30th Street, Suite 2803
Omaha, NE 68131
402-280-4100

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

Submitter : Dr. T. William Huang **Date:** 09/19/2006

Organization : Methodist Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-85-Attach-1.DOC

Attach #
85

September 13, 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:

This letter is written to express my concern regarding the proposed APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate. Thank you for this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule, as per the Federal Register publication on August 23, 2006.

The proposed reassignment will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial 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 reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital may decide to decline to offer this service. The catheter itself (at $2750) 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 radiation oncologist focused on offering the best care to my Medicare patients, I urge CMS to reconsider the proposed 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,

T. William Huang, MD, PhD

T. William Huang, MD, PhD
Radiation Oncologist
Methodist Hospital
8303 Dodge Street
Omaha, NE 68114

cc.

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : Dr. Stephen Dick **Date:** 09/19/2006

Organization : Methodist Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-86-Attach-1.DOC

Attach # 86

September 13, 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:

This letter is written to express my concern regarding the proposed APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate. Thank you for this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule, as per the Federal Register publication on August 23, 2006.

The proposed reassignment will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial 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 reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital may decide to decline to offer this service. The catheter itself (at $2750) 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 radiation oncologist focused on offering the best care to my Medicare patients, I urge CMS to reconsider the proposed 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,

Stephen J. Dick, MD, MPH

Stephen J. Dick, MD, MPH
Radiation Oncologist
Methodist Hospital
8303 Dodge Street
Omaha, NE 68114
402-354-4104

cc. Carol M. Bazell, MD, MPH, Director, Division of Outpatient Care
Prabhakar Tripuraneni, MD, 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. Eugene Chang **Date:** 09/20/2006

Organization : Delta Surgical Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-87-Attach-1.DOC

Attach #
87

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 CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. 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 will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

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,

Eugene Chang, MD

Eugene Y. Chang, MD, FACS
Delta Surgical Oncology
Portsmouth, VA

cc. 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 : Lynn Canavan **Date:** 09/20/2006

Organization : Texas Breast Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-88-Attach-1.DOC

Attachment 88

September 16, 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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Lynn Canavan, MD

Lynn Canavan, MD
Texas Breast Surgeons
4510 Medical Center Dr., Ste. 108
McKinney, TX 75069
(972) 562-5999

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

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Christine Rogness** **Date: 09/20/2006**

Organization : **Foothills Surgical Associates, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Christine D. Rogness, MD

Christine D. Rogness, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Rebecca Wiebe** **Date: 09/20/2006**

Organization : **Foothills Surg. Assoc., PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Rebecca Wiebe, MD

Rebecca Wiebe, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Elizabeth Brew** **Date: 09/20/2006**

Organization : **Foothills Surg. Assoc., PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Elizabeth Brew, MD

Elizabeth Brew, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Philip Neff** **Date: 09/20/2006**

Organization : **Foothills Surg. Assoc., PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Philip Neff, MD

Philip Neff, MD
Foothills Surgical Associates, PC
3555 Lutheran Pkwy., Ste. 380
Wheat Ridge, CO 80033
(303) 940-8200

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Johannes Czernin, M.D. **Date:** 09/20/2006

Organization : Academy of Molecular Imaging

Category : Device Association

Issue Areas/Comments

Myocardial PET Scans

Myocardial PET Scans

AMI believes that CMS's proposal to assign HCPCS code 78492, for multiple myocardial PET scans, to the same APC as the HCPCS codes describing single myocardial PET will significantly underpay providers for multiple scanning procedures. Please see the attached document for further discussion of this issue.

New Technology APCs

New Technology APCs

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is premature and unsupported by reliable cost data. Please see the attached letter for discussion of the issue.

CMS-1506-P-93-Attach-1.PDF

HHach #
93

ACADEMY OF MOLECULAR IMAGING
www.ami-imaging.org ami@mednet.ucla.edu

Box 951735
Los Angeles, CA
90095-1735
310.267.2614
Fax: 310.267.2617

September 19, 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:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1506-P, Hospital Outpatient Payment System and CY 2007 Payment Rates, published in the Federal Register on August 23, 2006. AMI is comprised of academicians, researchers and nuclear medicine providers utilizing positron emission tomography (PET) technology. AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past two years to increase beneficiary access to both standard PET and PET with computed tomography (PET/CT) through the development of the National Oncology PET Registry (NOPR).

Summary

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is premature and unsupported by reliable cost data. The proposed payment rate of $865 represents a decrease of over 30% from the 2006 rate; moreover, is far below the true costs of providing PET/CT, and fails to recognize either the unique clinical benefits of PET/CT or that PET/CT is associated with substantially higher costs than conventional PET. The proposed reassignment of PET/CT would seriously underpay hospitals, and risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

This comment focuses on two crucial points. First, PET/CT is a clinically distinct technology from conventional PET, and entails substantially higher capital, maintenance, and operational costs. Second, the CPT codes for PET/CT were only implemented for Medicare payment in April 2005. Because hospitals typically do not update their charge masters more than once every year, hospital claims data from the last nine months of 2005—the period cited by CMS as its evidentiary basis for the proposed rule—does not accurately reflect the true cost to hospitals of providing PET/CT. For these reasons, PET/CT should remain in New Technology APC 1514 (Level XIV) at a rate of $1,250 for one more year.

On August 23, 2006, the APC Advisory Panel heard presentations on PET/CT from CMS and from outside groups, including AMI. The APC Advisory Panel voted in favor of maintaining PET/CT in its current New Technology APC at a rate of $1,250. AMI supports the recommendation of the APC Advisory Panel. AMI has engaged in an extensive provider education effort with CMS as part of the implementation of the NOPR, and is committed to working with CMS to educate hospitals about PET/CT.

PET/CT Should Be Paid Under a Separate APC from PET

The proposed CY 2007 rule would assign conventional PET and PET/CT to the same APC classification for the first time. The assignment of PET and PET/CT to the same APC is inconsistent with Medicare regulations. As the proposed rule states, all of the items and services within a given APC group must be "comparable clinically and with respect to resource use." With regard to CMS's determination of a clinically appropriate APC, the agency has stated:

> After we gain information about actual hospital costs incurred to furnish a new technology service, *we will move it to a clinically-related APC group with comparable resource costs.* If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service. (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technicians can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy**. A PET/CT image can distinguish between malignant and benign processes, and reveal tumors that may otherwise be obscured by the scars and swelling that result from

therapies such as surgery, radiation, and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices. Moreover, as we have explained, PET/CT is technologically and clinically unique and entails substantially higher capital, maintenance, and operational costs than conventional PET. Due to these highly relevant dissimilarities, PET/CT should not be assigned to the same APC as conventional PET.

Background on Medicare Payment for PET/CT

During the rulemaking process for the CY 2005 Hospital Outpatient Prospective Payment System, PET/CT was a new technology with no identifiable Medicare claims data. At the time CMS set payment rates for CY 2005, PET/CT did not have an established CPT code. In the final hospital outpatient rule, published on November 15, 2004, CMS referred to PET/CT in its comments, but did not set a payment rate. CMS stated in the final rule:

> The current G code descriptors do not describe PET/CT scan technology, and should not be reported to reflect the costs of a PET/CT scan. At present, we have decided not to recognize the CPT codes for PET/CT scans that the AMA intends to make effective January 1, 2005, because we believe the existing codes for billing a PET scan along with an appropriate CT scan, when provided, preserve the scope of coverage intent of the PET G-codes as well as allow for the continued tracking of the utilization of PET scans for various indications. (69 FR 65682, 65717 (November 15, 2004))

The American Medical Association (AMA) subsequently granted three new CPT codes (78814, 78815, and 78816) to describe PET with concurrent CT when it is used solely for attenuation correction and anatomical localization, rather than for diagnostic purposes. In March 2005, in the Hospital Outpatient Quarterly Update Transmittal 514, CMS assigned these three new codes to New Technology APC 1514, at a payment rate of $1,250. PET/CT remained in New Technology APC 1514, at a payment rate of $1,250, for CY 2006.

Medicare Claims Data Under-represents the Costs of Providing PET and PET/CT

In anticipation of the 2007 hospital outpatient rule, AMI contracted with a leading hospital network, Premier Inc., to collect external hospital cost data for PET and PET/CT. The Premier data obtained by AMI for conventional PET indicates an average cost to hospitals significantly higher than the proposed payment rate of $865. The 14 Premier hospitals that calculate costs according to the ratio-of-costs-to-charges (RCC) method reported an average cost for PET CPT 78812—the PET code most commonly paid by Medicare—of $1,336. The 19 Premier hospitals that use the relative value unit (RVU) method reported an average cost of $1,143.

The data for PET/CT showed improbably wide variation in hospitals' reported "average costs" of providing PET/CT, ranging from as low as $400 per scan to more than $2,400 per scan for PET/CT CPT 78815—the PET/CT CPT code most commonly paid by Medicare. The "average cost" of administering PET/CT also varied substantially depending on the method of cost accounting employed by the hospital. The reported average cost to RCC hospitals of $1147 is significantly higher than the proposed rate. The results of the Premier analysis are included with this comment as Attachment A.

AMI has asked Premier to audit the hospitals to determine the reason for the dramatic variability in reported costs. It is highly likely, however, that many hospitals have not yet properly updated their charge masters since the PET/CT CPT codes were introduced for Medicare payment in April 2005. Hospitals typically update their charge masters at most once per year, and sometimes less frequently than that. Contracts with private payers often limit a hospital's ability to change its charge master during a fiscal year. Accordingly, it is not uncommon for it to take two to three years after the implementation of a CPT code for a new technology until the new code is reflected in hospital costs data. Vanguard Health Systems testified at the August 23 APC Advisory Panel meeting that hospitals typically do not update charge masters for new technologies for two to three years. This is precisely the rationale behind the New Technology classification, which affords hospitals two to three years to obtain reliable cost data for new technologies. This fact strongly supports leaving PET/CT in New Technology APC 1514, with a payment rate of $1,250, for at least one more year.

Hospital Costs are Higher for PET/CT than for Conventional PET

The proposed rate reduction, and particularly CMS's intention to pay PET and PET/CT at the same rate, ignores the fact that it is significantly more expensive for hospitals to provide PET/CT services than conventional PET. AMI believes that the respective payment rates should reflect the relatively higher cost to hospitals of acquiring, maintaining, and operating a PET/CT scanner than a conventional PET scanner. AMI has undertaken a cost analysis of PET/CT using a published, peer-reviewed cost model.[1]

[1] *See* Keppler JS and Conti PS, A Cost Analysis of Positron Emission Tomography, Am. J. Radiology: 177, July 2001.

AMI contracted with Jennifer Keppler to develop an external analysis of the cost to hospitals of providing PET/CT. The study is based on fixed capital and operating costs, and incorporates national averages to account for scan volume. The study, which is included as Attachment B for your review, places the average cost of furnishing PET/CT at $1,368.

Hospitals incur significantly higher capital, maintenance, and operating costs with PET/CT than with conventional PET. The current price for a new PET/CT scanner is approximately $1.8 million, compared to $1 million for a conventional PET scanner. Further, a PET/CT scanner entails an annual maintenance cost of approximately $216,000, compared to $100,000 for a conventional PET scanner. Finally, the average salary for a technologist qualified to operate a PET/CT scanner is $70,000, compared to $45,000 for the operation of a conventional PET scanner.

In the final rule for CY 2006, CMS acknowledged that *"PET/CT scanners may be more costly to purchase and maintain that dedicated PET scanners,"* but suggested that *"a PET/CT scanner is versatile and may also be used to perform individual CT scans [in the event that] PET/CT scan demand is limited."* (70 Fed. Reg. 68516, 68581 (November 10, 2005)). The proposed rule for CY 2007 appears to reiterate a similar rationale when it attributes claims data suggesting an apparent similarity between the median cost of PET and PET/CT to the fact that *"many newer PET scanners also have the capability of rapidly acquiring CT images for attenuation correction and anatomical localization . . . ."* The implication appears to be that the high capital and maintenance costs associated with PET/CT scanners can be offset by their supplemental performance of CT-only scans.

However, CMS has provided no data on the actual utilization of PET/CT scanners to support this assertion. In fact, a survey of AMI member PET/CT providers indicates that a solid majority do not use their PET/CT scanners to provide CT-only scans. Keppler's cost analysis nevertheless assumes that each PET/CT scanner is used to perform an average of 4.5 stand-alone diagnostic CT scans per day. Even after incorporating this conservative assumption, Keppler calculated a cost estimate of $1,368 per PET/CT scan.

CMS Should Continue to Pay PET/CT In a New Technology APC in 2007

The New Technology APCs were created specifically because it takes several years for hospital charges to reflect the costs of new transformative products. CMS has stated that it expects to assign an item or service to a new technology APC for at least two years, or until the agency can obtain sufficient hospital claims data to justify reassigning the item or service to an existing APC. As we noted above, CMS first implemented New Technology APC 1514 for PET/CT in April 2005. CMS now proposes to reassign PET/CT from a new technology APC to an existing APC after only 21 months, based on the agency's analysis of Medicare claims data *from nine months in CY 2005*.

This proposal is at odds with the common hospital practice of updating their charge master once per year, if not less frequently. A hospital that updated its charge master at the end of CY 2005 would not have reported cost data specific to PET/CT until *after* the period on which CMS proposes to base the reassignment of PET/CT. The "close relationship between median costs of PET and PET/CT" that CMS discovered in the claims data of 362 providers reflects not the cost similarity between PET and PET/CT, but rather the fact that hospitals generally do not update their charge masters frequently enough to account for new CPT codes that are implemented mid-way through a calendar year. Nine months worth of cost data is not a sufficient basis for terminating a new technology classification.

As the proposed rule explains, CMS will "retain a service within a new technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group." The decision to remove PET from a new technology classification is based on a review of five years worth of claims data. By contrast, because the PET/CT CPT codes and payment rate were only implemented in April 2005, sufficient Medicare claims data for PET/CT is not yet available. In light of CMS's own new technology guidelines, both the newness of the PET/CT CPT codes and the absence of accurate and reliable claims data militate heavily in favor of maintaining PET/CT's new technology status for CY 2007.

Payment for Myocardial PET

Finally, AMI believes that CMS's proposal to assign HCPCS code 78492, for multiple myocardial PET scans, to the same APC as the HCPCS codes describing single myocardial PET will significantly underpay providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as longer scan times, than single scans. The current two-tiered APC structure, under which single and multiple scanning procedures are paid at $800.55 and $2,484.88, respectively, reflects this fact.

CMS speculates that, as myocardial PET scans "are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly." However, CMS provides no data to support this assertion. Further, the hospital claims data relied upon by CMS to justify consolidating single and multiple scanning procedures into one unified APC (APC 0307) with a payment rate of $721.26 show an improbably dramatic reduction over the course of a single year—CY 2005—in the cost to hospitals of providing multiple myocardial PET. Stakeholders and CMS require additional time to gather data and to study the reasons that the 2005 claims data shows such precipitous decline in hospital costs.

AMI appreciates the serious attention that CMS has afforded this important issue, and looks forward to working with the agency to ensure that Medicare beneficiaries retain access to this breakthrough technology.

Sincerely,

Johannes Czernin, M.D.
President
Academy of Molecular Imaging

Attachment A

PREMIER

Table 2: Average cost and charges by ROC Hospitals

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**765**	**100.00%**	**$1,336**	**$2,824**	**761**	**100.00%**	**$277**	**$662**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 613009	5	0.65%	$1,135	$3,975	5	0.66%	$127	$445
HOSPITAL 623328	30	3.92%	$1,568	$3,323	30	3.94%	$198	$420
HOSPITAL 623332	56	7.32%	$1,509	$3,323	54	7.10%	$193	$420
HOSPITAL 623333	101	13.20%	$1,890	$3,226	101	13.27%	$160	$494
HOSPITAL 623336	42	5.49%	$1,668	$3,323	42	5.52%	$211	$420
HOSPITAL AL0122	104	13.59%	$808	$2,535	104	13.67%	$242	$758
HOSPITAL IL2028	267	34.90%	$1,533	$2,501	267	35.09%	$364	$593
HOSPITAL MD0048	1	0.13%	$1,582	$2,065				
HOSPITAL MS0028	5	0.65%	$1,243	$3,323	4	0.53%	$156	$420
HOSPITAL MS0057	37	4.84%	$557	$3,184	37	4.86%	$105	$602
HOSPITAL OH2278	21	2.75%	$704	$3,292	21	2.76%	$419	$1,959
HOSPITAL PA2006	56	7.32%	$856	$1,820	56	7.36%	$311	$662
HOSPITAL VA0001	1	0.13%	$1,025	$3,115	1	0.13%	$207	$629
HOSPITAL WV0036	39	5.10%	$984	$3,786	39	5.12%	$383	$1,473

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by All Hospitals

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,426**	**100.00%**	**$1,143**	**$3,502**	**1,340**	**100.00%**	**$236**	**$933**
Number of Hospitals	19				19			
Hospital Detail								
HOSPITAL 600501	2	0.14%	$392	$3,149	2	0.15%	$349	$822
HOSPITAL CA2011	8	0.56%	$348	$4,457	8	0.60%	$491	$1,681
HOSPITAL FL0287	101	7.08%	$732	$3,600	100	7.46%	$544	$1,147
HOSPITAL FL9120	173	12.13%	$2,214	$3,787	166	12.39%	$228	$1,147
HOSPITAL GA0126	124	8.70%	$1,103	$5,589	124	9.25%	$103	$525
HOSPITAL KS2072	141	9.89%	$915	$3,109	141	10.52%	$233	$791
HOSPITAL MO2190	1	0.07%	$1,178	$2,247	1	0.07%	$300	$600
HOSPITAL MT2001	8	0.56%	$1,290	$3,469	8	0.60%	$322	$867
HOSPITAL MT2003	85	5.96%	$1,503	$3,872	85	6.34%	$487	$802
HOSPITAL NC0153	1	0.07%	$2,026	$3,411	1	0.07%	$541	$910
HOSPITAL NC0302	1	0.07%	$1,544	$2,625	1	0.07%	$463	$788
HOSPITAL NE2001	16	1.12%	$992	$3,032	16	1.19%	$334	$1,021
HOSPITAL OH2004	192	13.46%	$2,444	$3,894	192	14.33%	$32	$1,306
HOSPITAL SC0053	106	7.43%	$1,695	$2,379	105	7.84%	$366	$564
HOSPITAL SC0074	1	0.07%	$367	$2,900	1	0.07%	$246	$1,034
HOSPITAL WI2004	6	0.42%	$1,115	$3,737	6	0.45%	$763	$761
HOSPITAL WI2007	4	0.28%	$490	$4,093	4	0.30%	$388	$693
HOSPITAL WI2033	1	0.07%	$1,426	$3,000	1	0.07%	$561	$641
HOSPITAL WV0013	455	31.91%	$189	$2,954	378	28.21%	$189	$895

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average cost and charges by ROC Hospital

Indication: Procedure Code 78815, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,688**	**100.00%**	**$1,147**	**$3,248**	**1,315**	**100.00%**	**$211**	**$748**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 626723	133	7.88%	$726	$2,186	133	10.11%	$287	$863
HOSPITAL CO2087	365	21.62%	$2,321	$4,866				
HOSPITAL FL0091	93	5.51%	$771	$2,900	93	7.07%	$153	$577
HOSPITAL FL0161	322	19.08%	$699	$3,125	322	24.49%	$307	$1,375
HOSPITAL GA2039	2	0.12%	$1,792	$4,901	2	0.15%	$272	$745
HOSPITAL KY0106	74	4.38%	$1,029	$3,429	71	5.40%	$282	$939
HOSPITAL MS0052	3	0.18%	$1,366	$3,650	3	0.23%	$178	$475
HOSPITAL NC0001	379	22.45%	$690	$2,011	376	28.59%	$59	$171
HOSPITAL NE2008	28	1.66%	$1,393	$3,032	28	2.13%	$604	$1,021
HOSPITAL NE2033	1	0.06%	$700	$2,917	1	0.08%	$133	$556
HOSPITAL OH2017	25	1.48%	$720	$3,320	25	1.90%	$102	$416
HOSPITAL PA2006	10	0.59%	$834	$1,789	10	0.76%	$309	$662
HOSPITAL VA0001	222	13.15%	$1,171	$3,685	220	16.73%	$237	$744
HOSPITAL VA0095	31	1.84%	$831	$3,115	31	2.36%	$195	$706

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by RVU Hospitals

Indication: Procedure Code 78815, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**3,607**	**100.00%**	**$846**	**$4,027**	**3,545**	**100.00%**	**$403**	**$769**
Number of Hospitals	23				23			
Hospital Detail								
HOSPITAL 600501	166	4.60%	$401	$3,155	166	4.68%	$347	$824
HOSPITAL 609531	61	1.69%	$1,024	$3,143	61	1.72%	$228	$625
HOSPITAL 620028	184	5.10%	$1,202	$6,064	177	4.99%	$198	$1,000
HOSPITAL AL0051	309	8.57%	$1,521	$2,884	309	8.72%	$512	$585
HOSPITAL CA2013	411	11.39%	$760	$4,426	406	11.45%	$382	$779
HOSPITAL FL0287	420	11.64%	$753	$3,800	412	11.62%	$545	$1,147
HOSPITAL GA0126	78	2.16%	$906	$4,493	74	2.09%	$103	$500
HOSPITAL GA0178	16	0.44%	$1,896	$3,946	16	0.45%	$433	$901
HOSPITAL KY0022	9	0.25%	$445	$2,127	9	0.25%	$138	$662
HOSPITAL MO2190	6	0.17%	$1,311	$2,247	6	0.17%	$300	$600
HOSPITAL NE2001	69	1.91%	$1,004	$3,032	69	1.95%	$338	$1,021
HOSPITAL OH2004	78	2.16%	$2,404	$3,894	78	2.20%	$32	$1,306
HOSPITAL SD2018	59	1.64%	$731	$2,377	59	1.66%	$296	$1,155
HOSPITAL TX0083	198	5.49%	$851	$3,916	198	5.59%	$846	$806
HOSPITAL TX0393	246	6.82%	$446	$4,379	208	5.87%	$33	$324
HOSPITAL VA0106	6	0.17%	$1,023	$5,182	6	0.17%	$1,023	$410
HOSPITAL VA0112	177	4.91%	$677	$5,182	177	4.99%	$215	$410
HOSPITAL VA2038	108	2.99%	$1,414	$5,182	108	3.05%	$222	$410
HOSPITAL WA2005	41	1.14%	$873	$3,497	41	1.16%	$873	$827
HOSPITAL WI2004	89	2.47%	$1,130	$3,734	89	2.51%	$756	$761
HOSPITAL WI2007	841	23.32%	$481	$4,093	841	23.72%	$388	$693
HOSPITAL WI2008	1	0.03%	$465	$4,093	1	0.03%	$388	$693
HOSPITAL WI2009	34	0.94%	$875	$3,221	34	0.96%	$90	$528

* Represents discharges with cost and charges > 0.

Attachment B

Cost Analysis of PET: Modification of Model for PET/CT

Jennifer S. Keppler

In 2001, a paper was published describing the results of a multi-year evaluation of the costs of providing PET services (*A Cost Analysis of Positron Emission Tomography, American Journal of Radiology: 177, July 2001* (Keppler JS and Conti PS), "Cost Model"). The publication was the result of a 3-year study funded under a *Cost-Effective Health Care Technologies* award by the National Science Foundation/Whitaker Foundation. The purpose of the study was to identify the cost of PET to providers using several different operating models. In the Cost Model, a one-way sensitivity analysis found that throughput, the number of scans/day, was found to be the most significant success factor.

Since the paper was published, the utilization of PET technology has evolved. Commercial providers for the F-18 FDG have penetrated nearly all of the major population centers in the US, obviating the need for cyclotron-based PET centers. Accurate data are now available to show the average number of scans performed per day, based on FDG sales. The most significant change to the field was the introduction of a new technology in 2000, the PET-CT scanner. This new device provides a significant advancement in imaging capabilities, as well as additional complexity in the operation. Nearly 100% of all devices sold currently that image PET isotopes are PET/CT scanners.

To account for this changing environment, the authors have modified the original cost model for PET to the new technology of PET/CT. Outlined below (in **Tables 1, 2, and 3**)are the key assumptions that were changed, as well as the results of the addendum to the cost analysis.

Table 1: Model General Assumptions

Parameter	Previous value	New value	Source of new value
Number of PET/CT scans per day	2.9 PET scans/day	3.8 PET-CT scans/day	Bio-Tech Systems Industry report, 2006; AMI 2005
Stand alone diagnostic CT scans on patients not having a PET scan	None	Average 4.5 diagnostic CT scans billed per day	AMI Survey: 30% of sites perform 8 additional CT scans /day (not on PET pts)
CT scan revenues to offset costs	None	Average $280 payment/CT scan for total of ~$300,000 add'l revenues	50:50 blend of Thorax CT w/ contrast and w:w/o contrast (APC 283 and 333)
Professional Component	PC included in the total "cost" in the study	Reduce costs $128	CMS PFS payment is $128 (APC1514 in 2006)
FDG	FDG included in the total "cost" in the study	$ –	Eliminate cost of FDG because paid separately

Table 2: Capital Costs

Parameter	Previous value	New value	Source of new value
Scanner purchase price	$1,000,000	$1,800,000	NEMA

Table 3: Operating Costs

Parameter	Previous value	New value	Source of new value
Technologist Salary	$45,000/year	$69,837/year*	Avg of 2004 NMT estimates by AMA & ASRT; increased 8.5% for "PET" (which was the 2001 NMT:PET differential by NMTCB survey)
Service Contract	10% of scanner purchase price	12% of scanner purchase price = $216,000/yr	Informal survey of RBMA members indicate CT, and PET-CT service higher (range 12 – 20%)
Sealed Source	$15,000	$ -	Not needed: CT used for attenuation correction

* Corroborated by PET-CT job advertisements on the web: Baton Rouge, LA = $56 – 83K; NY $55 – 85K; CA $66 – 94K

Results:

Incorporating these new assumptions adequately and conservatively address the change in the technology from PET to PET/CT. Survey data from professional associations, as well as other published data were utilized to assure that the assumptions were appropriate.

Table 4 shows the average cost for a PET/CT scan, less the payment for FDG and professional component.

Table4: Cost of the PET/CT scan

All costs (including TC, PC, Rx)	**$1,717**
Minus FDG	$ 221
Minus MD paymt	$ 128
PET-CT cost	**$1,368**

Notably, since the average number of scans performed by a site per day has increased, the overall average cost per scan is less. At current levels of utilization, taking into account use for CT scans only, the cost of a PET-CT scan is $1,368.

Submitter : **Janine Meza** **Date: 09/20/2006**

Organization : **Janine Meza**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-94-Attach-1.DOC

Attach #
94

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

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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Janine Meza, MD

Janine Meza, MD
1601 E. 19th Ave
Denver, CO 80218
(303) 226-7400

Cc: Representative Diana DeGette, Energy and Commerce Health Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Kerri Perry **Date:** 09/20/2006

Organization : Kerri Perry

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-95-Attach-1.DOC

Attach #
95

September 15, 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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Kerri Perry, MD

Kerri Perry, MD
2817 South Mayhill Rd., Ste. 270
Denton, TX 76208
(940) 243-9759

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

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Mark Dickson **Date:** 09/20/2006

Organization : Mark Dickson

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-96-Attach-1.DOC

Attach #
96

September 16, 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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Mark Dickson, MD

Mark Dickson, MD
1014 Memorial, Ste 208
Denison, TX 75020
(903) 416-6240

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

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Alison Laidley** **Date: 09/20/2006**

Organization : **Breast Surgeons of N. TX**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-97-Attach-1.DOC

Attach # 97

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; 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.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Alison Laidley, MD

Alison Laidley, MD
7777 Forest Lane, Ste. C-614
Dallas, TX 75230
(972) 566-7499

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

Helen Pass, MD, President, American Society of Breast Surgeons

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Manoj Shaw **Date:** 09/20/2006

Organization : Dr. Manoj Shaw

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-98-Attach-1.DOC

Attach #
98

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,

Manoj Shaw, MD
Parkside Center
1875 Dempster, Ste 280
Park Ridge, IL 60068
847-723-5990

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. Allen Saxon **Date:** 09/20/2006

Organization : Dr. Allen Saxon

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-99-Attach-1.DOC

Attachment
99

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,

Allen Saxon, MD
1555 Barrington Road
Suite 2550
Hoffman Estates, IL 60195
847-884-7700

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. Philip Lobo **Date:** 09/20/2006

Organization : Dr. Philip Lobo

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-100-Attach-1.DOC

Attach #
100

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 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,

Philip Lobo, MD
800 West Central Road
Basement – Radiation Oncology
Arlington Heights, IL 60005
847-618-6560

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. Michael Kinney **Date:** 09/20/2006

Organization : Dr. Michael Kinney

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-101-Attach-1.DOC

Attach #
101

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,

Michael R. Kinney, MD
850 W. Central Road, Suite 7300
Arlington Heights, IL 60005
847-797-9099

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. Stephen Nigh **Date:** 09/20/2006

Organization : Dr. Stephen Nigh

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-102-Attach-1.DOC

ATTACH
102

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 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,

Stephen Nigh, MD
Radiation Oncology Associates
847-618-6560

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. Sung Chang **Date:** 09/20/2006

Organization : Dr. Sung Chang

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-103-Attach-1.DOC

Attach H
103

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 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,

Sung Chang, MD
2520 Elisha Avenue
Zion, IL 60099
847-731-4184

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. Lon McCroskey **Date:** 09/20/2006

Organization : Dr. Lon McCroskey

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-104-Attach-1.DOC

Attach #
104

September 13, 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 two matters. Namely, the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, as well as the APC reassignment of CPT 19296 from the 'New Technology' to the 'Clinical' payment rate. Thank you for this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule, as per the Federal Register publication on August 23, 2006.

The reductions and reassignment as proposed will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is an important option for my patient population.

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 offer this service. The catheter itself ($2750) 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

As a physician 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 review in this important matter.

Sincerely,

Lon McCroskey, MD
5701 W. 119th Street
Suite 220
Overland Park, KS 66209
913-696-1146

cc. Senator Sam Brownback, Co-Chair, Senate Cancer Coalition
Carol M. Bazell, MD, MPH. Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. Amie Jew **Date:** 09/20/2006

Organization : Dr. Amie Jew

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-105-Attach-1.DOC

Attach 11
105

September 13, 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:

This letter is written to express my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, as well as the APC reassignment of CPT 19296 from the New Technology to the Clinical payment rate. Thank you for this opportunity to provide comment on The Centers for Medicare and Medicaid Services' proposed rule, as per the Federal Register publication on August 23, 2006.

The proposed reductions and reassignment will significantly impact my ability to care for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial 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 decide to decline to offer this service. The catheter itself (at $2750) 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 physician 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 and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Name
Title
Address

cc. Senator Sam Brownback, Co-Chair, Senate Cancer Coalition
Carol M. Bazell, MD, MPH. Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 09/21/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 19, 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 for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Regards,

Harvey Greenberg, MD
H. Lee Moffitt Cancer Center & Research Institute

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women s Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women s Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

CMS-1506-P-106-Attach-1.DOC

Attach A
106

H. LEE MOFFITT Cancer Center & Research Institute
The End Of Cancer Begins Here.
A National Cancer Institute Comprehensive Cancer Center
At the University of South Florida

September 19, 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 for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Regards,

Harvey Greenberg, MD
H. Lee Moffitt Cancer Center & Research Institute

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

NCI CCCC
12902 Magnolia Drive
Tampa, Florida 33612-9497
Phone (813) 972-4673
Fax (813) 972-8495
www.MoffittCancerCenter.org