Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Jennifer Harper, MD
Dept of Radiation Oncology
Medical University of South Carolina

CMS-1506-P-201-Attach-1.DOC

HHCAF
201

MUSC
RADIATION ONCOLOGY

169 Ashley Avenue
PO Box 250318
Charleston • SC 29425

(843) 792-3271
Fax (843) 792-5498

Jennifer L. Harper, M.D.
Joseph M. Jenrette, III, M.D.
David T. Marshall, M.D.
Anand K. Sharma, M.D.

September 25, 2006

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

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

Dear CMS Administrator:

As a board certified Radiation Oncologist on staff at the Medical University of South Carolina (MUSC), I am very concerned about the 2007 CMS HOPPS proposed rule # CMS-1506-P and the impact these new rates will have on breast conservation surgery and brachytherapy irradiation treatments. My concerns lie in the proposed re-assignment of CPT codes 19296 and 19297 to new APCs and the proposed new payment methodology for brachytherapy sources in 2007.

I appreciate the opportunity to provide comments and truly believe CMS should continue with CPT codes 19296 and 19297 being assigned to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 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%

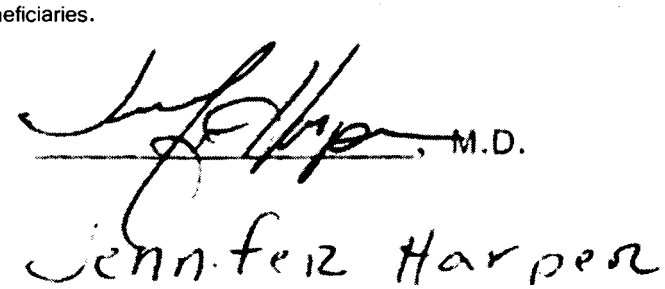
If CMS passes the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

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 assigned, must cover the cost of the device. Of note: the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

In relation to the proposed new payment methodology for brachytherapy sources, our hospital purchases the radiation source that is used in breast conservation treatment and bills C1717 for the HDR Iridium 192. I must inform you that it is very necessary for CMS to continue with the cost to charge ratio payment methodology in order to continue providing breast conservation treatment to your Medicare patients. Our hospital must be able to cover the costs of the radiation source; if not, we will not be able to continue to provide this less invasive, highly-effective cancer treatment to your 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. And further recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.



M.D.

Jennifer Harper

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
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
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

Submitter : **Michael Bewak** **Date: 10/02/2006**

Organization : **UNM Hospital**

Category : **Hospital**

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

Device-Dependent APCs
Section (IV)(A)(4) Proposed Payment Policy When Devices are Replaced Without Cost or Where Credit for a Replaced Device Is Furnished to the Hospital (71 FR 49574)
We support the CMS proposal to adjust (i.e. reduce) the APC payment amount when devices are replaced without cost or where credit for a replaced device is furnished to the hospital, for the reasons outlined by the CMS in the proposed rule.

OPPS: Cost-to-Charge Ratios

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Cost-To-Charge Ratios
Section (II) (A) (1) (c) Proposed Revision to the Overall Cost-to-Charge Ratio (CCR) Calculation
(71 FR 49528)
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OPPS: Drug Administration

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Packaged Services

Packaged Services

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Special Packaged Codes (71 FR 49535)
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We wish to thank the CMS for its discussion on billing claims that contain only codes for items that the CMS considers packaged (71 FR 49535 column 3). Perhaps this discussion will inspire some hospitals (ours included) to submit claims with only packaged codes so that the information becomes available to the CMS.

Visits

Visits

Visits
Section IX Proposed Hospital Coding and Payments for Visits (71 FR 49604)
General Comment We support the AHA/AHIMA s three levels of clinic and ED visits rather than the proposed five-level of visits. We have used the AHA/AHIMA three-level system and have found it straightforward and relatively easy to use. It is a system that is unique to the hospital setting. Under a five-level system some facilities may still want to force the level of visit to match the physician s level, even if the hospital uses G codes rather than the CPT codes.

The two levels added by CMS also add a new level of complexity to the coding process. In the proposed guidelines CMS indicates that if three of the asterisked Level 1(3) interventions are rendered, this changes the level to a Level 2(4). (There are non-asterisked interventions, as well.) On the surface this may sound simple, but in the clinical setting such a requirement of trying to identify asterisked versus non-asterisked interventions can create confusion for the staff, resulting in an incorrect level being assigned and billed The three-level system avoids this complexity.

Hospitals are trying to receive fair reimbursement for the E/M services they are rendering. We believe this can be accomplished using the AHA/AHIMA s three levels of clinic and ED visits.

We support using the two Critical Care codes also. However, we would prefer to have both codes paid, rather than having one paid and one packaged.

CMS-1506-P-202-Attach-1.DOC

HTT ... 202

THE UNIVERSITY OF NEW MEXICO • HEALTH SCIENCES CENTER

UNM HOSPITAL

October 2, 2006

Michael O. Leavitt, Secretary
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-1506P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-1506-P

Dear Secretary Leavitt:

We wish to take this opportunity to offer comments on various proposals contained in the Medicare Outpatient Prospective Payment System (OPPS) proposed rule appearing in the August 23, 2006 edition of the Federal Register.

Cost-To-Charge Ratios
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2211 Lomas Blvd. N.E. • Albuquerque, New Mexico 87106 • (505) 272-2111

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Visits
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The two levels added by CMS also add a new level of complexity to the coding process. In the proposed guidelines CMS indicates that if three of the asterisked Level 1(3) interventions are rendered, this changes the level to a Level 2(4). (There are non-asterisked interventions, as well.) On the surface this may sound simple, but in the clinical setting such a requirement of trying to identify asterisked versus non-asterisked interventions can create confusion for the staff, resulting in an incorrect level being assigned and billed The three-level system avoids this complexity.

Hospitals are trying to receive fair reimbursement for the E/M services they are rendering. We believe this can be accomplished using the AHA/AHIMA's three levels of clinic and ED visits.

We support using the two Critical Care codes also. However, we would prefer to have both codes paid, rather than having one paid and one packaged.

Emergency Department Visits (71 FR 49607) – Type "B" Emergency Department (ED) Visits
As proposed we cannot support the proposal to have a Type B ED. We could support the proposal to institute Type B EDs if the Type B definition is limited to the CPT definition of an emergency department excluding the 24 hour/day 7 day/week requirement (24/7). As pointed by the CMS at 71 FR 49615 there are hospitals that operate full-service EDs, but not 24/7 due to the lack of patients at certain times of the day. In these cases the hospitals have chosen to provide an essential (and expensive) service to their communities, and should be appropriately reimbursed for the resources used to provide the service.

It appears that the definition [of a Type B ED] as proposed (71 FR 49608) could also encompass hospital-based "urgent care centers", if at least ⅓ of the center's visits are "outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment". Urgent care centers provide essential medical care when open, however they may not be designed as or intended to be an emergency department, nor is the staff necessarily trained as emergency department staff. For these reasons we believe that urgent care centers or any department that operates primarily with scheduled appointments should be excluded from the definition of a Type B Emergency Department.

71 FR 49615
D. Proposed Treatment of Guidelines
We support using the AHA/AHIMA guidelines as a base for hospital E/M coding. However we don't agree with all the modifications (see comments below) as proposed by CMS to these guidelines.

General Comment – We believe that the guidelines as modified by CMS overlooks the basic ED or clinic visit which is comprised of: registration, use of the facility, and discharge. It may also include triage or initial clinical assessment. Although the hospital's staff may provide additional interventions for some of the visits, what level of visit is a hospital entitled to charge when none of the "additional" interventions are required? By eliminating the "initial clinical assessment" from the ED Level 1 interventions, and the "use of room, etc" from the clinic Level 1 interventions, the CMS has eliminated the basic ED or clinic visit. In which case the modified guidelines seem contrary to their primary purpose: identify the hospital resources needed to provide a medically necessary ED or clinic visit.

A physician may charge an O/P VISIT, EST PATIENT - LEVEL 1 (CPT 99211) for as little as five minutes of face-to-face time with patient. The hospital, on the other hand, could not charge for any level of visit (according to the modified CMS guidelines) if all that was done was to: register the patient, provide the use of the room, and discharge the patient, even though the total staff time required for these services could easily exceed five minutes.

Thus we believe that the guidelines require an intervention that is the baseline ED or clinic visit, which is basically the use of the facility. (These types of visits actually do occur in the hospital outpatient setting and we believe that's why the AHA/AHIMA guidelines list the basic visit as a Level 1 visit.) The record itself will show that the patient was present. Since this would not be an asterisked intervention it would not contribute to increasing a Level 1 or Level 3 visit to the next higher level, if the five levels are adopted as proposed. (Note, per the CMS modified guidelines three of the Level 1 or Level 3 asterisked interventions would increase the level of the visit to a Level 2 or a Level 4 visit, respectively.)

Clinic Visit Guidelines
We disagree that the use of the facility for greater than 60 minutes by a physician counseling a patient equates to a Level 1 visit for the hospital. As stated above we believe a baseline clinic visit is the use of facility for a "reasonable" period of time. We could support an intervention such as this one if the intervention is included as a "contributory factor" and would increase a lower level visit to the next higher level. However, as proposed we believe that it is expecting too much from the hospital community for such minimal reimbursement.

71 FR 49616
b. Lack of Clarity for Some Interventions – "Patient registration, room set up, patient use of room, room cleaning"...
See discussion above regarding a basic visit.

c. Treatment of Separately Payable Services – Our policy is to exclude separately payable services from the visit level determination. We believe that the resources used to provide the separately payable service would be reimbursed under the payment for that service. Thus our position is that interventions pertaining to separately payable services should be excluded from the visit level determination. We believe that to include such interventions in the visit level determination results in an inconsistent coding process, possible incorrect and/or duplicate billing, and confusion for the clinical and coding staffs.

We appreciate CMS' concern as expressed at 71 FR 49616 that in some cases an intervention-based guideline system may not accurately assign the visit level which reflects all of the hospital's resources used for the visit. However, rather than include interventions from separately payable services as part of the visit level, perhaps the list of contributory factors could include one or more provisions that would allow the visit level to be increased.

71 FR 49617
g. Differentiation Between New and Established Patients, and Between Standard Visits and Consultations
We don't necessarily agree that new-patient visits or consultation visits cost more then the standard established-patient visits. We are concerned that the cost differences as calculated by the CMS are the results of hospitals

choosing to charge higher prices for new and consultation visits. Thus when multiplied by the CCR, the costs of the visits appear to be higher then the cost of an established-patient visit.

We are also concerned that hospital billing for new and consultation visits may be inaccurate or incomplete. One of the items posted 02/15/06 to the CMS web site is the utilization data that was prepared for a Townhall Meeting. These data show that the distribution for facility-based new and established standard clinic visits and consultation visits for physician services to be: new patient visits 5 percent, and consultation visits 11 percent. The 5 percent for new patient visits is about the same as the distribution in the non-facility setting.

The distribution of "single-claims" data used for the proposed CY 2007 OPPS rule shows the distribution of visits to be: new patient visits 5 percent, consultation visits 4 percent. Given that the definition of "new patient" for hospital billing is significantly different than that for physician billing we expected to see a smaller percentage of new patient visits billed for hospital services. This is not the case. The question that comes to mind is: Are hospitals following the CMS definition of a "new patient" for billing clinic visits?.

Based on the comparison of consultation visit billing between physician and hospital billing, it appears as though hospitals may be billing the standard visit codes when consultation services are provided by the physician. In which case the number of hospital billed consultation visits would be understated. Currently, for hospital billing we would bill consultation visits using the standard visit codes.

In conclusion, from the hospital billing perspective, we do not believe that having separate codes for "new" and "established" patients or consultation visits would add value to any E/M coding guidelines proposed by the CMS.

Contributory Factors – We disagree with the removal of "Language Barrier" as a contributory factor, when an interpreter is required. Under the ADA we may be required to provide some accommodations to hearing and/or vision impaired individuals, as they may be defined as "individuals with disabilities". Interpreter services to these individuals would not increase the level of visit. However, we don't see how this applies to an individual who simply does not speak or understand English. In some cases an individual may simply choose not to learn the language of the area in which s/he reside. In order to understand the patient's complaint (reason for the visit) and render the appropriate care, an interpreter may be required. This is an additional resource provided to the patient, at an additional cost to the hospital. We believe that the use of this resource should be taken into account when determining the level of E/M visit.

We appreciate the opportunity to express our views on selected sections of the proposed CY 2007 OPPS rule.

Very truly yours,
/s/MBewak

Michael Bewak
Sr. Financial Analyst
505-272-2575
mbewak@salud.unm.edu
For:
UNM Hospital

Submitter : **Michael Bewak** **Date: 10/02/2006**

Organization : **UNM Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Clarifying note:
I attempted to submit all our comments using the electronic forms, but when I printed out the results only a portion of our comments pertaining to the "Visits" issue were in the file.

I am all resubmitting all our comments in the enclosed attachment.

CMS-1506-P-203-Attach-1.DOC

Attach 11
203

THE UNIVERSITY OF NEW MEXICO ◆ HEALTH SCIENCES CENTER

UNM HOSPITAL

October 2, 2006

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Centers for Medicare and Medicaid Services
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Very truly yours,
/s/MBewak

Michael Bewak
Sr. Financial Analyst
505-272-2575
mbewak@salud.unm.edu
For:
UNM Hospital

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

David Rice MD

CMS-1506-P-204-Attach-1.DOC

CMS-1506-P-204-Attach-2.DOC

HM-204
204

21st Century Oncology

A TEACHING AFFILIATE OF MASSACHUSETTS GENERAL HOSPITAL

David J. Rice, M.D.
Medical Degree:
University of Michigan Medical School
Ann Arbor, MI
Residency:
Radiation Oncology
University of Michigan Medical School
Ann Arbor, MI

Daniel E. Dosoretz, M.D.
Medical Degree:
University of Buenos Aires, Argentina
Residency:
Massachusetts General Hospital
Harvard Medical School
Chief Resident:
Massachusetts General Hospital
Harvard Medical School
Fellow:
American College of Radiology
American College of Radiation Oncology

Michael J. Katin, M.D.
Medical Degree:
University of Pennsylvania
Residency:
Hematology/Oncology:
Fox Chase Cancer Institute, Temple
Radiation Oncology:
Massachusetts General Hospital
Harvard Medical School
Fellow:
American College of Radiology
American College of Physicians
American College of Radiation Oncology

Michael N. Shevach, M.D.
Medical Degree:
University of Miami
Miami, FL
Residency:
University of Maryland Medical System
Baltimore, MD
Fellowship:
University of Maryland Medical System
Baltimore, MD

Daniel H. Galmarini, M.S.
Director of Physics

September 28, 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 CMS Administrator:

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am very concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs. I would like to continue providing HDR breast brachytherapy services to Medicare eligible women; however, I may not be able to do so with the proposed, drastic cuts to the hospital for placement of the device.

Should CMS finalize the proposed APC assignments; the cost of the device will surpass the proposed payment rate. Hospitals will not purchase the device and this will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

CMS should continue assigning CPT codes 19296 and 19297 to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 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%

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Sergio Villegas, MD
Surgeon Miami FL

CMS-1506-P-205-Attach-1.DOC

salazar
santiago
villegas
sabates, & cabral, p.a.

Attach 205

BRAULIO SABATES, M.D., F.A.C.S.
JUAN SALAZAR, M.D., F.A.C.S.
CARLOS SANTIAGO, M.D., F.A.C.S.
SERGIO VILLEGAS, M.D., F.A.C.S.
AMADEO H. CABRAL, M.D., F.A.C.S.
GENERAL, VASCULAR, ONCOLOGIC & LAPAROSCOPIC SURGERY

September 25, 2006

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

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

Dear Administrator:

I appreciate the ability to comment on the 2007 HOPPS Rule # CMS-1506-P. There are problems with the proposed reassignment of CPT codes 19296 and 19297 to new APCs. The reassignment of these codes would result in significant decreases in 2007 payments; and I am extremely concerned that the proposed rates will have a negative impact on breast conservation surgery and subsequent partial breast irradiation therapy. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
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19297 Breast interstitial radiation treatment, immediate	1523	$2,750	0029	$1,732.69	($1,017.31)	**-37.0%**

Should CMS uphold the proposed APC assignments, it will limit our ability to offer the breast brachytherapy breast cancer treatment option to Medicare eligible women. Breast brachytherapy CPT codes 19296 and 19297 are classified as device-dependent procedures. The codes rely on the use of a high-cost device that is bundled into the procedure payment. The cost of the device will surpass 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. CMS needs to reevaluate and reassign these codes to a more appropriate APC for 2008 since the APC they are assigned to **must** cover the cost of the device. The cost of the device is the same when implanted at time of lumpectomy or during a separate office-based procedure.

APC 648 Breast Reconstruction with Prosthesis includes procedures similar to those of 19296 and 19297. The similarities are in clinical and cost. Should CMS discontinue the assignment of 19296 and 19297 to the new tech APCs, an alternative request is for both CPT codes to be reclassified to APC 648.

In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS 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 in advance for your assistance,

Sergio Villegas, M.D., F.A.C.S.

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
Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Juan Salazar, MD

CMS-1506-P-206-Attach-1.DOC

salazar
santiago
villegas
sabates, & cabral, p.a.

CMS-1506-P
206

BRAULIO SABATES, M.D., F.A.C.S.
JUAN SALAZAR, M.D., F.A.C.S.
CARLOS SANTIAGO, M.D., F.A.C.S.
SERGIO VILLEGAS, M.D., F.A.C.S.
AMADEO H. CABRAL, M.D., F.A.C.S.
GENERAL, VASCULAR, ONCOLOGIC & LAPAROSCOPIC SURGERY

September 25, 2006

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

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

Dear Administrator:

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In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS 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 in advance for your assistance.

Juan Salazar, M.D. F.A.C.S.

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
Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Carlos Santiago, MD

CMS-1506-P-207-Attach-1.DOC

santiago
villegas
sabates, & cabral, p.a.

Attachment
207

BRAULIO SABATES, M.D., F.A.C.S.
JUAN SALAZAR, M.D., F.A.C.S.
CARLOS SANTIAGO, M.D., F.A.C.S.
SERGIO VILLEGAS, M.D., F.A.C.S.
AMADEO H. CABRAL, M.D., F.A.C.S.
GENERAL, VASCULAR, ONCOLOGIC & LAPAROSCOPIC SURGERY

September 25, 2006

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

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

Dear Administrator:

I appreciate the ability to comment on the 2007 HOPPS Rule # CMS-1506-P. There are problems with the proposed reassignment of CPT codes 19296 and 19297 to new APCs. The reassignment of these codes would result in significant decreases in 2007 payments; and I am extremely concerned that the proposed rates will have a negative impact on breast conservation surgery and subsequent partial breast irradiation therapy. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

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In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow CMS 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 in advance for your assistance,

Carlos Santiago, M. D., F.A.C.S.

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
Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Braulio Sabates MD

CMS-1506-P-208-Attach-1.DOC

santiago
villegas
sabates, & cabral, p.a.

HH
908

BRAULIO SABATES, M.D., F.A.C.S.
JUAN SALAZAR, M.D., F.A.C.S.
CARLOS SANTIAGO, M.D., F.A.C.S.
SERGIO VILLEGAS, M.D., F.A.C.S.
AMADEO H. CABRAL, M.D., F.A.C.S.
GENERAL, VASCULAR, ONCOLOGIC & LAPAROSCOPIC SURGERY

September 25, 2006

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

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

Dear Administrator:

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Thank you in advance for your assistance.

Braulio Sabates, M.D. F.A.C.S.

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
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Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

see attachment
Amadeo Cabral, MD

CMS-1506-P-209-Attach-1.DOC

salazar
santiago
villegas
sabates, & cabral, p.a.

BRAULIO SABATES, M.D., F.A.C.S.
JUAN SALAZAR, M.D., F.A.C.S.
CARLOS SANTIAGO, M.D., F.A.C.S.
SERGIO VILLEGAS, M.D., F.A.C.S.
AMADEO H. CABRAL, M.D., F.A.C.S.
GENERAL, VASCULAR, ONCOLOGIC & LAPAROSCOPIC SURGERY

CMS-1506-P
209

September 25, 2006

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

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

Dear Administrator:

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Thank you in advance for your assistance.

Amadeo H. Cabral, M.D. F.A.C.S.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
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Carol Bazell, MD, Director, Division of Outpatient Care
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Dr. John Horney **Date:** 10/02/2006

Organization : Metro Atlanta Endoscopy, LLC

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

Submitter : **Dr. Thomas McGahan** **Date: 10/02/2006**

Organization : **Ambulatory Surgical Center**

Category : **Physician**

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

Submitter : **Date: 10/02/2006**

Organization :

Category : **Other Technician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHEMENT
LEN HURST, MS, DABR

CMS-1506-P-212-Attach-1.DOC

1414 414
212

CATAWBA VALLEY MEDICAL CENTER

September 27, 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

Rule: Hospital Outpatient Prospective Payment Svstem (OPPS) Medicare Program, Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program - HCAHPS Survey, SCIP and Mortality

Dear CMS 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). This letter is written to show my deep concern regarding the pending changes.

Catawba Valley Medical Center provides Partial Breast Irradiation (PBI) Therapy treatment to your Medicare beneficiaries. PBI uses a surgically implanted catheter to deliver the radiation directly to the tumor bed and uses high dose radiation to treat the tumor bed. Partial Breast Irradiation Therapy is a very important alternative treatment modality to conventional External Beam Radiation Therapy for Medicare age women, since it provides women the option to shorten their course of therapy from 6-7 weeks to five days.

I am quite concerned about the proposed changes to 19296 and 19297 and respectfully request that CMS keep APC #1524 assigned to this new technology for an additional year until better data can be collected. The proposed reassignment to APC #0030 is not sufficient payment for the catheter, which is priced at $2,750.

Again, I appreciate the opportunity to comment on file #CMS-1506-P. Medicare patients should have availability and access to all breast cancer treatment options. I strongly urge CMS to reconsider the assignment of breast brachytherapy to APC #0030 and keep breast brachytherapy assigned to the old APC #1524.

I greatly appreciate your time and attention to this very important issue.

Len Hurst, MS DABR
Dept. of Radiation Oncology
Catawba Valley Medical Center
810 Fairgrove Church Rd.
Hickory, NC 28602

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

see attachment
Nancy Bednarz, MD

CMS-1506-P-213-Attach-1.DOC

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213

MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
James D. Kinard, PhD, M.D.
Justin J. Wu, M.D.
Matthew A. Manning, M.D.
Nancy M. Bednarz, M.D.

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

Response to Rule # CMS-1506-P: Hospital Outpatient Payment System (OPPS)

Dear Administrator,

Thank you for allowing me 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 some serious concerns regarding your proposed changes.

CPT code 19296 was linked to APC #1524 in 2006 which = $3250 in reimbursement for the placement of the brachytherapy balloon catheter. CMS is proposing a 23% reduction by moving CPT codes 19296 & 19297 to a new APC#. The proposed 2007 APC# is 0030 which = $2508 in reimbursement for the placement of the catheter. This is less than the catheter cost of $2750.

The proposed APC reassignment from "New Technology" to "Clinical" is inadequate. Our facility may decline offering this service to your Medicare beneficiaries.

Our recommendation is for CMS to keep APC #1524 for at least one more year so additional data can be collected on this service. The Centers for Medicare and Medicaid Services should consider actual supply and other cost data in establishing the 2007 APC assignment for Placement of breast brachytherapy catheters for interstitial radioelement application (CPT codes 19296 and 19297).

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Nancy Bednarz MD

Nancy Bednarz, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee,
Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

see attachment
Robert Murray, MD

CMS-1506-P-214-Attach-1.DOC

MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
James D. Kinard, PhD, M.D.
Justin J. Wu, M.D.
Matthew A. Manning, M.D.
Nancy M. Bednarz, M.D.

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

Response to Rule # CMS-1506-P: Hospital Outpatient Payment System (OPPS)

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Respectfully,

Robert Murray, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHMENT

CMS-1506-P-215-Attach-1.DOC

MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
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September 20, 2006

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

Response to Rule # CMS-1506-P: Hospital Outpatient Payment System (OPPS)

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We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Matthew Manning, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee,
Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

see attachment
James Kinard, MD

CMS-1506-P-216-Attach-1.DOC

MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
James D. Kinard, PhD, M.D.
Justin J. Wu, M.D.
Matthew A. Manning, M.D.
Nancy M. Bednarz, M.D.

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

Response to Rule # CMS-1506-P: Hospital Outpatient Payment System (OPPS)

Dear Administrator,

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We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

James Kinard, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee,
Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHMENT
ADAM RIKER, MD

CMS-1506-P-217-Attach-1.DOC

UNIVERSITY OF SOUTH ALABAMA
MITCHELL CANCER INSTITUTE

September 25, 2006

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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS 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.

Additionally, the opening of the NSABP-B-39 trial has also allowed us to accrue patients who have node-positive disease, yet another important indication for patients desiring to have partial breast irradiation.

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

Respectfully,

Adam Riker M.D.

Adam Riker M.D., F.A.C.S.
Chief of Surgical Oncology
USA-Mitchell Cancer 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
Carol Bazell, MD, 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 : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHMENT

CMS-1506-P-218-Attach-1.DOC

HIT-0F
218

John R. Russell, M.D., M.S.
Diplomate in Radiation Oncology
Fellow, American College of Radiation Oncology

E. Henry Amos, M.D., F.A.C.R.
Diplomate in Radiation Oncology
Fellow, American College of Radiology

THE CANCER CENTER
of Southern Alabama

Michael D. Williams, Ph.D.
Diplomate in Medical Physics
Matthew D. Williams, M.S.

PROGRAM DEVELOPMENT
Cathy C. Tinnea, L.P.N.

3 Mobile Infirmary Circle, Suite 306 Mobile, AL 36607-3515 Phone: (251) 544-5400 Fax: (251) 433-3122

September 25, 2006

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

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

Dear CMS Administrator:

As a Board Certified Radiation Oncologist practicing at THE CANCER CENTER OF SOUTHERN ALABAMA, I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am very concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs and the proposed new payment methodology for brachytherapy sources in 2007.

CMS should continue assigning CPT codes 19296 and 19297 to the New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 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%**

If CMS moves forward with the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

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. CMS should reevaluate and reassign these CPT codes to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC assigned, must cover the cost of the device. Of note: the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Additionally, our hospital 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 the cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of the radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, I recommend:

1. 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.

2. that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.

Regards,

John R. Russell

John R. Russell, M.D., M.S., FACRO

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

Submitter : **Ms. Sajini Thomas** **Date: 10/02/2006**

Organization : **wright medical technology**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Wright Medical Technology requested CMS to assign K status for the GRAFTJACKET(R) XPRESS FLOWABLE SOFT TISSUE MATRIX currently billed with the pass through code, C9221, Decellularized soft-tissue scaffold, per 1 cc . This product is regulated by CBER as a Tissue Biologic. However, in the proposed rule, the associated J code, J7350 is proposed to be packaged for 2007. We request CMS to assign the K status for J7350 when billing GRAFTJACKET(R) XPRESS as it meets the requirements for separate payment:
1) The XPRESS product is not a surgical supply; it is a micronized form of the sheet produet. GRAFTJACKET? XPRESS Flowable Soft Tissue Scaffold is flowable graft that is applied with a cannula to sinus eavity wounds that are difficult to heal.
2)The cost of the product is approximately $1,795/cc; it exceeds the $50 threshold established by MMA for separate payment in the HOPD.
3)In the HCPCS database, the BETOS indicator for the J7350 code also is 01E for Other Drugs and the TOS indicator is 1 for a medical product.

Therefore, Wright Medical Technology requests that CMS assign the K status to the J7350 eode when used to bill the XPRESS product.

Respectfully,

Sajini Thomas
Director, Wright Medical Technology Reimbursement Services

Submitter : **Date: 10/02/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

SEE ATTACHMENT

CRISTINA LOPEZ-PENALVER, MD

CMS-1506-P-220-Attach-1.DOC

220

ADVANCED SURGICAL ASSOCIATES

September 27, 2006

Advanced Surgical Institute
Moises Jacobs, MD, F.A.C.S.
Cristina Lopez-Penalver, MD, F.A.C.S.
Eddie Gomez, MD, F.A.C.S.

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 CMS 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.

Thank you in advance for your assistance,

Cristina Lopez-Penalver, M.D., F.A.C.S.

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
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Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, 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. Jorge Cassir **Date:** 10/03/2006

Organization : Shore Memorial Hospital, Somers Point, NJ

Category : Physician

Issue Areas/Comments

New Technology APCs

New Technology APCs

The proposed cuts in reimbursement for G0339 and G0340 will seriously impact the introduction of Robotic Stereotactic Radiosurgery which is quite expensive and time consuming, but which offers a revolutionary approach to selected cancer patients. Please reconsider the proposed changes, and allow the medical community to move forward in introducing this promising technology. Physicians and institutions in our area are interested in offering this to our patients, but the cut backs appear sufficient to disuade us from moving forward.

Submitter : **Kim Moore** **Date: 10/03/2006**

Organization : **St. John Health**

Category : **Hospital**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

RE: File Code CMS-1506-P

Drug Administration Coding and Payment

CMS is proposing to continue requiring a combination of HCPCS C-codes and CPT codes for use in 2007. While there is a need to standardize the coding for all payers there is a need to define the CPT codes as they relate to outpatient hospital settings. The terminology associated with the CPT codes are not easily adaptable in an outpatient hospital setting due to the variation in types of cases not seen normally in a physician s office. We support the continued use of the HCPCS C-codes until CMS clarifies the descriptions of the CPT codes. Concepts such as subsequent, sequential, and concurrent are not well defined and again difficult to employ across multiple nursing units and hospital departments.

One particular area of concern is that of IV Push Administration (currently C8952). The previous CPT code (90784) did not include any language limiting use by the drug , and hospitals were able to bill for each and every separately identifiable IV Push. The Medicare Claims Processing Manual, Chapter 4, section 230.2 on Intravenous or Intra-Arterial Push was updated following the Final 2006 OPPS Federal Register changes stating Hospitals are to bill for additional IV pushes of different substances or drugs using multiple units of the appropriate push code . The comments were clarified in a document published by CMS as Questions Related to Pub 100-04, Medicare Claims Processing, Chapter 4, Section 230.2 . The clarification indicated HCPC code C8952 may only be billed with a unit of one for the same substance, even when the drug is provided at a different time during the same encounter.

The document referenced the Final 2006 OPPS Federal Register stating, we expect that all drug administration codes used in the CY 2006 OPPS, including the new C-codes will conform to CPT guidance". Which when placed in context with the remaining portion of the sentence - we expect that all drug administration codes used in the CY 2006 OPPS, including the new C-codes will conform to CPT guidance regarding under what clinical circumstances they may be appropriately billed , does not state that they conform to the specific CPT description listed by the AMA.

Additionally, the Final 2006 OPPS Federal Register stated it would not change 2005 drug payment polices for 2006 and C8952 was created to allow straightforward billing of each push. The CMS clarification in Transmittal 785 definitely created a decrease in payments to hospitals and does not allow for straightforward billing of each push. It should also be noted that a facility s cost does not decrease when multiple injections of the same substance are given at different times during the encounter

Since the Final 2006 OPPS Federal Register did not indicate that C8952 would be limited as suggested in Transmittal 785, facilities were not given the opportunity to comment on the negative financial impact of the change.

If CMS retains the current coding structure we would ask that the instructions associated with C8952 be revised to reflect the intent of the Final 2006 Federal Register allowing hospitals to charge and be paid for additional injections of the same substance to ensure reimbursement for the cost of the service and the packaged drug costs.

Submitter : **Dr. Sandra Tincher** **Date: 10/03/2006**

Organization : **Brookwood Regional Cancer Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 2, 2006

The 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 CY 2007 OPPS Proposed Rule

Dear Administrator:

I am sending this letter with the hope that Medicare will reconsider the payment method proposed in the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS 1506-P) for I-125 Iodine, a liquid radionuclide source used in patients diagnosed with brain cancer. I appreciate that CMS encourages and requests public comment and believe this an important matter to bring to your attention.

Iotrex, an Iodine I-125 liquid radioisotope source (HCPCS C2632) is infused through a catheter and into a balloon that has surgically been implanted in the cavity space where a malignant brain tumor or glioblastoma had existed before its removal by a neurosurgeon. The tumor excision and implantation of the balloon catheter is performed in the same surgical session. Once the patient is fully recovered and is discharged from the hospital, radiation therapy can begin in the outpatient setting. Onc of the more important benefits in using Iotrex during the internal radiation therapy course is that it provides the cancer patient an opportunity to experience a quality of life and increased survival that might not otherwise be available when faced with this devastating illness.

I urge to CMS to reconsider the proposal for payment of I-125 as outlined in CMS-1506-P and respectively request continued payment based on cost following hospital charge adjustment. The proposed payment rate is insufficient in meeting the cost of the liquid source along with handling and any other administrative costs associated with the source itself. Hospitals must be able to continue offering this vital brain cancer radiotherapy option hence setting an adequate rate is imperative.

Thank you for allowing me to submit comment with respect to this serious matter that being continued access to and the offering of cancer treatment services to Medicare beneficiaries.

In regard,

Sandra Tincher, MD

Sandra A. Tincher, M.D.
Brookwood Regional Cancer Center
2010 Brookwood Medical Center Drive
Birmingham, AL 35209
(205) 877-CARE (877-2273)

cc: Senator Jeff Sessions, State of Alabama
Senator Richard C. Shelby, State of Alabama
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : **Dr. john mauriello** **Date: 10/03/2006**

Organization : **Dr. john mauriello**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Kim Moore **Date:** 10/03/2006

Organization : St. John Health

Category : Hospital

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

For CY 2006, CMS created a new HCPCS G-code,G0332 for pre-administration related services for IV infusion of immunoglobulin (IVIG), to offset hospital expenses associated with the extra work related to the problems experienced due to the unavailability of the IVIG product. The 2007 OPPS Proposed Rule, indicates that a separate IVIG pre-administration payment is no longer necessary in CY 2007.

Hospitals continue to have difficulty getting our complete supply of IVIG. This drug is produced in limited supply and is made available to us through allocation, at a time when our demand has increase. We are on an allocation basis for ordering each month, and the contracted amount that wc can buy on allocation is not enough. We have to buy further product off contract at siginificantly higher prices. It may appear to CMS that utilization is down, but that is more of a result of supply than need.

We would urge CMS to continue the payment for IVIG services under HCPCS G0332.

Submitter : Dr. RANDALL OREM **Date:** 10/03/2006

Organization : FAIRINGTON CARDIOVASCULAR AND WELLNESS CENTER

Category : Physician

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predieate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28

Submitter : **Wayne Baldwin** **Date: 10/03/2006**

Organization : **MD Services**

Category : **Health Care Industry**

Issue Areas/Comments

Ancillary Outpatient Services

Ancillary Outpatient Services

In my role as a financial and legal consultant to seven IDTF outpatient positron emission tomography facilities, I have reviewed the financial condition, cost factors and continued viability of each center. Based on this review and analysis, I can safely say, without reservation, that the continued existence of each of these facilities is very unlikely if the changes to the PET proposed reimbursement are implemented as planned. If I understand the effect of the laws and regulation set to go into effect, the combination of the Deficit Reduction Act and the proposed changes to the Hospital Outpatient PPS will reduce outpatient IDTF PET reimbursement to $862 per non-myocardial PET procedure. This represents a cut of approximately 60% to 70%. PET is primarily a cancer study with an elderly patient base resulting in a high ratio of Medicare patients.

It is my understanding that the rational for the DRA's mandate to lower radiology reimbursement was a reaction to reports of over utiliztion. While there may be instances of over utilization involving modalities other than PET such as MRI or CT, PET is not in the same situation. Subspecialty physicians (such as orthopedists and cardiologists) have installed MRI and CT scanners as part of their practices. Very few oncology or other sub-specialty practices have their own PET scanners. To paint PET with the same brush is not only unfair, it is inaccurate. None of the IDTF PET facilities I have reviewed appear to have such issues. All of them are operating below capacity, and the majority struggle to break even. This is true whether the facility operates a PET or PET/CT scanner. Costs to acquire and install PET technology are substantial (typically $2,000,000 to $2,500,000 per facility). PET and CT technologists are in short supply driving costs up further. IDTFs do not have the ability to use capital resources available to hopsital outpatient facilities, some of which

IDTFs provide PET to patients who are often unable to reach a hospital. The proposed rated would seriously under-pay IDTF PET facilities and undermine an important source of PET services to patients not able to access PET through hospitals due to either unavailability, distance or payor limitations.

We have observed a substantial change in the management of cancer patients after PET. These changes in management can reduce unnecessary procedures and reduce the expense of total patient care.

Having witnessed the rise in utilization of MRI and CT scanning over the years, it is apparent to me that the rise in PET utilization has substantial limiting factors not present in MRI or CT. In the IDTF arena, PET is still primarily an oncology study, and even then, PET is not applicable to all oncology patients. The number of oncology related PET studies pales in comparison to the widespread application of MRI and CT to multiple injuries and diseases. Other uses for PET are still in the early stages. The DRA was apparently intended to curb the perceived over-utilization of diagnostic radiology procedures in IDTF and group practice settings, but the same logic applied to PET cannot be supported.

Finally, the reimbursement cuts of 60% o 70% are not supported even by a brief review of average outpatient cost factors. PET patient encounters are typically 90 to 120 minutes for a normal ambulatory patient. Patients with significant problems (blood sugar too high, non-ambulatory, collapsed viens, etc.) can be in the PET center for over 3 hours. This not only limits through put, it also drives up costs. Compare to throughput on MRI (30-40 minutes per patient on average) and CT (half that of MRI or less). PET equipment costs are also substantially higher than MRI or CT (by as much as $1,000,000) and the construetion costs (due to heavy lead shielding) are substantially higher ($20,000 to $40,000). Yet, at $862 per study, the reimbursement does not come close to accounting for these differences.

Submitter : Dr. Arthur Olch **Date:** 10/03/2006

Organization : Chidlrens Hospital Los Angeles

Category : Other Practitioner

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

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

Dear Dr. McClellan:

Our hospital is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule. This comment letter specifically addresses the proposed payment methodology for brachytherapy sources in 2007.

Our hospital is located in Los Angeles, California, and has been providing cancer care to the community for over 40 years. We are concerned that the proposed payment rates for brachytherapy sources may impact our ability to continue our current cancer programs offered by our hospital.

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for each of these brachytherapy sources. Brachytherapy sources are provided as low dose rate (LDR) and high dose rate (HDR) permanently or temporarily implanted based upon the type and site of tumor. The current configurations of the brachytherapy sources and the wide range in radioactive intensities offer physicians an appropriate array of treatment approaches to ensure the therapy effectively treats the size, location and histology of the tumor. The variations in cost of each source require a unique payment methodology for radioactive sources.

We do not believe that the recommended payment methodology will appropriately captures the variation of brachytherapy source configurations and urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device. Appropriate payment for brachytherapy sources is required to ensure that our hospital can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of this important issue.

Sincerely,
Arthur Olch, Ph.D.
Chief of Physics, Radiation Oncology Program

Submitter : Mrs. Catherine Morris **Date:** 10/03/2006

Organization : Diomed, Inc.

Category : Nurse

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
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36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Dr. Rodney Rodriguez **Date:** 10/03/2006

Organization : Dr. Rodney Rodriguez

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-230-Attach-1.DOC

Attach #
230

September 21, 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:

I appreciate the forum 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 change in APC codes for the hospital for radiation/oncology brachytherapy services.

There are two areas of issue in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and 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. Now CMS is proposing to reassign these codes from New Technology APCs to clinical APCs in 2007. This proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment, which would result in the hospital not being able to make this service available to Medicare patients. The table below illustrates the reductions, ranging from -22.8% to -37.0%. This is truly significant.

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%

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

CMS should preserve 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may continue to collect claims data and other cost data through calendar year 2006. This will allow CMS to more accurately re-evaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned to 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 procedure done at a later time.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge 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,

Rodney Rodriguez, MD

Rodney Rodriguez, MD
Radiation Oncologist
Doctors Medical Center
2000 Vale Road
San Pablo, CA 94806

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congresswoman Nancy Pelosi (D)

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

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

cc: American College of Radiation Oncology
James Rubenstein, MD, Chairman, American College of Radiation Oncology

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

Submitter : Mr. Paul Viviano **Date:** 10/03/2006

Organization : Alliance Imaging

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-231-Attach-1.DOC

CMS-1506-P-231-Attach-2.DOC

HHS-OIG
231

ALLIANCEIMAGING
1900 S. State College Blvd. Suite 600
Anaheim, California 92806
TEL 800.544.3215 FAX 714.688.3333
www.allianceimaging.com

October 2, 2006

The Honorable Mark McClellan, M.D.
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: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates/New Technology APCs: Nonmyocardial Positron Emission Tomography (PET) Scans and PET/Computed Tomography (PET/CT) Scans

Dear Dr. McClellan:

Alliance Imaging ("Alliance") is pleased to have this opportunity to comment upon the Centers for Medicare and Medicaid Services' ("CMS's") recently proposed rule, CMS-1506-P (the "Proposed Rule"), which includes the collective reassignment of PET and PET/CT (CPT codes 78814, 78815 and 78816) scans from their current new technology APCs to clinical APC 0308. For the reasons set forth below, and consistent with the August 2006 recommendations of the Advisory Panel on APC Groups, Alliance urges CMS to retain the current new technology APC for PET/CT scans.

Alliance is the largest national provider of diagnostic imaging services in the United States and provides in the aggregate approximately 1 million diagnostic imaging exams on an annual basis (including approximately 100,000 PET and PET/CT scans) on behalf of over 1,200 hospital and healthcare clients. Currently, Alliance operates approximately 334 MRI units and 76 PET and PET/CT scanners. Most of our diagnostic imaging services, and almost all of our PET and PET/CT services, are provided to our hospital clients on a "shared" or mobile basis where the unit is available to scan patients at a specific hospital during the day and is then moved in the evening (often several hundred miles) to another location to service a different hospital the next day.

Based on a review of IMV's Medical Information Division Benchmark Report for PET 2005/2006, we believe that substantially more than half of the roughly 1,700 current providers of PET/CT in United States utilize shared mobile services to provide this clinical service to their patients.

Over the past five years, non-myocardial positron emission tomography ("PET") has become an integral part of the diagnosis, treatment and monitoring of many cancers by allowing for the metabolic (rather than purely anatomic) imaging of diseased tissues. With the recent advent of combined PET and computed tomography ("PET/CT") scanners, physicians can simultaneously assess the aggressiveness of a tumor and its precise location more accurately than ever before. The availability of PET/CT has undoubtedly improved treatment planning, surgery staging and post-therapy monitoring of cancer patients with access to these imaging services. These technological advances in imaging have been of particular benefit to Medicare beneficiaries in light of our referral data which suggests over 40% of patients receiving PET and PET/CT scans are covered by Medicare.

We strongly believe that the proposed reduction in PET/CT's reimbursement from $1,250 to $865 per scan is unwarranted and inappropriate for the following reasons:

(i) PET/CT procedures have only been classified a New Technology APC for approximately twenty months, and insufficient PET/CT claims data supports the reimbursement reduction as set forth in the Proposed Rule;

(ii) equivalent pricing of PET and PET/CT scans ignores the significant and demonstrably higher costs of PET/CT; and

(iii) a 32% reduction in 2007 hospital outpatient reimbursement will curtail the availability of PET/CT services, particularly in rural areas, reducing beneficiary access and/or increasing patient travel times in those areas not served by a PET/CT provider.

New Technology APC Status Should Be Extended for CY 2007

As the Proposed Rule correctly states, new technology APCs are instituted to provide an appropriate period of time to collect sufficient claims data to assign new procedures to a clinically appropriate APC. Under the final rules issued in November 2001, while procedures can be reassigned from a new technology APC after two years, such a reassignment should only be considered where sufficient claims data have been gathered on the new procedure. We note that CMS obtained five years worth of hospital claims data before moving nonmyocardial PET scans from a New Technology APC to a clinical APC. Conversely, for PET/CT claims data, CMS analyzed claims submitted over the course of less than one year (CY 2005), and during a time when a significant number of providers were migrating from PET to PET/CT (as evidenced by the significant decline in PET procedures and corresponding increase in PET/CT procedures from CY 2004 to CY 2005). We believe that the data collected is not sufficient to warrant the early termination of PET/CT's new

technology APC status. In particular, we are concerned that reliance on an incomplete year's worth of data during a period of significant technology adoption is not justifiable, especially when there can be no assurance that (i) new providers of PET/CT have updated their gross charge master files to accurately reflect the costs of providing the service or (ii) the data collected reflects a sufficiently broad spectrum of providers upon which credible cost analysis can be based.

For this reason, we believe there is not sufficient justification for the early termination of PET/CT's new technology APC status, and instead request that new technology treatment be extended at least through CY 2007.

Equivalent Pricing of PET and PET/CT Procedures Ignores Significant Cost Differentials

As noted above, PET/CT has quickly become the standard of care in oncology related imaging. With its simultaneous fusion of metabolic and anatomical data, PET/CT is a diagnostic tool which allows for coordinated treatment, intervention and monitoring by a wide range of physician specialists. This significant technological advance in capability beyond simple PET requires the additional costs of: (i) incorporating a CT scanner onto a PET platform resulting in an average unit price today of approximately $1.85 million to $2.0 million (versus an average cost of $1.1 million to $1.2 million for a PET-only unit); (ii) maintaining and operating the PET/CT system whose average annual maintenance cost is approximately $70,000 to $80,000 more per year than an equivalent PET-only scanner (due to the added maintenance of its CT component which requires regular replacement of costly x-ray tubes) and (iii) requiring technical personnel trained and accredited in two diagnostic imaging modalities (x-ray and nuclear medicine), resulting in a wage premium over their single modality peers of approximately 20% to 30%.

The Proposed Rule's finding that median PET/CT costs are equivalent to those for PET-only procedures is inconsistent with our extensive experience in providing these services. It is unclear what may be the cause or causes of this inconsistency, but we believe using an incomplete dataset of CY 2005 claims (as compared to a PET dataset collected from CY 2002 through 2005) may be at the root of the problem. In addition to the possible over or under representation of certain classes of providers in the data set (e.g., academic versus non-academic, urban versus rural, high volume versus low volume), we believe that there was insufficient time for new hospital providers to reflect the additional costs associated with PET/CT, therefore rendering the data inaccurate and unreliable. Keeping the PET/CT procedure codes in the new technology APC for CY 2007 gives hospitals more time to update their charge masters and implement accurate coding strategies such that hospital claims going forward will adequately represent the real costs of the procedures.

Given the unexplained contradiction between (i) the demonstrable costs differences of PET and PET/CT and (ii) the Proposed Rule's finding of cost equivalence, we believe that

the Proposed Rule's reassignment of PET/CT to APC 0308 should be postponed until a more complete and reliable dataset can be collected as the basis for such reassignment.

Adverse Impact on Rural Access to PET/CT Services.

Under the Proposed Rule, the average hospital payment for outpatient PET/CT services will be reduced from $1,250 per scan to $865 per scan effective January 1, 2007. This reduction of more than 30% will have an obvious and negative impact on any hospital clients currently considering an expansion into PET/CT services as well as those that currently provide such services, particularly hospitals who contract with out-source providers like Alliance. Since many of these contracts call for fixed payments per scan in excess of the reimbursement to be imposed by the Proposed Rule, the proposed reimbursement reductions will force some providers to choose between eliminating the service altogether or providing it at a loss to Medicare beneficiaries.

We estimate that approximately 20% of Alliance's approximately 320 mobile PET and PET/CT hospital clients are located in rural areas (as defined by the Stark II regulations). In the case of such rural providers, the problems of reduced reimbursement may be further exacerbated due to lower numbers of cancer patients (and therefore lower annual PET/CT scan volumes) and higher costs of service (due to greater geographical distances which must be traveled to such facilities). For this reason, the Proposed Rules' reimbursement reductions may force rural providers to forego expanding their cancer treatment services to include PET/CT, or put more pressure on existing providers to terminate their agreements if they are already providing the service at a loss. In the event that one or two rural clients elects to terminate service based on the economic pressures of reduced reimbursement, it is possible such terminations would render their rural PET/CT route financially unsustainable, and cause all of the hospitals on such route to lose their service. If that were to occur, cancer patients in those underserved markets would be required to travel greater distances to receive appropriate medical care.

To ensure continued beneficiary access to PET/CT services, particularly in rural areas, we believe that the Proposed Rule's assignment of PET/CT services to a clinical APC should be postponed until reliable claims data can be collected and used to ensure that such procedures are assigned to a clinically appropriate APC with payment levels that will minimize any adverse impact on beneficiary access. We therefore support the August 2006 conclusions of the Advisory Panel on APC Groups, and support their recommendation that PET/CT procedure codes remain in their New Technology APC for CY 2007.

* * * * * *

We appreciate the opportunity to comment on the Proposed Rule, and thank you for your attention to this important matter. In the event that you have any questions regarding the foregoing, please feel free to contact me at (714) 688-3301 and I will be happy to assist you with your questions or concerns.

Sincerely,

Paul S. Viviano
Chairman of the Board and
Chief Executive Officer

Submitter : Dr. Robert Aki **Date:** 10/03/2006

Organization : Dr. Robert Aki

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-232-Attach-1.DOC

Attachment
232

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,

Robert Aki, MD

Robert Aki, MD
605 W. Central Road, #201
Arlington Heights, IL 60005

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 : **Mr. Stanford Miller** **Date: 10/03/2006**

Organization : **Neuronetics, Inc.**

Category : **Device Industry**

Issue Areas/Comments

OPPS: New HCPCS and CPT Codes

OPPS: New HCPCS and CPT Codes

See Attachement

CMS-1506-P-233-Attach-1.DOC

Attachment
233

NEURONETICS

October 3, 2006

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

VIA ELECTRONIC DELIVERY

RE: OPPS: New HCPCS and CPT Codes: Comments on the Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule; CMS-1506-P

To Whom It May Concern:

Neuronetics, Inc. (Neuronetics) is pleased to respond to the proposed rule and request for comments published by CMS in the August 23, 2006 Federal Register.

Neuronetics is the manufacturer of a transcranial magnetic stimulation (TMS) system that is currently under review by the FDA for the treatment of major depression. Two new category III CPT codes were recently released (January 2006) and implemented (July 2006) for this procedure (0160T and 0161T). Neuronetics believes that these codes have been mapped to an inappropriate APC (0340) in the proposed rule. Neuronetics asks CMS to un-map these CPT codes and leave them un-mapped until Neuronetics commercializes the technology and provides data that will allow appropriate mapping.

Request to Un-Map 0160T and 0161T from APC 0340

Neuronetics has developed the NeuroStar TMS Therapy™ system for the treatment of major depression. The NeuroStar is not FDA cleared and is not being used in clinical practice outside of research protocols. Importantly, there are no TMS devices that are FDA cleared at this time for any therapeutic indication. Therapeutic use is the intended use described by 0160T and 0161T. Neuronetics expects the NeuroStar to be cleared for use by the FDA in January 2007 and Neuronetics plans to launch the NeuroStar in the first quarter of 2007.

TMS is a non-invasive technique for stimulating cortical neurons resulting in reduction of depressive symptoms in a difficult-to-treat population. The NeuroStar TMS Therapy system consists of both capital equipment and single use devices (one device needed per treatment). TMS therapy will typically be outpatient and consist of daily treatments over a number of weeks. TMS may be used as maintenance therapy as well. Psychiatrists will administer TMS Therapy, and a typical treatment session lasts roughly 45 minutes. TMS represents a unique technology with unique applications, requiring specific equipment and a specialized operator skill set.

A more detailed overview of the NeuroStar is included as Appendix A. An overview of a TMS Therapy procedure described by these new codes is included as Appendix B.

TMS Therapy CPT Codes: In response to Neuronetics' application and with the support of the American Psychiatric Association and the American Neurological Association, the AMA released (January 2006) and implemented (July 2006) two new category III CPT codes for TMS:

- 0160T Therapeutic repetitive transcranial magnetic stimulation treatment planning
- 0161T Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session

The proposed rule maps each of these codes to APC 340 "Ancillary Medical Procedure":

APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0340	Minor Ancillary Procedures	X	0.6211	38.23		7.65

We are not aware of any valid basis for these assignments (see Appendix C for additional discussion). TMS Therapy is clearly not a "minor ancillary procedure" (See Appendix B). TMS is a complex brain mapping and stimulation treatment process for the treatment of difficult recurrent depression. Additionally, the resources necessary to provide 0160T and 0161T are significantly greater than reflected by the payment rate for APC 0340. Unfortunately, at this time we don't know exactly how much greater and these data will not be available until commercialization of the NeuroStar system. At the very least, for example, although final pricing has not yet been determined, we are confident the NeuroStar's single use device along will cost the providing facility several times the payment rate for APC 0340. Additionally, TMS Therapy must be preformed in a dedicated room due to several technical and procedural issues. The exact costs of the single use device, NeuroStar capital equipment, and additional overhead are simply not available at this time. We also believe 0160T and 0161T will require different APCs, due to the significantly different resources used in providing the two distinct and mutually exclusive procedures. Finally, as the procedures (0160T and 0161T) are mutually exclusive and may be performed on the same day, and because there may be occasion to provide two treatments (0161T) in the same day (morning and afternoon, for example), it is very important that when these codes are mapped in the future, the status indicators for the mapped APCs allow for separate, non-discounted payment when performed on the same day.

We do not believe mapping 0160T and 0161T to another APC is appropriate at this time. As the costs are currently unknown, mapping to another APC at this time would be arbitrary and could significantly over or under compensate providers. Given this risk, we believe these two CPT codes should simply be un-mapped at this time.

We realize that un-mapping the CPT codes may result in no payment for TMS in the hospital outpatient setting for calendar year 2007. And we understand that this will likely limit access for some patients. However, there simply are not the data necessary to appropriately map 0160T and 0161T at this time. We look forward to working with the APC Advisory Panel in 2007 to

determine appropriate mapping and to ensure access for appropriate patients to this important therapy.

Thank you for the opportunity to comment on the CY 2007 proposed rule. We are happy to provide additional information upon request. If you have any questions regarding these comments, please do not hesitate to contact me at 610-640-4202, ext 1002 or 770-420-8225. My email is smiller@neuronetics.com.

Sincerely,
Neuronetics, Inc.

Stanford W. Miller
Vice President, Health Policy and Access

Attachments:

Appendix A	NeuroStar TMS Therapy™ System Product Profile
Appendix B	Clinical Vignettes for Transcranial Magnetic Stimulation (TMS) for the Treatment of Major Depression (CPT 0160T and 0161T)
Appendix C	History of TMS Coding (CPT 0018T, 0160T and 0161T)

Appendix A

NeuroStar TMS Therapy™ System Product Profile

The NeuroStar TMS Therapy system consists of a treatment chair with a coil alignment system and a mobile stimulator console. The components of the mobile stimulator console can be seen in Figure 1 below. The stimulator is operated by the physician via the touch panel display were patient data is entered, information determined in the procedure described by 0160T are stored for future recall and use, and the treatment sessions described in 0161T are programmed and subsequently controlled.

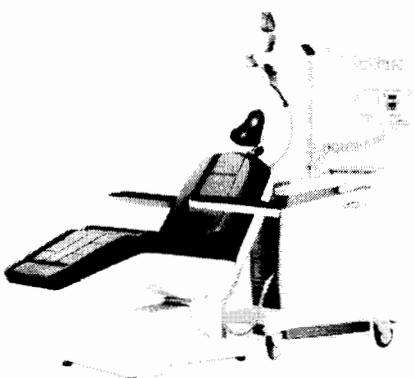

Figure 1: NeuroStar TMS Therapy System

Figure 2: Physician Installing SenStar Treatment Link

TMS Therapy is performed on major depression patients in the position shown in Figure 1 above. Note the coil is placed over the left prefrontal cortex while the patient remains awake and alert for the treatment. The system is capable of producing very significant magnetic field strength in very brief 200 microsecond pulses. These pulses are of the intensity sufficient to excite the surface of the cortex inducing neuronal firing and subsequent neurotransmitter release. System operation requires the use of a single use device called the SenStar treatment link for each treatment session. It fits between the treatment coil and the patient providing an integral link. It performs several important functions to facilitate safe and effective treatments. The functions include:

- Contact sensing to ensure good patient contact throughout the treatment course, maximizing potential efficacy
- Magnetic field strength output monitoring to facilitate safe and effective treatments
- Partial surface E-field cancellation to facilitate high patient adherence to protocol
- Serves as a hygiene barrier from patient to patient

The SenStar™ treatment link fits on the outer surface of the coil for easy replacement. (Figure 2 above)

Appendix B

Clinical Vignettes for Transcranial Magnetic Stimulation (TMS) for the Treatment of Major Depression (CPT 0160T and 0161T)

TYPICAL PATIENT

The patient is a 34-year-old female who presents with a clinical diagnosis consistent with DSM-IV defined Major Depressive Disorder. Her symptoms include severely depressed mood on a daily basis, diminished interest and enjoyment of usual activities, decreased sexual interest, initial insomnia and disrupted sleep patterns, guilt feelings, somatic distress including gastrointestinal complaints and diffuse musculoskeletal pain, intermittent suicidal ideation, anxiety, and diminished ability to concentrate leading to impairment in work and routine household responsibilities. She has failed to receive benefit from an adequate trial of antidepressant pharmacotherapy, and her treating physician has now included the possible use of electroconvulsive therapy as an appropriate treatment option. She has no unstable medical conditions, and has no contraindications to TMS Therapy. A patient similar to the one described here, but in whom medication therapy is either contraindicated, or where the patient is intolerant of such medications, is also a good candidate for TMS Therapy.

- **0160T Therapeutic repetitive transcranial magnetic stimulation treatment planning**

Dose determination and targeting are performed at the initial assessment and at clinically appropriate points periodically during a course of TMS Therapy. With each dose determination and targeting session a comprehensive medical appraisal is made to determine any relevant medical history that may be expected to influence the patient's risk profile with regard to the use of TMS, or to have led to an alteration in the patient's previously determined dose level.

The patient is seated comfortably in the treatment chair and the physician applies a headset to the patient which will assist in locating both the site over the primary motor cortex where the motor threshold (MT) will be determined and the location over the prefrontal cortex where the magnetic stimulation will be delivered. Next, the patient is provided with ear plugs and their head is placed in the headrest and the headset is adjusted for patient head size and comfort. Prior to placement of the electromagnetic coil on the patient's head, a component is attached to the face of the coil which assists the physician in measuring coil proximity to the scalp, improves the comfort during the procedure and provides system confirmation of the appropriate output magnetic field strength. Patient specific information that has been entered in the TMS Therapy system in advance of the treatment session is verified with the patient and the electromagnetic coil is then placed on the patient's head over the motor strip area above the ear on the same hemisphere as where the treatment stimulation will be delivered. For determination of the motor threshold (MT), the TMS system is set to a pulse rate of less than 1 Hz. Operationally, the MT value is defined as the lowest level of system output power which produces a visible movement in the contra-lateral thumb or next most proximate digit, as observed by the evaluating physician. The physician moves the coil across the surface of the scalp overlaying the area of motor cortex in a systematic grid pattern, to identify the optimal MT location, adjusting the stimulator output in a gradual fashion until the optimal location on the motor strip that controls the movement of the thumb or

finger is found. This location is marked on the headset for future use since the same headset is ordinarily used throughout a course of therapy. The stimulator output power is now titrated to determine the exact output power that is sufficient to induce a motor response, but in no excess. This process is repeated in a standardized manner four times with the final value computed by the system by finding the 50% probability power level of the known probability distribution that best fits the physician's observations of the thumb movement. The output power level determined by this process is called the MT value. This value is saved in the TMS Therapy system and rechecked periodically throughout a course of therapy on subsequent treatment days as needed based on the medical determination of the treating physician. The physician then measures 5cm anterior on an oblique saggital arc ending up over the prefrontal cortex which will be the site of therapeutic stimulation. This position is also marked on the headset to future use. The coil is positioned on the patient's head by combining this location information with proximity sensor feedback to determine the coil resting position. The coil is then fixed to remain in good contact with the patient's head for the duration of treatment. This process typically takes up to one hour for the first MT determination, and may take 30 to 45 minutes on repeat determinations. After MT is determined, the treatment is now ready to begin.

- **0161T Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session**

Once the headset is in place on the patients head, the MT value is determined and the coil is in the treatment position, then the treatment can begin. The prescribed treatment parameters are selected by the physician and stored in the system. A typical treatment will consist of 10 Hz stimulation at an intensity of 120% of the MT value. At this frequency and intensity, the stimulation is typically delivered in 4 second bursts beginning 30 seconds apart. A total of 75, 4 second bursts are delivered to the patient to total 3000 stimulations per treatment session. A typical treatment session takes about 45 minutes. During the treatment session, the patient must be closely monitored at all times to ensure good coil to head contact. If this is lost due to patient motion or other factors, the system provides an alarm to the physician, and the coil must be repositioned before continuing treatment to facilitate the most robust outcomes possible. The user must monitor the system continually and respond to these and any other alarm conditions indicated by the system. In addition, the physician must monitor the patient's clinical status for comfort and tolerability and, if necessary adjust coil position and potentially, customize the stimulation parameters to mitigate discomfort. Finally, although the risk is extremely low (<1%), patients must also be monitored for any signs or symptoms that may indicate the emergence of an ictal event, and the physician must be ready to respond if necessary.

This procedure is repeated daily, Monday through Friday for an average duration of 4 to 6 weeks, followed by a taper phase of 3 days/week for one week, then 2 days/week for one week and finally 1 day for the last week. This schedule constitutes a typical complete course of therapy which may vary up to 30 days depending on patient response.

Periodic review of a patient's clinical status should be performed during a course of TMS Therapy, to determine whether adjustment of the treatment parameters is required. This assessment should include an evaluation of the tolerability of the procedure itself and the clinical management of the more common adverse events, such as headache or pain, or more complex

medical phenomena, such as pre-ictal signs and symptoms. Clinical evaluation to determine the medical significance of these observations should include a detailed discussion of the types of events experienced by the patient, and the temporal course of these events, and whether they abate between treatment sessions. The patient's clinical history should also be periodically reviewed to assess the presence of other events or routine health habits, including but not limited to changes in medications, caffeine or nicotine intake, or sleep; that may be expected to alter the patient's motor threshold (MT), requiring that a new motor threshold (MT) value be determined. This management session typically takes approximately 15 minutes to 30 minutes for a typical patient and is performed periodically throughout a course of treatment.

PROCEDURE NOTE

The two codes which make up the components of a course of TMS Therapy are mutually exclusive. Treatment planning (0160T) must always be completed prior to the initial treatment delivery session (0161T). Treatment planning with new MT determination will be performed periodically throughout a course of treatment, dependent on a patient's clinical response, tolerability of the procedures, and general medical judgment of the treating physician. Treatment delivery will be performed as prescribed by the treating physician over a number of days, typically organized into sequential and continuous five day blocks of treatment. The treatment management portion of 0161T may be performed less frequently (for the typical patient) than the treatment delivery portion of 0161T. Both portions of 0161T may be performed on the same day. When 0160T and 0161T are performed on the same day, they are mutually exclusive procedures with no overlap in resource use or provider time requirements.

Appendix C

History of TMS Coding
(CPT 0018T, 0160T and 0161T)

The coding history for TMS may be of interest to CMS and help explain why 0160T and 0161T are inappropriately mapped and why 0018T is being deleted from the CPT system.

Historical Clinical Use and Research Using TMS

TMS has been and is being utilized to investigate neuropsychological function (e.g. attention, memory, movement, speech, vision) and to evaluate disease processes in the central and peripheral nervous systems for many years. More than 2,000 TMS devices (mostly diagnostic/research systems) are in use worldwide. Research studies evaluating TMS for major depression are widespread. As a result of this work, there is a robust body of clinical literature on the use of TMS for the treatment of major depressive disorder (MDD), spanning over 10 years and including over 1,500 patients.

Importantly, there have been no rigorously conducted large, multicenter TMS clinical trials in the treatment of patients with MDD (before the current Neuronetics' study described below). Results of clinical trials using TMS are mixed and depend on the population studied and the treatment protocol used. Nevertheless, published meta-analyses have found that daily left prefrontal TMS delivered over several weeks has antidepressant effects statistically greater than sham treatment.

Neuronetics has recently completed the largest and most robust clinical trial using TMS in MDD patients. Based on these results, Neuronetics has filed to obtain FDA clearance to market Neuronetics' TMS system in the US for the treatment of MDD. The 325 patient trial was multi-center (23 sites, including 20 in the US, 1 in Canada and 2 in Australia. It included US institutions such as the Mayo Clinic, Columbia, Duke, Emory, Stanford and Univ. of Michigan. The design was double-blind, prospectively randomized, and sham controlled. FDA clearance is expected by Jan 2007 (there is a late October 2006 advisory panel meeting already on the books).

There are approximately 14 million adults afflicted annually with depression in the US. Roughly 7.2 million receive some type of mental health care. Roughly 4 million (of those receiving care) are not adequately served by psychotherapy, medications and electroconvulsive therapy (Kessler, 2003). The most severe patients may be treated with electroconvulsive therapy, representing upwards of 100,000 patients (utilizing about 1 million treatments) annually. TMS is expected to be useful to a subset of the 4 million adults who are not adequately served currently. It is expected to be useful to many of those currently treated with ECT at a minimum.

History of 0018T, 0160T and 0161T

During 1998 and 1999, Neotonus, a small, venture funded company was conducting a multi-site, double blinded, clinical trial to prove the safety and efficacy of TMS in the treatment of depression. However, due to the limited financial resources of the company, the trial was stopped before its target enrollment was finished. The data was nonetheless complied, analyzed and submitted to the FDA for clearance to market in the US in the spring of 2000. The safety data

was very strong, however the efficacy was not as convincing. The company believed that if the study had been implemented with different, higher power treatment parameters, and the planned number of patients treated, it most likely would have been successful.

In anticipation of a late 2000 FDA approval, in August of 2000, Neotonus applied for a CPT Category III code. The code, 0018T, was granted in November of 2000 and first appeared in the 2002 CPT book.

In mid 2001, Neotonus became insolvent. The intellectual property that described the unique TMS technology was sold to a medical technology incubator in the summer of 2001 and a new company, Neuronetics, Inc. was formed around this intellectual property. Successful rounds of venture financing for Neuronetics has funded the pivotal trial described above to prove the safety and efficacy of TMS in the treatment of MDD using a different device than Neotonus's and using significantly different treatment protocols and techniques. Neuronetics remains well funded and has filed with the FDA for clearance.

In late 2005, Neuronetics (with the support of the American Psychiatric Association and the American Neurological Association) applied for two new CPT category III codes and asked the AMA to delete 0018T because it was grossly inadequate to describe health resource utilization during TMS therapy, which the AMA granted. 0018T was inappropriate and inadequate to describe the use of therapeutic TMS using the Neuronetics system for a number of reasons:

- 0018T does not incorporate the important treatment planning function prior to treatment delivery.
- 0018T does not specify "repetitive" which is the accepted nomenclature among relevant physician specialties and is necessary to effective treatment.
- 0018T does not specify therapeutic treatment delivery. TMS is being used and researched for diagnostic purposes. In fact, two recently added CPT Category I codes incorporate TMS for diagnostic purposes (95928, Central motor evoked potential study (transcranial motor stimulation); upper limbs, and 95929, lower limbs). Because 0018T is not specific, tracking the use of the TMS therapeutic procedure (one of the key rationales for obtaining Category III codes) and technology that is being used to obtain FDA clearance may be compromised due to confusion and miscoding.
- 0018T does not specify a "non-invasive" treatment.
- TMS for treatment of MDD has evolved since 0018T was requested, which was prior to the full maturation of the procedure and related technology. A better understanding of the necessary components to provide a safe and effective treatment is now available.

In discussions between CMS and Neuronetics to prepare these comments, CMS provided the following historical data on claims for 0018T:

Year	Code	APC	Single Claims
2002	0018T	215	5
2003	0018T	215	10
2004	0018T	215	12
2005	0018T	215	0

After being issued, 0018T was mapped to APC 215 (Level I Nerve and Muscle Tests, roughly a $35 payment) which is consistent with a neuro-diagnostic procedure, not a therapeutic treatment for depression. Neither Neotonus nor Neuronetics was involved in determining this mapping—Neotonus was no longer in the TMS business by the time this was mapped. Neuronetics believed this mapping was inappropriate but as Neuronetics was in the process of applying for the new CPT codes for TMS, it was not concerned about 0018T. Neuronetics believes APC 215 is inappropriate, for similar reasons that APC 340 is inappropriate.

Neuronetics applied for the two new therapeutic CPT codes for TMS and asked that 0018T be deleted in 2005. Neuronetics expects to ask that the new CPT codes be mapped to appropriate APC's in 2007, once the procedure and technology are cleared by the FDA.

Regarding the historical claims data for 0018T above, Neuronetics can only conclude the these claims were for diagnostic uses of TMS or given the extremely low numbers, these are instances of miscoding. Given diagnostic codes now exist that include diagnostic TMS applications (95928 and 95929) and therapeutic codes now exist (0160T and 0161T) that describe therapeutic TMS, there is no need for 0018T and it should be deleted from the system. The AMA agrees with this position which was reflected in its action to delete 0018T from CPT at the November 2005 panel meeting.

Submitter : Dr. Richard Neville **Date:** 10/03/2006

Organization : Richard Neville, M.D.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Mrs. Denise Merlino **Date:** 10/03/2006

Organization : Nuclear Medicine APC Task Force

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1506-P-235-Attach-1.PDF

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225

NUCLEAR MEDICINE APC TASK FORCE

1850 Samuel Morse Drive
Reston, VA 22090-5316
(703) 708-9000
Fax: (703) 708-9015

Academy of Molecular Imaging
American College of Nuclear Physicians
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides and Radiopharmaceuticals, Inc.
National Electrical Manufacturers Association
Society of Nuclear Medicine
Society of Nuclear Medicine - Technologist Section

October 3, 2006

Dr. Carol Bazell, Acting Director
Division of Outpatient Care
Hospital and Ambulatory Policy Group
Center for Medicare Management
Centers for Medicare and Medicaid Services
Room C4-07-04, MS C4-07-07
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Bazell:

On behalf of the Nuclear Medicine APC Task Force, I thank you and your staff for meeting with us on Thursday, September 28, 2006. This was a valuable opportunity to share our concerns regarding the 2007 proposed HOPPS rule, as well as discuss recommendations for the 2007 final HOPPS rule. In brief, we discussed:

1. Maintaining clinical homogeneity for PET tumor, PET brain, cardiac PET APCs;

2. Retaining PET/CT in a new technology APC and separate clinical APC for tumor PET; agreed with CMS proposed payment for PET 78811-13 in APC 0308 and recommended that PET/CT 78814-16 reimbursement not be changed in 2007;

3. Sustaining Level I and Level II Cardiac PET APCs for single versus multiple studies. The Task Force also believes that reimbursement for CPT 78492 should be based on a dampening formula that determines payment solely for 2007 based a blend of the 2006 APC rate for 78492 and the mean of CMS FY2005 hospital data for 78492, G0031, -35, -37, -45, -47.

4. Maintaining separate APCs for single (78806) versus multiple (78804) day whole body imaging studies and reimbursing for CPT 78804 based on its FY2005 claims data;

5. Paying separately for the new HCPCS codes J2805 and A9567, rather than bundling the cost of the products;

6. Eliminating the proposed $55 threshold for all drugs and radiopharmaceuticals. We noted some RPs that should not be packaged if CMS persists in retaining packaging;

7. Request for an explanation and analysis of the contributions of packaged radiopharmaceutical into the median cost of each nuclear medicine APC;

8. Retaining the current method for payment of radiopharmaceuticals into 2007; the FY2005 claims data undervalues 24/54 radiopharmaceuticals, especially the monoclonal based diagnostic and therapy products;

9. Briefly discussed the major effort that is being made by the nuclear medicine community to explore alternative methods to prospectively determine hospital RP acquisition costs.

One issue that the Task Force did not have time to discuss was the great help that it would be to us to see CMS' 2006 radiopharmaceutical claims data prior to the 2007 winter/spring APC Advisory Panel meeting. The 2005 data was made available during last February's meeting, and this was extremely useful. We strongly encourage CMS to run the 2006 data and make it available prior to the meeting (preferably in this December) so that we can assess it in advance of the meeting and provide comments.

We look forward to working with you on the final rule and would welcome meeting again to discuss the rule after it has been published. If you need additional information please contact the NM APC TF staff, Emily Gardner at 703-652-6760 or egardner@snm.org.

Sincerely,

Kenneth A. McKusick, MD
Chair, Nuclear Medicine APC Task Force

Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Joan Sanow, CMS
Nuclear Medicine APC Task Force

APC 0308: Tumor Positron Emission Tomography (PET) imaging

CPT	Description	Transference
78811	Tumor imaging (pet), limited	Do not move
78812	Tumor image (pet)/skull-thigh	Do not move
78813	Tumor image (pet) full body	Do not move

APC XXXX: Brain PET Imaging

CPT	Description	Transference
78608	Brain imaging (PET)	From APC 0308

APC 1513: New Technology-Level XIV ($1200- $1300)
Tumor Positron Emission Tomography/Computed Tomography (PET/CT) imaging

CPT	Description	Transference
78814	Tumor image pet/ct, limited	From APC 0308
78815	Tumor image pet/ct skull-thigh	From APC 0308
78816	Tumor image pet/ct full body	From APC 0308

APC XXXX: Myocardial Positron Emission Tomography (PET) imaging Level I

CPT	Description	Transference
78459	Heart muscle imaging (PET)	From APC 0307
78491	Heart image (pet), single	From APC 0307

APC XXXX: Myocardial Positron Emission Tomography (PET) imaging Level II

CPT	Description	Transference
78492	Heart image (pet), multiple	From APC 0307

APC 0406: Tumor Imaging Single Day Whole Body

CPT	Description	Transference
78806	Abscess imaging, whole body	From APC 0408

APC XXX: Tumor Imaging Multiple Days Whole Body

CPT	Description	Transference
78804	Tumor imaging, whole body	From APC 0408

Submitter : Eddy Luh **Date:** 10/03/2006

Organization : Eddy H Luh MD PC

Category : Physician

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

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Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrcquency fibers.

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We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Submitter : Dr. David Charles **Date:** 10/04/2006

Organization : Alliance for Patient Access

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-237-Attach-1.RTF

HHS-1 PT
237

THE ALLIANCE FOR PATIENT ACCESS

October 3, 2006

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking
Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Proposed Revisions to the Hospital Outpatient Prospective Payment System for Calendar Year 2007
CMS-1506-P
Comments on OPPS: Non-Pass-Through Drugs, Biologicals and Radiopharmaceuticals

Dear Dr. McClellan:

As chairman of the Alliance for Patient Access (AfPA), an organization of physicians throughout the nation whose mission is to ensure and protect patient access to approved medical treatments in the U.S., and as a neurologist who has been practicing in an academic setting for 12 years, I am pleased to submit comments on the Proposed Rule for the 2007 Medicare Hospital Outpatient Prospective Payment System. The Proposed Rule outlines changes to the payments for hospital outpatient procedures and for drugs and biologicals administered incident-to physician services in that setting.

For 2006, CMS has set the payment rate for incident-to drugs and biologicals at 106% of the average sales price. This payment has matched the payment for the same drugs furnished in a physician's office. For most drugs, the payment has been adequate to cover hospitals' costs, and the parity between the hospital and physician office settings has meant there is no financial incentive to choose one site over the other. This has been the first time in many years when the payments for drugs and biologicals have been the same across different settings of care, which has been a welcome change for those who provide services to beneficiaries of the Medicare program across different settings.

In the Proposed Rule, CMS is proposing a reduction in the formula for determining payments for drugs and biologicals to 105% of average sales price. CMS does not provide any detailed justification for this reduction other than to state conclusorily that this is consistent with CMS's estimate of hospital acquisition costs. I would urge CMS to share with the public detailed information on these data, including evidence as to how many hospitals can afford to provide these drugs at a payment rate of 105% of ASP when considering drug acquisition costs, pharmacy overhead and handling. In addition, I am concerned that this signals a move away from having consistent rates for drugs and biologicals across settings of care and will lead to financial incentives driving the choice of setting rather than clinical need.

Therefore, I respectfully request that CMS not change the payment formula for incident-to drugs and biologicals for 2007, but rather maintain the 106% of ASP formula. If CMS believes that hospital acquisition costs (including overhead and handling) are truly lower in the hospital setting than in the physician office setting, CMS should collect these data over a period of at least two years, present these data to the public for comment and also consider the potential impact of different payment formulae in different settings on choice of setting **before** CMS adopts any change in the payment formula.

Thank you for your consideration of my comments.

Sincerely yours,

P. David Charles, M.D.
Associate Professor
Department of Neurology
Vanderbilt University
348 MCS
Nashville, TN 37212-3375
Tel: (615) 936-2025
Fax: (615) 936-1229
Email: david.charles@vanderbilt.edu

Submitter : Dr. Anthony Armini **Date:** 10/04/2006

Organization : Implant Sciences Corporation

Category : Device Industry

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See attachment

CMS-1506-P-238-Attach-1.PDF

Attach #238

October 4, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

Implant Sciences is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

This comment letter specifically addresses the proposed payment methodology for brachytherapy sources in 2007 and the rationale for recommending the current payment methodology of hospital charges reduced to costs be continued.

Implant Sciences was incorporated in 1984 and develops and manufactures technology for homeland security, semiconductor and medical device industries. The Company develops, manufactures and sells radioactive products for the treatment of cancer, including radioactive seeds for the treatment of prostate cancer and a new, FDA cleared radioactive source, Ytterbium- 169.

Ytterbium-169 (C2637)

Ytterbium-169 is a High Dose Rate (HDR) brachytherapy source and has been cleared by the FDA (510(k) No. K042864) in 2005. As required by the MMA, CMS assigned a HCPCS code for Ytterbium so hospitals could appropriately report the cost of the source to CMS. This source will be available in 2007 and we understand that CMS does not have hospital claims data to determine an appropriate cost for Ytterbium-169.

CMS considered four (4) options in establishing payment for Ytterbium-169. CMS proposes to assign Ytterbium-169 (C2637) to its own APC with a payment rate set at or near the lowest proposed payment rate for any brachytherapy source paid on a per source basis (Option 2).

Ytterbium-169 is a HDR source with unique characteristics and differences in application than other sources. Ytterbium-169 (C2637) has a shorter half-life than HDR Iridium-192 (C1717) and requires source replacement every 32 days vs. 90 days for HDR Iridium-192. In addition, Ytterbium-169 requires different shielding and has a unique target activity compared to HDR Iridium-192.

107 Audubon Road, #5 Wakefield, MA 01880 • Tel: 781.246.0700 • Fax: 781.224-7676

Since there are no other sources that are comparable to this new brachytherapy source, the most appropriate payment methodology for Ytterbium-169, and any new brachytherapy source, would be to establish a charge reduced to cost (CCR) methodology in order to collect cost data from hospitals. This option would be similar to the CMS policy for New Technology APCs.

Implant Sciences recommends that CMS adopt Option 1 proposed by CMS and reimburse Ytterbium-169 (C2637) at charges adjusted to cost, consistent with the payment methodology that should be used for all brachytherapy sources.

HOPPS Proposed Payment Methodology for Brachytherapy Sources

Currently, there are twelve very different brachytherapy sources recognized by CMS and used to treat a number of different cancers. Sources are provided as low dose rate (LDR) and high dose rate (HDR) permanently or temporarily implanted based upon the type and site of tumor. The current configurations of the brachytherapy sources and the wide range in radioactive intensities offer physicians an appropriate array of treatment approaches to ensure the therapy effectively treats the size, location and histology of the tumor. We appreciate the effort that CMS has put forward to develop categories for brachytherapy sources.

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish payment rates for each of these brachytherapy sources. The variation in cost of each source requires a unique payment methodology for radioactive sources. One source may have a cost variation of over 10 times based upon the intensity of the source. HDR sources, including Ytterbium, will vary in cost to the hospital based upon the number of fractions used during a period of time.

The CMS claims data shows large variations in per unit cost reported on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set br achytherapy devi ce payments in 20 07. We do not believe that the r ecommended payment methodology will appropriately capture the variation of brachytherapy source configurations and urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device.

Implant Sciences recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting.

Conclusion

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,

A.J. Armini
President & CEO

107 Audubon Road, #5 Wakefield, MA 01880 • Tel: 781.246.0700 • Fax: 781.224-7676

Submitter : Dr. Martin Smith **Date:** 10/04/2006

Organization : Virginia Skin and Vein LLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28

Submitter : Dr. Jennifer Williams **Date:** 10/04/2006

Organization : St. Anne Mercy Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Regarding the new Pharmacist medication therapy management service codes (0115T, 0116T and 0117T) created by the AMA in 2006---should be paid for. Not only for the welfare of your patients, but for cost savings! There are several published studies proving that pharmacists' involvement decreases medical costs!

Submitter : Mr. Jerry Stringham **Date:** 10/04/2006

Organization : Medical Technology Partners, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment.

CMS-1506-P-241-Attach-1.PDF

ATTACH #
241

MEDICAL TECHNOLOGY PARTNERS

October 4, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1321–P
P.O. Box 8015
Baltimore, MD 21244–8015

Re: CMS–1321–P

Dear CMS:

I am commenting on the proposed payment for CPT code 36566.

At the August 23-25, 2006 meeting of the APC Panel, the proper placement of HCPCS code 36566 was discussed. To summarize, the Panel recommended the following:

- HCPCS code 36566 should require the use of C1881 in the future. This was not permissible in 2005 or 2006 because 36566 was assigned to a new technology APC.
- HCPCS code 36566 should be assigned to an appropriately paying APC with payment between $3,500 and $4,750 for 2007.
- CMS should use correctly coded claims to guide APC payment. The Panel recommended that CMS receive information on claims from Medical Technology Partners.

Importance of Pricing for 36566

HCPCS 36566 is used exclusively for dialysis patients. Since CMS provides insurance for all ESRD patients, including those under the age of 65, the overwhelming majority of ESRD patients are insured by Medicare. In effect, these patients are largely covered under a one payer system; therefore, if payment is inadequate, there are immediate and substantial access issues for patients.

Data

As compared to other vascular access procedures, 36566 is rare. Many claims do not include charges for the implantable device, which costs $3,500 per patient ($1,750 for each of two required devices). In addition, a very small number of miscoded claims

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from other vascular access procedures with similar descriptions create a large number of false claims for this HCPCS code.

Using the most recently available dataset (OPPS 2 005), MTP identified 4 3 claims containing both 36566 and C1881. These claims exhibited the following:

Number of Claims:	43
Median Claim Cost:	$5,542
Median Claim Charges:	$16,162

These 43 claims consisted of 36 multi-major claims and seven single-major claims. Examining only the seven single-major claims:

Number of claims:	7
Median Claim Cost:	$5,592
Median Claim Charges:	$15,004

A differential of $2,000 between the cost of the device and the median claim cost appears reasonable. As discussed at length during the APC Panel meeting, HCPCS 36566 covers the implantation of two devices whereas other vascular access procedures are billed twice. Therefore, it is improper to place 36566 with other vascular access procedures.

In examining the 43 claims, I am not confident in CMS' method of calculating the hospital's cost. For one claim, the charge for C1881 was $25,002 and CMS' estimated cost was $1,775. For another claim, the charge for C1881 was $4,550 and CMS' estimated cost was $9,754. The actual device cost is $3,500 per patient.

Difference Between 36566 and Other Vascular Access Procedures

CPT 36566, *Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)*, requires two catheters via two separate venous access sites. Two systems are typically used for each patient, costing $1,750 each or $3,500 per procedure.

As previously mentioned, other vascular access procedures are per device. The American Medical Association created the 36566 code using the existing language because the procedure is always performed with two devices.

Sincerely,

Jerry Stringham
President

APPENDIX 1
Number of Times 36566 Billed with C1881

Times Billed	# Claims	Median Claim Costs	Median Claim Charges
36566 (x1) and C1881 (x2)	33	$6,167	$16,120
36566 (x1) and C1881 (x1)	8	$3,211	$16,668
36566 (x1) and C1881 (x3)	1	$10,829	$27,923
36566 (x2) and C1881 (x2)	1	$6,971	$18,507
Overall	43	$5,542	$16,162
7 Single-Major Claims	7	$5,592	$15,004

APPENDIX 2
Example of Correctly Coded Claim

Claim Level Report - 2005 OPPS Data

36566 and C1881

040088 **MEDICAL CENTER OF SOUTH ARKANSAS**
EL DORADO AR

Claim ID: 2112663
Type: MMAJ
Service: 16
Outlier: $0

Line	CPT	Units	Revenue	Charges	Cost	Payment
1		15	250	$560	$79	$0
2		2	258	$165	$23	$0
3		2	270	$273	$28	$0
4		4	272	$265	$27	$0
5	C1725	1	278	$810	$84	$0
6	C1881	2	278	$3,500	$363	$0
7	36415	1	301	$12	$1	$3
8	85049	1	305	$77	$9	$6
9	85610	1	305	$82	$9	$6
10	85730	1	305	$92	$10	$9
11	75827	1	320	$2,170	$515	$471
12	75978	1	320	$1,695	$402	$360
13	75998	1	320	$616	$146	$0
14	35476	1	360	$890	$356	$875
15	36566	1	360	$4,531	$1,814	$4,452
				$15,737	**$3,867**	**$6,181**

APPENDIX 3
Example of Incorrectly Coded Claim

Claim Level Report - 2005 OPPS Data

36566 and C1881

010033 **UNIVERSITY OF ALABAMA HOSPITAL**
BIRMINGHAM AL

Claim ID: 239739
Type: MMAJ
Service: 14
Outlier: $0

Line	CPT	Units	Revenue	Charges	Cost	Payment
1		13	250	$408	$106	$0
2		21	270	$2,095	$534	$0
3		1	271	$180	$46	$0
4	C1750	1	272	$765	$195	$0
5	80051	1	301	$31	$5	$4
6	82565	1	301	$8	$1	$3
7	82947	1	301	$8	$1	$2
8	84520	1	301	$8	$1	$2
9	71010	1	320	$324	$45	$42
10	76000	1	320	$472	$65	$0
11	36566	1	360	$6,260	$1,786	$4,516
12		13	370	$1,636	$244	$0
13		2	710	$1,550	$245	$0
				$13,746	**$3,275**	**$4,569**

Submitter : Mrs. Gail Keuneke **Date:** 10/04/2006

Organization : Parkview Comprehensive Cancer Center

Category : Nurse

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am a nurse care coordinator at a comprehensive cancer treatment center. We have treated many patients with Cyberknife technology who had no other treatment options available to them. We have seen excellent responses in many different types and locations of tumors. The cost of cyberknife is less than Gammaknife and is much more accurate and able to treat a greater variety of tumor sites.

I am asking that you will reverse your proposal and maintain current payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery technology, codes G0339 and G0340.

Thank you for your consideration,

Sincerely,
Gail Keuneke RN, BSN, CCM

Submitter : Dr. Stuart Burri **Date:** 10/04/2006

Organization : Carolinas Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-243-Attach-1.DOC

HH-114
243

Carolinas Medical Center

The 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

October 3, 2006

Regarding: CY 2007 OPPS Proposed Rule (CMS-1506-P)

Dear Administrator:

Thank you for the opportunity to submit comment on the Medicare Program's Proposed Rule filed in the Federal Register filed August 23, 2006. My letter is written to comment on the proposed new Medicare payment methodology for a liquid radionuclide source used with internal radiation for malignant brain tumors. The radionuclide is an Iodine I-125 source sometimes referred to by its brand name of Iotrex. I believe the code used by hospitals to report use of Iotrex during outpatient radiation therapy is C2632.

As a Radiation Oncologist, I want to be able to provide my patients, many of whom are Medicare beneficiaries the benefit of different treatment options available based on the type, location and size of malignant tumors. Additionally age and general health is also factored into determining what radiation therapy treatments will best serve the patient. With respect to persons with malignant brain tumors one treatment option involves internal radiation using a balloon catheter implanted during a craniotomy. Following discharge from the hospital for surgery, a patient returns to the hospital radiation oncology department and has infused through the catheter into the balloon the liquid radionuclide, I-125 Iotrex. The patient goes home with the Iotrex remaining inside the balloon for 4-5 days. Once the patient has received the radiation, s/he returns to the hospital where the Iotrex is removed. The catheter is also explanted and the patient goes home.

I share this treatment flow with you to illustrate the value in being able to provide this effective internal radiation therapy to brain tumor patients. Benefits include an increase to survival and sustained quality of life; internal radiation targets the area most likely to contain cancer with healthy tissue around the tumor site less likely to be damaged by radiation. This is a treatment option we can give to people today, however, if Medicare moves forward in its proposed payment method for Iotrex, it will halt the treatment option as hospitals will not be able to continually afford purchasing Iodine I-125 due to its cost exceeding expected Medicare payment.

Bearing this in mind, I ask that and believe CMS should continue paying the hospitals their charges adjusted to cost for Iodine I-125. I agree with and support the APC Advisory Panel's recommendation to CMS with respect to radiopharmaceutical and brachytherapy sources. Furthermore, I also agree and support the PPAC's recommendation to CMS regarding sources, as well.

Your reconsideration and evaluation of this issue is greatly appreciated.

Sincerely,

Stuart H. Burri, M.D.

Stuart H. Burri, M.D.
Carolinas Medical Center
Department of Radiation Oncology
P.O. Box 32861
Charlotte, NC 28232-2861
704-355-2272

cc: Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Representative Sue Myrick, Energy and Commerce Health Subcommittee; Co-Chair House Cancer Caucus
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force