

Submitter :

Date: 01/06/2006

Organization :

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-FC-9-Attach-1.PDF



SOCIETY OF
INTERVENTIONAL
RADIOLOGY

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January 6, 2006

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

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-FC]

Dear Administrator McClellan:

The Society of Interventional Radiology (SIR) is a physician association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States.

SIR appreciates the opportunity to comment upon the final rule, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates as published in the November 10, 2005 *Federal Register*.

SIR's comments are directed to:

1. **Payment for Multiple Diagnostic Imaging Procedures**
2. **Treatment of New CY 2006 HCPCS Codes**
3. **Interrupted Procedure Payment Policies**
4. **Changes to Packaged Services**
5. **Inpatient-Only List**
6. **Treatment of New Mid-Year Category III CPT Codes**
7. **Requirements for Assigning Services to New Technology APCs**
8. **New Technology Services**
9. **APC-Specific Policies**

Payment for Multiple Diagnostic Imaging Procedures (Page 68708)

SIR supports CMS' decision not to finalize the proposed discounting of payments for multiple diagnostic imaging procedures.

Many issues became apparent with the proposal to discount the payment for multiple diagnostic imaging procedures. Chief among these methodological issues is the use of cost-to-charge ratios for adjusting hospitals' charges to their costs. Concern was

expressed that hospitals already discount their charges for multiple imaging services. As a result, the proposed policy would add a duplicate cut upon already discounted charges.

The second issue was the magnitude of the reduction. It was unclear whether the proposed 50 percent discount appropriately reflected any "savings" from multiple imaging services. CMS' research into both topics was inconclusive.

Treatment of New CY 2006 HCPCS Codes

Percutaneous Mechanical Thrombectomy (CPT Codes 37184 - 37188)

SIR recommends that the new CPT codes for mechanical thrombectomy be assigned to APC 0088 (Thrombectomy).

Mechanical thrombectomy entails the use of a device to remove clot intravascularly. In the final rule, CMS announced its decision to move coronary mechanical thrombectomy (CPT code 92973) to APC 0088 on the rationale that mechanical thrombectomy requires the use of a costly [mechanical thrombectomy] catheter. The same holds true with the new CPT codes for arterial and venous mechanical thrombectomy (37184-37188). CMS, in the final rule, has these codes under APC 0653 (Vascular Reconstruction/Fistula Repair with Device) or APC 0103 (Miscellaneous Vascular Procedures). However, unlike CPT code 36870 [Thrombectomy, percutaneous, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis)] which is represented by APC 0653, the new mechanical thrombectomy codes are unrelated to fistulae declotting. In fact, they have more in common with their surgical analogs in the 342XX series of CPT which are assigned to APC 0088. As for mechanical thrombectomy add-on codes 37185 and 37186, they too should be added under APC 0088, like code 92973, because the surgical discounting rule would come into play when billed with other services. By having nearly all of the mechanical thrombectomy codes under APC 0088, the effect should be improved standardization of these services.

Evaluation of Central Venous Access Device (CPT Code 36598)

SIR recommends CMS assign new CPT code 36598 to APC 0263 (Level 1 Miscellaneous Radiology Procedures).

The new code for radiological venous catheter evaluation (36598) represents a focused contrast and fluoroscopic assessment of the central venous access device and the immediate adjacent vein with the production of an archived image. The use of contrast and fluoroscopy makes code 36598 more resource intensive than standard fluoroscopy (CPT code 76000; APC 0272) and APC 0340 (Minor Ancillary Procedures) from the final rule. A more appropriate clinical analogy is CPT code 76080 (Radiologic examination, abscess, fistula or sinus tract study, radiological supervision and interpretation) which can be an evaluation of an existing drainage catheter following contrast injection (code 49424; bundled under HOPPS). CPT code 76080 is represented by APC 0263.

Percutaneous Radiofrequency Ablation of Renal Tumor(s) (CPT Code 50592)

SIR agrees with CMS' assignment of new CPT code 50592 to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures).

Percutaneous radiofrequency (RF) ablation is a minimally-invasive technique that delivers thermal therapy to treat tumors. Code 50592 is RF ablation applied to renal tumor(s) percutaneously. The predicate example is CPT code 47382 which describes percutaneous radiofrequency ablation of liver tumor(s). For CY 2006, code 47382 is assigned to APC 0423. We support CMS' decision to place code 50592 in the same APC as code 47382.

Percutaneous Cryoablation of Renal Tumor(s) (CPT Code 0135T)

SIR recommends that new CPT Category III code for percutaneous cryoablation for renal tumors (0135T) be assigned to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures).

Percutaneous cryoablation is another form of thermal therapy in the treatment of tumor(s). Like new code 50592, we believe that CPT Category III code 0135T should be assigned to APC 0423 for CY 2006.

Kyphoplasty (CPT Codes 22523-22525) (Pages 68608 – 68609)

SIR suggests that CMS revisit the APC assignment of kyphoplasty once new data are available.

Both kyphoplasty and vertebroplasty involve the use of cement to treat vertebral body compression fractures. In vertebroplasty, the cement is injected directly into the vertebral body under imaging guidance, either fluoroscopy or CT. In kyphoplasty, a cavity is created in the vertebral body using a balloon inserted via a cannula/trocar under imaging guidance. From a resource perspective then, the major differences between the two procedures are the costs of the cannula/trocar and balloon. Vertebroplasty is assigned to APC 0050 which has a CY 2006 HOPPS rate of \$1,424.50. Kyphoplasty has been assigned to APC 0052 which has a rate of \$2,592.03. CY 2006 hospital claims data should be useful in determining whether this differential is supported by hospitals' charges.

Interrupted Procedure Payment Policies (Page 68708)

SIR recommends that the definition of "anesthesia" for purposes of HOPPS policy towards payment of interrupted procedures include local anesthesia and conscious sedation. We further recommend that HOPPS pay fully for procedures interrupted once the patient has entered the procedural suite (e.g., operating room, angiography suite).

SIR recommends that CMS' anesthesia definition extend to local anesthesia and conscious sedation. Hospitals incur costs associated with both of these forms of anesthesia. Additionally, a patient's ability to tolerate local anesthesia and conscious sedation will be a factor in whether the procedure proceeds or is discontinued. For many minimally-invasive procedures, most of the hospital's consumable medical supplies are committed to the procedure once the patient has entered the procedural room and before anesthesia (conscious sedation and/or local) is administered.

Changes to Packaged Services

Imaging Guidance for Vascular Access (Pages 68543 - 68545)

SIR maintains that CPT codes 76937 and 75998 should be payable separately under HOPPS.

SIR is disappointed by the decision to package CPT codes 76937 (Ultrasound guidance for vascular access) and 75998 (Fluoroscopic guidance for vascular access) for CY 2006. In our comments on the proposed rule, SIR argued that imaging guidance improves the safety of patients undergoing vascular access services and that the use of imaging should be encouraged rather than discouraged. A policy of separate payment would allow data collection on the incidence and prevalence on the use of imaging stratified by device type, site of service, patients' risk factors, and operator. SIR would appreciate the opportunity to work with the Packaging Subcommittee once more recent claims data become available.

Renal Vein Renin Sampling (Codes 36500 and 75893) (Page 68546)

SIR recommends that CMS provide for the separate payment for renin sampling under HOPPS. We seek the opportunity to review with CMS any additional data that may become available.

Renal vein renin sampling is a vital diagnostic test of peptides, which are associated with renal artery stenosis. Renal artery stenosis, in turn, is an important risk factor for cardiovascular morbidity and mortality. For over a decade, the only two codes recommended for renin sampling have been 36500 (venous catheterization for selective organ blood sampling) and its associated fluoroscopic/angiographic code 75893. As a result of both codes being "bundled", hospitals are denied reimbursement under HOPPS. SIR, therefore, recommends that codes 36500 and 75893 be separately payable under HOPPS.

Procedures That Will Be Paid Only as Inpatient Procedures (Page 68695)

SIR appreciates CMS' decision to remove TIPS revision (code 37183) from the Inpatient Only List.

SIR is grateful to CMS for considering our previous recommendation to remove TIPS revision (code 37183) from the inpatient only list of services. CMS' decision is appropriate since TIPS revisions are expected to be performed on an outpatient basis.

SIR agrees with public comments to remove CPT codes 37182 [Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS)] and 61624 [Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system] from the inpatient-only list.

The relatively atraumatic methods involved in percutaneous image-guided therapies make them ideally suited to be done as outpatients. The public comments received on TIPS and neuroembolization reflect the broad and growing consensus that these therapies are safe and effective, that decreases patient morbidity and reduces hospital costs by eliminating inpatient hospital stays. In the case of TIPS, while not usually an outpatient, the procedure can be readily performed as an outpatient depending on patient selection and conditions. As for neuroembolization, many embolizations such as intracranial tumor embolization or AVM embolizations can and should be done as outpatients.

Treatment of New Mid-Year Category III CPT Codes (Page 68567)

SIR is supportive of more timely inclusion of new CPT Category III codes in HOPPS.

In the final rule, CMS announced its plans to implement in the regular quarter HOPPS updates the biannual releases of Category III codes. This approach has merit. SIR trusts that there will be an opportunity to provide comment to CMS as new Category III codes are introduced into HOPPS.

Requirements for Assigning Services to New Technology APCs (Pages 68572 – 68575)

SIR concurs with CMS' decision not to require a CPT application for new technologies.

While we appreciate CMS' need for a systematic review of new technologies, we raised questions in our comments on the proposed rule whether the CPT Editorial Panel is the appropriate body to carry out such efforts. The CPT Editorial Panel considers physician work. The New Technology APCs, on the other hand, are often device, equipment, drug, etc. specific. Also, there is no consideration of the additional workload this proposal would place on the Editorial Panel and the expected outcomes of this process.

New Technology Services

Ablation of Bone Tumors (Page 68575)

SIR encourages CMS to revisit the APC placement of bone ablation (CPT code 20982) once more recent claims data become available.

The CPT code for percutaneous bone ablation came into being in 2004. Accordingly, the relatively few claims for the service in CY2004 and the variability in charges come at no surprise. This code contains both the ablation and the use of CT to guide and monitor the ablation which may add further to the variability. We, therefore, recommend that CMS revisit the APC assignment of code 20982 based on more recent claims data.

APC-Specific Policies

Endovenous Ablation (Pages 68590-68591)

SIR supports CMS' decision to assign endovenous ablation codes 36475-36479 to APC 0091. Since the codes for endovenous ablation are relatively new, SIR encourages CMS to revisit this issue once more recent data are in hand.

SIR agrees with CMS' assertion in the final rule that both radiofrequency and laser endovenous ablation require the use of disposables and other resources that warrants their assignment to the higher paying APC 0091, than APC 0092 in 2005. More extensive APC reconfiguration should wait until more current claims data can be brought to bear on the issue.

Vascular Access Procedures (Pages 68592 – 68594)

SIR appreciates CMS' continued efforts refining the APCs for vascular access services. APCs 0621, 0622, and 0623 better represent the services provided and are a marked improvement over previous classifications.

Computed Tomographic Guidance (Page 68597 – 68598)

SIR agrees with CMS' decision to move CPT code 76362 (CT guidance for tumor ablation) from APC 0332 to 0333.

CMS stated that the move of CPT code 76362 from APC 0332 to 0333 was to reflect more accurately the scanner time involved with the procedure. We concur.

Computerized Reconstruction (Page 68598)

SIR agrees with CMS' decision not to revise the descriptor for G0288.

CMS elected not to adopt a request that the descriptor for G0288 be changed to read, "Three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation in accordance with measurements and modeling specifications of the Society for Vascular Surgery." SIR finds the proposed new descriptor language vague and offers little improvement over the existing descriptor. We support CMS' decision to maintain G0288's current descriptor.

Mark McClellan, MD, PhD
January 6, 2006
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Magnetic Resonance Guided Focused Ultrasound Ablation (Pages 68600 - 68601)

SIR appreciates CMS' decision to move CPT Category III codes 0071T and 0072T into APCs which provide payment more consistent with the costs of the services rendered. However, we are not entirely in agreement with their assignment into APCs traditionally representing female reproductive surgical services. SIR suggests CMS revisit this issue once more recent claims data become available.

Magnetic resonance guided ultrasound ablation is a new treatment of uterine fibroids. CMS is partially correct in that it utilizes existing MR and ultrasound technologies. However, the combination of the two modalities in the delivery of thermal tissue ablation makes this "new" and without current predicate services for APC setting. SIR is concerned that the previous APC assignment (APC 0193) would undervalue the procedure relative to its costs. Assignment of codes 0071T and 0072T to APCs 0195 and 0202, respectively, or to New Technology APCs as proposed in the comment period and by the APC Panel provide a workable interim solution until more claims data can be obtained. SIR looks forward to working with CMS in the future to better classify this new hybrid technology

SIR appreciates the opportunity to comment on the final rule for the 2006 Medicare hospital outpatient prospective payment system (HOPPS). If you have any questions or require additional information, please contact Michael R. Mabry, Assistant Executive Director at (703) 460-5561 or mabry@sirweb.org.

Sincerely,



Michael E. Edwards, MD
Councilor, Health Policy & Economics

CMS-1501-FC-10

Submitter : John Settlemyer
Organization : Carolinas Healthcare System
Category : Hospital

Date: 01/06/2006

Issue Areas/Comments

**Classification assignments of
HCPCS codes identified in
Addendum B with comment
indicator NI.**

Classification assignments of HCPCS codes identified in Addendum B with comment indicator NI.

See Attachment

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See Attachment

CMS-1501-FC-10-Attach-1.PDF

January 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-FC
PO Box 8016
Baltimore, MD 21244-8018

**RE: File Code CMS-1501-FC
SUBMITTED ELECTRONICALLY**

Thank you for the opportunity to provide comments on the 2006 OPPS final rule with comment period for new procedure codes (comment indicator "NI" in Addendum B) as follows:

Medication Therapy Management Services

Please review the following codes that were temporarily assigned to SI "B":

0115T – Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial encounter

0116T – subsequent encounter

0117T – each additional 15 minutes (add-on code for either of the above)

According to Daniel Buffington, a pharmacist on the CPT editorial panel's Health Care Professionals Advisory Committee, these codes were created to "articulate pharmacy services in general, regardless of the payer type or practice setting" and the "CPT editorial panel themselves struggled making sure that what was produced in terms of coding was not to be confused as being limited to a Medicare Part D beneficiary".

Medicare beneficiaries frequently need medically necessary medication management / monitoring for optimal safe and therapeutic drug efficacy, and this occurs by pharmacists via "incident-to" provisions in both the OPPS and Physician office settings across the country. This is direct, face-to-face patient care that, in the long run reduces additional IP and OP expenditures. Sometimes this is limited to a very specific medication (neither multiple conditions nor multiple drugs involved) so it will not meet the definition of MTMS as defined in the Part D benefit.

Hospitals across the country have been providing medically necessary physician-ordered pharmacist management services in the OP setting, and providers typically include this type of service under their criteria for OP/Clinic Visit assignment.

These services do not need to be assigned to New Technology APCs, and CMS has even instructed providers to bill for this type of service as a low-level clinic visit. CMS previously posted an FAQ on its website (Answer ID 2101, which is no longer available) that states "when a face-to-face medication therapy management is provided by qualified hospital staff...a hospital may bill CPT 99211 if the services are medically necessary and constitute a distinct, separately identifiable E/M service that is consistent with the hospital's criteria for a low-level clinic visit."

We recommend the following designation for mid-year 2006 update:

0115T	SI "V"	APC 601
0116T	SI "V"	APC 600
0117T	SI "N"	

DRUG ADMINISTRATION

CMS was perhaps overwhelmed with the various alternatives that were submitted as options to implement 2006 CPT coding for Drug Administration services. CMS has chosen to regress by assigning certain Drug Administration codes to SI "B", while creating new C-codes that mirror previous CPT codes.

CMS has a history of instructing providers to ignore certain parts of CPT codes for use under OPSS. In retrospect, we agree that this could be construed as contrary to HIPAA, but it still does not negate the overarching premise that hospitals will never be able to get around if using CPT codes for OPSS services: these codes are owned by the AMA for use by physicians.

CMS must admit and keep in mind that the 2005-2006 CPT code changes for drug administration were the result of MMA mandate to placate physicians who were concerned about losing payments for drugs. They were designed to pay physicians for each and every instance or combination of drug administration service(s), primarily for Oncology practices. The hospital industry was never consulted about the impact of these changes because, as mentioned, CPT is written for physicians. Even though CMS believes the concepts of "initial", "sequential", and "concurrent" and the "accompanying expectations" should theoretically be applicable in the hospital outpatient setting, you must remember that hospitals are paid differently for their drugs than are physicians. Drug administration payments for hospitals include all those drugs below the \$50 packaging threshold. Physicians are paid separately for each and every drug. This is the paramount reason why it would be inequitable to apply the 2006 CPT logic in its entirety on the outpatient side. If CMS does ultimately decide to implement drug administration CPT codes in their full conceptual context, then CMS must also pay separately for all drugs in the OP setting by utilizing the MFPS.

We will reiterate what we submitted in the proposed rule comments:

- Drug administration charges are generally assigned on a department-specific basis at the point of care. That is, the HCPCS codes are embedded in the chargemaster and the departmental personnel are responsible for charging based on the services provided to the patient while in their care.
- Under the current process stated in the first bullet point, having separate codes for initial, subsequent and concurrent infusions may be virtually impossible to implement in hospitals, because patients often move from one to another care area, and drug administration charges are most often charged by the respective department in real-time.
- As a general rule, HIM coders do not assign coding or charges for drug administration. If they are required to do so in the future, it will add exponential amounts of workload to the coding process. Further, if we are forced to write "back-door" edits in our billing systems, this also adds unnecessary work for providers.

Last year, we supported CMS' proposal to require providers to use CPT codes to report drug administration services (after the industry asked CMS multiple times to do so). But to clarify

why we and others in the industry supported this change, it was not necessarily because we "wanted" CPT codes...it was because we wanted a standard of charging based on the concept of 1st hour/additional hours. This was feasible at the time under the previous CPT codes. It is not feasible, however, to utilize the new 2006 codes and follow their nomenclature in the current manner we apply charges (as mentioned above, at the point of care).

For 2006, we will utilize CMS's guidelines, coding scenarios, and combination of C-codes/CPT codes in our chargemasters to bill drug administration services to all payers. In most instances, the HCPCS detail is not required and will not be printed on our commercial claims because commercial claims are generally not paid on a fee schedule. For those isolated plans that do require HCPCS detail, we will first offer the C-code. If the plan will not accept the C-code we will crosswalk it to an appropriate CPT code. But we will not be charging at the point of care with the "initial/subsequent/concurrent" logic.

Thank you for your consideration.

Sincerely,

John Settlemyer
Director, Financial Services
Carolinas HealthCare System
PO Box 32861
Charlotte, NC 28232-2861

Submitter : Mrs. Valerie Rinkle
Organization : Asante Health System
Category : Hospital

Date: 01/06/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1501-FC-11-Attach-1.DOC



January 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

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

**RE: File Code CMS-1501-FC
November 10, 2005 Final Rule with Comment Period**

Asante Health System (Asante) includes two acute care hospitals in Southern Oregon. These comments are in relation to new codes with comment open as discussed in the Final Rule published in the Federal Register on November 10, 2005.

You may call our Revenue Cycle Director at 541-789-4923 should you have any questions concerning these comments.

Medication Therapy Management

Asante asks CMS to carefully review the current status indicator assignment for the following new CPT codes that were assigned to SI "B":

0115T – Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial encounter

0116T – subsequent encounter

0117T – each additional 15 minutes (add-on code for either of the above)

The intent of these codes when created by the CPT Editorial Panel was to “articulate pharmacy services in general, regardless of the payer type or practice setting” and [ensure the codes were] not to be confused as being limited to a Medicare Part D beneficiary”.

In an outpatient hospital, medication therapy management services are performed by hospital employed licensed pharmacists credentialed to perform patient assessments and address the patient’s drug regimen.

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Licensed pharmacists' scope of practice covers this service. A Medicare beneficiary's treating physician orders the patient to be evaluated by the outpatient hospital pharmacist. For example, such a visit is often for patients on a coumadin regimen or geriatric patients on numerous prescriptions that need the assessment of the pharmacist. The physician needs the advice and opinion of the pharmacist to management the patient's care appropriately.

Before these new CPT codes were created, CMS instructed hospitals that this service was covered and should be billed with E/M codes. A previously posted OPPTS FAQ on the CMS website (Answer ID 2101, which is no longer available) states "when a face-to-face medication therapy management is provided by qualified hospital staff...a hospital may bill CPT 99211 if the services are medically necessary and constitute a distinct, separately identifiable E/M service that is consistent with the hospital's criteria for a low-level clinic visit."

The reason CMS gave this reply is that these services are clearly covered under the Social Security Act.

Section 1861 (s) (B) defines Medicare Part B covered services and specifies: "hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services." Medication therapy management services rendered by hospital pharmacists to hospital outpatients are therefore, "medical and other health services" that are covered under this provision. Furthermore, the services are medically necessary under 1862 of the Act and meet the following other Medicare regulations:

42 CFR 210.2 Defines Hospital Outpatient. *Outpatient* means a person who has not been admitted as an inpatient but who is registered on the hospital or Critical Access Hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH. Medication therapy management patients are *registered outpatients of the hospital*.

42 CFR 210.2 Defines Outpatient Hospital Encounter. *Encounter* means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient. *The pharmacist has direct personal contact with the patient to assess the patient. This falls under scope of practice for pharmacists. Medical staff physicians order medication therapy management services from the pharmacist on behalf of their patient that they are managing in their offices. The pharmacist reports the care back to the ordering physician. This meets the statutory requirement of 1861 (s) (B) "incident to" physician services.*

Publication 100-02, Chapter 6. Section 20.4.1 - Coverage of Outpatient Therapeutic Services. Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. *Medication therapy management services meet the definition of covered outpatient therapeutic hospital services.*

Given the statutory coverage for these services and CMS' advice to bill and be paid under OPPTS for these services with E/M codes, Asante recommends the following designation for these CPT codes:

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0115T	SI "V"	APC 601
0116T	SI "V"	APC 600
0117T	SI "N"	

Asante also asks about the "B" status of CPT 0130T for "Validated, statistically reliable, randomized, controlled, single-patient clinical investigation of FDA approved chronic care drugs, provided by a pharmacist, interpretation and report to the prescribing health care professional." How is an outpatient hospital to report this service when it is performed by hospital pharmacist for a hospital patient on order from a physician? Should be code be a status indicator "N" so that, at a minimum, CMS may track the instances when hospital pharmacists perform this service for hospital outpatients?

Drug Administration

Asante's comments are based on the November 10th Final Rule as well as the December 16, 2005 Transmittal 785 regarding the use of the C-codes under comment.

CMS states in Transmittal 785 under 230.2.2 A for Chemotherapy Drug Administration that: "Medicare's general policy regarding physician supervision within hospital outpatient departments meets the physician supervision requirements for use of CPT codes 96401-96549." Asante wishes to know whether this statement is also true for CPT codes (or their replacement C-codes) regarding non-chemotherapy meaning codes 90760-90779 and C8950-C8952? Does Medicare's general policy regarding physician supervision within hospital outpatient departments meets the physician supervision requirements for use of these codes as well?

With regard to C8952 and C8953, 96420 – CMS states in the Transmittal 785 that "hospitals are to bill for additional IV pushes of different substances or drugs using multiple units of the appropriate push code." This language did not exist for the 2005 CPT codes for IV push injections. As such, each separate IV push injection was billed as confirmed by CMS in the November 10, 2005 Final Rule on page 68679 which states "The C-codes will permit straightforward billing of types of infusions and intravenous pushes, for the first hour and then each additional hour of infusion or for each intravenous push, an approach to coding the commenters indicated was consistent with current patterns of delivery and billing of drug administration services in the hospital outpatient setting." CPT code 90784 existed prior to 2005 and has been paid under OPPS for each push injection, regardless of whether it was a push injection of the same or different drug. If CMS keeps the definition change that C8952 and C8953 and 96420 is to be used only for injections of different substances, then OPPS payments to hospitals will decline significantly and this was not modeled in the APA –required impact analysis of the Final Rule. Asante believes that this language was inserted unintentionally from the 2006 CPT language regarding CPT 90775. Note that the CPT language for 96411 and 96420 appears to allow each push injection whether or not it is the same or a different drug.

With regard to drug administration using the 20 2006 CPT codes and the 13 C-codes, the introduction section to Transmittal 785 has a new "included services" section that is replicated from the CPT 2006 manual heading under Chemotherapy Administration. This heading was created to address physician office settings. There is a unique difference to the included services in the outpatient hospital setting and that is letter e. Standard tubing, syringes and supplies are often separately reported with charges under the

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packaged revenue code for supplies. It does not generate separate OPSS payment, but it is the correct manner to separately report the cost of patient-specific sterile and non-sterile supplies. These charges meet Medicare requirements at Provider Reimbursement Manual HCFA Pub. 15, Section 2203.2 which states that to be separately chargeable, a supply item must be:

- Directly identifiable to the individual patient with specific documentation or easily inferred documentation (e.g., documentation of a laceration repair specifying the location, size and type of suture would be sufficient for inferring the suture tray charge).
- Furnished at the direction of a physician because of specific medical needs (i.e., a specific physician order. The order may be a formal protocol or standing order.), and
- Either it is not reusable or represents a cost for each preparation.

We believe that the Transmittal language is appropriate for physician billing under RBRVS, but not for outpatient hospital billing under OPSS where many of services are separately and properly reportable under packaged revenue codes so that hospitals may correctly report costs and resource utilization to CMS. Please clarify that hospitals may continue to report separate charges for patient supplies used in drug administration.

Intracranial Procedures

Asante does not understand the status indicator "B" assignment for new CPT codes 61630 through 61642 for intracranial procedures.

CPT states: 61630 and 61635 include all selective vascular catheterization of the target vascular family, all diagnostic imaging for arteriography of the target vascular family, and all related radiological supervision and interpretation. When diagnostic arteriogram (including imaging and selective catheterization) confirms the need for angioplasty or stent placement, 61630 and 61635 are inclusive of these services. If angioplasty or stenting are not indicated, then the appropriate codes for selective catheterization and imaging should be reported in lieu of 61630 and 61635.

CPT also states: 61640, 61641, 61642 include all selective vascular catheterization of the target vessel, contrast injection(s), vessel measurement, roadmapping, postdilatation angiography, and fluoroscopic guidance for the balloon dilatation

Status Indicator "B" means "codes are not recognized by OPSS because an alternative codes may be available. Asante could not find the applicable alternative code. Please explain the alternative code or consider another status indicator assignment even if it is "C" for Inpatient Only.

Ambulatory Glucose Monitoring

Asante does not understand the status indicator "B" assignment for new CPT code 95251 for Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report. How are hospitals that own the equipment and whose staff set up the glucose monitor to bill for this service. Under RBRVS this CPT does have a practice expense showing there

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is equipment and other facility cost associated with this service. How is a hospital to be paid for this type of encounter?

Specialty Supplies

A5512 and A5513 for diabetic foot specialty supplies. Asante does not under the status indicator "B" assignment. Why aren't these supplies either status indicator "Y" or "A"?

Also, A6513 for compression burn mask: why is this status indicator "B" when it appears to be a surgical dressing appropriate for status indicator "A"?

Regarding codes L8680 through L8688: why are these status indicator "B" rather than the non-implantable prosthetic and orthotic device status indicator "A" as is the case for all other non-implantable L-codes?

Why do compression bandages A6530 through A6549 have status indicators of "E" as opposed to status indicator "A." Often compression and lymphedema bandages are take home surgical dressings. Medicare has a benefit under Chapter 4 Part B Hospital Section 10.1 and Chapter 20 DMEPOS Section 130.1. Section 130.1 states that the hospital must enroll with National Supplier Clearinghouse and bill the DMERC except for "those items or services that are considered outside the PPS rate [that] may be billed by the ...hospital to the FI." Section 10.1 defines those items or services that are outside the OPSS. "The Secretary has the authority under §1883(t) of the Act to determine which services are included [in OPSS]. Medicare will continue to pay for clinical diagnostic laboratory services, orthotics, prosthetics (except as noted above [meaning implantable]), and for take-home surgical dressings on their respective fee schedules." If these supplies are not allowed as take home surgical dressings, then patients post-mastectomy and post-orthotic surgery cannot be provided these items by the hospital. Please consider changing the status indicator to "A".

Laparoscopic Procedures

Asante noted the Inpatient Only status indicator designation for most of the new laparoscopic CPT codes 43770 through 45402. One key clinical point about laparoscopic procedures is that they are clinically less invasive and are often performed on an outpatient basis. What was the clinical rationale to assign all these codes to the Inpatient Only list?

Thank you for this opportunity to comment.

Very truly yours,

Valerie A. Rinkle
Revenue Cycle Director

Asante®

Submitter : Mr. Geoff MacKay

Date: 01/06/2006

Organization : Organogenesis

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-FC-12-Attach-1.DOC

CMS-1501-FC-12-Attach-2.DOC

Organogenesis Inc.

LIVING TECHNOLOGY



January 3, 2006

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

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates --
Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs

Dear Administrator McClellan:

Organogenesis, Inc. is writing to comment on payment rates in the final rule, CMS-1501-FC, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to our product Apligraf and related procedure codes. Organogenesis is a biotechnology company based in Canton, Massachusetts and we manufacture and market Apligraf® (J7340), a living, bi-layered skin construct FDA has approved for the treatment of Venous Leg Ulcers and Diabetic Foot Ulcers. We appreciate the attention that agency staff provided to reviewing the proposed payment rate for Apligraf during the public comment period. The final rule correctly reimburses hospitals for Apligraf at averages sales price (ASP) plus 6% similar to other biologicals.

We are now notifying the agency regarding a New Interim (NI) code assigned for the procedures "Tissue cultured allogeneic skin substitute, first 25 sq cm or less" code 15340 and "each additional 25 sq cm" code 15341. In the final rule CMS states "We will consider comments on the payment classification assigned to HCPCS codes identified in Addendum B with the NI comment code. . . ." We are concerned that assigned payment rate for these NI codes does not take into account the RUC review and subsequent increase in the assigned relative value units for 2006 for these respective codes. We respectfully request that CMS review and increase the payment rate to hospitals for the procedure codes 15340 and 15341.

Background on Apligraf® and Its Procedure Codes

Apligraf® is a unique, bioengineered, cell-based living human skin substitute for the treatment of chronic, hard-to-heal venous leg ulcers and diabetic foot ulcers. Like human skin, it is made from living cells and it is composed of two layers, a dermis and an epidermis, comprised of healthy, functioning, responsive cells that stimulate the wound to heal. Apligraf® is the only active wound-healing product approved by the U.S. Food and Drug Administration (FDA) to treat both venous leg ulcers and diabetic ulcers.

Before the development of Apligraf®, physicians had few options for treating hard-to-heal venous leg ulcers, which comprise approximately one-third of all treated venous ulcers. Apligraf® has preserved and improved the quality of life of tens of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of them would have had to undergo limb amputations without the benefit of Apligraf®. Apligraf® and similar advanced bioactive products have been specified by leading clinicians in published algorithms as the standard of care for wounds that have not responded to conventional therapy. Apligraf® is a proven cost-effective therapy for chronic foot ulcers, providing savings in wound care costs of \$7,500 for these patients.

Physicians bill procedures codes for the application of Apligraf. In 2005, physicians billed CPT 15342 only once per day, regardless of the number of ulcers treated, or whether or not the sites are bilateral. Additional claims for 15342 for the same date of service were denied by Fiscal Intermediaries. Physicians billed CPT 15343, if necessary, multiple times per day, depending on the number of additional 25 sq cm grafts required to treat the aggregate ulcer surface. The number of services reported was the number of additional sq cm grafts required to treat the aggregate ulcer surface (beyond the initial 25 sq cm), and not the number of ulcers being treated. The American Medical Association/Specialty Society RVS Update Committee (RUC) reviewed the procedure codes for all skin related products which resulted in the deletion of some codes, creation of new codes, and a review of the relative value units. The procedure codes for the application of Apligraf were changed from 15342 to 15340 and from 15343 to 15341.

Payment Rates for Apligraf®'s Procedure Codes

This details the payment changes from 2005 to 2006 for the procedure codes for Apligraf.

2005

As noted above, in 2005 15342 and 15343 were utilized as the procedure codes for the application of Apligraf. The "Fully Implemented Facility PE RVU" was 1.66 for 15342 and 0.37 for 15343 with a payment rate of \$101.10 each.

The Honorable Mark McClellan

January 3, 2005

Page 3

2006

In 2006, the RUC also reviewed the relative value units assigned. Based on this review, the RUC increased the relative value units from 1.66 in 2005 to 6.89 in 2006 for code 15340 and from 0.37 in 2005 to 0.76 in 2006 for code 15341

For the physician's office setting, CMS addressed the changes by increasing the payment rate in the Physician Fee Schedule for code 15340 from \$112.18 in 2005 to \$294.48 in 2006. Also, CMS increased the payment rate of \$14.02 in 2005 to \$42.32 in 2006 for code 15341.

In the final Hospital Outpatient rule the payment rates for 15340 and 15341 are listed with a comment indicator NI and a Status Indicator (SI) "T." Status indicator "T" is designated for "Significant Procedures, Multiple Reduction Applies." The payment rates for 15340 and 15341 were decreased from \$101.10 in 2005 to \$92.32 in 2006. The final Hospital Outpatient rule does not account for the increase in the relative value units for the procedure codes 15340 and 15341. The payment rate for the initial application for Apligraf is intended to be higher than subsequent applications. Under the proposed Hospital Outpatient rates both 15340 and 15341 are paid at the same rate.

Conclusion

The Hospital Outpatient payment rate is not inline with the physician setting and will significantly underpay hospitals for the procedure codes for the application of Apligraf. We are concerned that this will limit beneficiary access to Apligraf in the Hospital Outpatient setting. We respectfully requested that the proposed NI codes for 15340 and 15341 in the final hospital outpatient rule be paid at the same rate as in the physician setting. In this regard, we are available to meet with agency to further discuss this. You may contact me directly at 1 (781) 401-1040.

Thank you for your attention to this issue

Sincerely,



Geoff MacKay

cc: James Hart (Director, Division of Outpatient Services)

Submitter : Mr. James McGlone

Date: 01/09/2006

Organization : Oncura

Category : Device Industry

Issue Areas/Comments

**Classification assignments of
HCPCS codes identified in
Addendum B with comment
indicator NI.**

Classification assignments of HCPCS codes identified in Addendum B with comment indicator NI.

HCPCS 0135T Assigned to APC 0163 Level IV Cystourethroscopy and other Genitourinary Procedures

GENERAL

GENERAL

See Attachment

CMS-1501-FC-13-Attach-1.PDF

CMS-1501-FC-13-Attach-2.PDF



January 5, 2006

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

VIA: HAND DELIVERY

RE: Final Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; [CMS-1501-FC]

Dear Administrator McClellan:

These comments are submitted on behalf of ONCURA,¹ a leading manufacturer of state-of-the-art medical products and systems that employ novel hypothermic surgical technologies to destroy cancerous tissues. Our products include cryoablation systems, which offer highly effective and minimally invasive therapies for kidney and prostate. Additionally, we provide brachytherapy source products for the treatment of cancer.

We appreciate the opportunity to comment on the final rule published by the Centers for Medicare & Medicaid Services ("CMS") on November 10, 2005, *Federal Register* notice which changes the Hospital Outpatient Prospective Payment System (the "OPPS") for 2006. See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Vol. 70, No. 217 (November 10, 2005) (the "Final Rule").

We wish to comment on the following specific APC assignments related to cryotherapy:

HCPSC 0135T assigned to APC 0163 *Level IV Cystourethroscopy and other Genitourinary Procedures*

* * *

Assigning percutaneous renal cryoablation (described by HCPSC 0135T) to APC 0163 *Level IV Cystourethroscopy and other Genitourinary Procedures* is inappropriate because the 0135T procedure is a qualitatively different and considerably more resource intensive procedure than the other procedures assigned to APC 0163. This APC significantly underpays for the percutaneous renal cryoablation procedure. Unlike percutaneous

¹ ONCURA was created in July 2003 by the merger of Amersham's brachytherapy business with Galil Medical Ltd's urology business.

renal cryoablation, the majority of the procedures assigned to APC 0163 are surgical procedures that **do not** require the use of complex new technology medical devices. The cryoablation probes required to perform percutaneous renal cryotherapy are no longer paid separately under OPPS (separate pass-through payment for these devices expired on December 31, 2003), and therefore should be accounted for in the payment for the procedure. However, it appears that CMS has not included the cryoablation device costs in the assignment of 0135T to APC 0163, because APC 0163 does not cover the cost of these probes. We recommend that because percutaneous cryoablation of a renal mass is a relatively new procedure that has only rarely been performed in the outpatient setting, **CMS should assign HCPCS 0135T to a New-Technology APC until meaningful outpatient cost data can be obtained for the procedure.** A preliminary cost analysis suggests that the cost to hospitals to provide this procedure in a hospital outpatient setting is approximately \$ 9000 per case. Accordingly, we recommend that CMS assign HCPCS 0135T to a New Technology Level XXXVI APC 1536, with a payment range of \$9000 - \$9500. Oncura plans on filing a New Technology APC application in the near future for this procedure..

We discuss these issues in further detail below.

* * *

I. BACKGROUND ON RENAL CRYOSURGERY

In recent years, renal cryosurgery has become an increasingly important therapeutic option for Medicare beneficiaries suffering from renal cell carcinoma (RCC). With developments in the field of imaging, renal tumors are being detected in an early and asymptomatic stage. Cryotherapy systems are designed to treat renal cell cancer by destroying cancerous tissue through the application of extreme cold temperatures delivered by cryoablation probes.² At the 23rd World Urological Congress Meeting on Endourology, more than 23 papers were presented on renal cryotherapy. The May of 2005 American Urological Association (AUA) annual meeting included an all day course on minimally invasive treatments for renal cell carcinoma and the appropriateness of renal cryotherapy as a treatment for Renal Cell Carcinoma. Additionally, the American Urological Association Health patient website states the following regarding cryotherapy of renal tumors *"Since renal tumor ablation is a relatively new procedure, long-term results are unknown. However, ablation may be less invasive than nephrectomy and may be useful in patients who cannot tolerate a more extensive surgery. Tumor ablation may also permit a better chance of preserving kidney function in situations when multiple tumors are present."*³

Many of the renal cryotherapy procedures performed to date have been performed on Medicare beneficiaries who are not candidates for traditional surgery, and many of these patients have only one functioning kidney. Percutaneous renal cryotherapy is often the most appropriate and only treatment option for these patients. Percutaneous ablation of renal tumors via cryotherapy enables the targeted destruction of select, small renal tumors in lieu of open or

² These probes are inserted through the skin percutaneously and into the kidney. Argon gas circulating through the probes generates very low temperatures causing the formation of ice, which destroys targeted cancer cells and tumor.

³ The AUA's on-line patient information resource, UrologyHealth.org was written and reviewed by urology experts in partnership with the American Urological Association Foundation. Website address: <http://www.urologyhealth.org>

laparoscopic partial nephrectomy, and thus provides important benefits for patients by minimizing the invasiveness of the surgical intervention and the incidental damage to surrounding tissue. In some cases, this procedure has allowed physicians to treat the renal cell carcinoma and save enough of a single remaining kidney to avoid the patient going on dialysis, which would result in significant savings to the Medicare program.

In the Final Rule, HCPCS 0135T was assigned to APC 0163, which maps to a total of ten procedures. Of the ten procedures assigned to APC 0163, eight of the procedures are cystoscopy or prostate surgical procedures. Percutaneous Renal Cryotherapy (CT, MR or US guided) is the **only procedure** of the ten procedures grouped into APC 163 which is performed to treat renal cell carcinoma. The one remaining procedure assigned to APC 0163, Kidney Endoscopy, is not performed to treat renal cell carcinoma. There is nothing clinically homogenous with Percutaneous renal cryotherapy and the other procedures assigned to APC 0163. Nor are the resources, medical devices, or surgical supplies utilized in the other procedures assigned to APC 0163 similar to Percutaneous Renal Cryotherapy.

Percutaneous renal cryotherapy requires the use of Cryotherapy equipment, cryoablation probes, temperature sensor devices, surgical disposable supplies, and the presence of specially trained staff, above and beyond what is necessary to perform the other procedures assigned to APC 0163. Accordingly, the assignment of both HCPCS 0135T and the other procedures grouped to the same APC is inconsistent with legislative requirements that procedures assigned to the same APC be clinically homogenous.

The following is a brief list of equipment and supplies required for Percutaneous Renal Cryotherapy:

- Capital Equipment includes the procedure being performed in an Interventional CT Scanner
- Typical Procedure time is two hours
- Cryoablation Machine
- Procedure is performed under general anesthesia or local sedation
- Cryoablation Needle Probes - \$5000. ASP
- Argon Gas (6000psi) – \$200. (plus shipping/delivery)
- Helium Gas (6000psi) – \$200. (plus shipping/delivery)
- Imaging Contrast material
- Surgical supplies (procedure is performed using full sterile technique). Some of the required "other" surgical supplies include Sterile Water - 500cc; Saline Solution 0.9% 1000 ML INJ; Surgical Gowns; Sterile Drape Pack; Sterile Towels; Sterile Gloves; Prep Kit - wet skin scrub; Dressing Plain 4 x 4; Suture Vicryl 2.0.
- In addition to the Interventional nursing staff needed to assist the physician(s) (often an Interventional Radiologist and Urologist perform the procedure together) during the procedure, specially trained cryotherapy staff also must be present to operate the cryosurgical unit.
- The patient is cared for in a pre-operative and post-operative same day recovery suite for 23 hours or less when the patient is not admitted to the hospital.

As noted above, percutaneous renal cryosurgery is an emerging technology that has rarely been performed in the outpatient setting. Based on the absence of a specific CPT code prior to January 1, 2006, the outpatient hospital cases performed prior to this date have been coded under the general unlisted CPT 53899 according to AMA guidance. It is therefore

currently impossible to use claims data to delineate the actual procedure costs because the unlisted code is used to describe many different procedures other than percutaneous renal cryotherapy. As a result, there is very little information concerning the total cost to outpatient facilities of performing this procedure. Absent any available claims for this procedure, CMS should not assign this procedure to an established APC, rather the agency should assign the procedure to a New-Technology APC based on the actual cost to perform the procedure. This will enable the agency to collect sufficient cost information on which to base an appropriate clinical APC assignment in the future that will provide adequate payment for this important technology.

Percutaneous Renal Cryotherapy meets the New Technology APC criteria as set forth by CMS:

Criteria 1: The service is one that could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.

Percutaneous renal Cryotherapy was previously reported under a miscellaneous CPT code and rarely performed in 2004 on an outpatient hospital basis. It is impossible to identify the claims that are related to percutaneous renal cryotherapy based on an unlisted procedure code.

Criteria 2: The service does not qualify for an additional payment under the transitional pass-through provisions established under section 1833(t)(6) of the Social Security Act and in Subpart G, Transitional Pass-through Payments in the regulations at 42 CFR 419.

The cryoablation probes which are the devices utilized for this treatment are described by HCPCS C-2618, probe, cryoablation. The pass-through payment for this device expired in 2003.

Criteria 3: The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.

As noted above, Percutaneous Renal Cryotherapy is not clinically homogenous to any of the procedures in the established APC groups.

Criteria 4: The service falls within the scope of Medicare benefits under section 1832(a) of the Act.

Percutaneous Renal Cryotherapy is a surgical treatment performed in hospitals for the treatment of renal cancer.

Criteria 5: The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Social Security Act.

Many of the renal cryotherapy procedures performed to date have been performed on Medicare beneficiaries who are not candidates for traditional surgery, and many of these patients have only one functioning kidney. Percutaneous renal cryotherapy is often the most appropriate and only treatment option for these patients. Percutaneous ablation of renal tumors via cryotherapy enables the targeted destruction of select, small renal tumors in lieu of open or laparoscopic partial nephrectomy, and thus provides important benefits for patients by

minimizing the invasiveness of the surgical intervention and the incidental damage to surrounding tissue. In some cases, this procedure has allowed physicians to treat the renal cell carcinoma and save enough of a single remaining kidney to avoid the patient going on dialysis, which would result in significant savings to the Medicare program.

II. RECOMMENDATION FOR RENAL CRYOABLATION

Due to the lack of claims data for this procedure, we urge CMS to assign the 2006 payment for HCPCS 0135T to a New Technology APC. The assignment of a New Technology APC would ensure that the payment for Percutaneous Renal Cryotherapy cover the costs incurred by hospitals in performing this procedure. Adequate payment for new technology in the OPSS is necessary to prevent hindering the adoption of this emerging and groundbreaking therapy.

III. CONCLUSION

ONCURA appreciates the opportunity to submit comments on the Final OPSS Rule, and we are eager to provide CMS with any information or clarification that would enable the agency to ensure Medicare beneficiaries continued access to this treatment option in the outpatient setting. We recognize that a system as complex as the OPSS will continue to encounter challenges for specific types of services, including cryotherapy. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me or you may also contact Lisa Hayden at (703) 948-7685.

Sincerely,

James McGlone

James McGlone
President/CEO Oncura

Submitter : Mr. Jim Hayes

Date: 01/09/2006

Organization : Allergan Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-FC-14-Attach-1.PDF

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

January 9, 2006

VIA ELECTRONIC SUBMISSION

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

**RE: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Final Rule
CMS-1501-FC
Interim Ambulatory Payment Classification for new codes 64650 and 64653
Interim Ambulatory Payment Classification for new code 46505
Interim Ambulatory Payment Classification for new codes 95873 and 95874**

Dear Dr. McClellan:

On behalf of Allergan Inc. ("Allergan"), we are pleased to submit comments in response to the above-captioned Final Rule with Comment Period ("Final Rule") on the Medicare Hospital Outpatient Prospective Payment System ("OPPS") for 2006. Allergan develops and manufactures BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex. BOTOX® is a biologic that is approved and used to treat patients with blepharospasm (a disorder involving involuntary closure of the eyelids), strabismus (a disorder of muscles that move the eyes), cervical dystonia (abnormal movements of the neck muscles) and severe primary axillary hyperhidrosis (disorder of sweat glands).¹ Botulinum toxin type A is administered by physicians in hospital outpatient departments as well as physician offices. Botulinum toxin type A is covered as a biological provided incident-to a physician's service under Medicare Part B.²

As explained more fully below, we support the following interim APC assignments for the new chemodenervation and associated EMG guidance procedure codes that are reported as part of the administration of botulinum toxin type A:

¹ The current package labeling includes the following indications for BOTOX®:

BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

In addition, BOTOX® Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX® Cosmetic is never covered by Medicare.

² Soc. Sec. Act §§ 1861(s)(2)(A),(B).



CPT	CPT Descriptor	CI	SI	APC	APC Descriptor	Relative Weight	Payment Rate
46505	Chemodenervation anal musc	NI	T	0148	Level I Anal/Rectal Procedures	3.5047	\$ 208.57
64650	Chemodenerv eccrine glands	NI	T	0204	Level I Nerve Injections	2.2667	\$ 134.89
64653	Chemodenerv eccrine glands	NI	T	0204	Level I Nerve Injections	2.2667	\$ 134.89
95873	Guide nerv destr, elec stim	NI	S	0215	Level I Nerve and Muscle Tests	0.6025	\$ 35.86
95874	Guide nerv destr, needle emg	NI	S	0215	Level I Nerve and Muscle Tests	0.6025	\$ 35.86

1. Interim Ambulatory Payment Classification for New Codes 64650 and 64653

Administration of botulinum toxin type A comprises a chemodenervation procedure. The most common codes used to report chemodenervation procedures are: 64612, 64613 and 64614. These codes were adopted in 1992 and 2001³ and have been assigned to Ambulatory Payment Classification Group 0204 "Level I Nerve Injections."

With the recent FDA approval of botulinum toxin type A for the treatment of patients with severe primary axillary hyperhidrosis, the American Medical Association's CPT Editorial Panel approved two new chemodenervation codes, effective January 2006, to report chemodenervation of eccrine glands for the treatment of patients with severe focal hyperhidrosis. These codes are:

64650 Chemodenervation of eccrine glands; both axillae

64653 Chemodenervation of other area(s) (eg, scalp, face, neck), per day

These chemodenervation procedures are similar in many respects to the other well-established chemodenervation procedures in the 646xx series requiring specific identification of the sites to be treated, injections into multiple sites by trained practitioners, and monitoring post-injection. The chemodenervation of eccrine gland procedures differ from other chemodenervation procedures in that the Minor's starch iodine test is included as part of the eccrine gland procedure, to identify sites to be treated and to assess effectiveness of previous treatments, whereas in the chemodenervation of muscle procedures, EMG or electrical stimulation or endoscopy may be required as additional procedures to localize the target treatment sites.

We submitted comments in response to the Notice of Proposed Rulemaking recommending that these two new chemodenervation of eccrine gland procedures be assigned to APC 0204 together with the older chemodenervation of muscle codes in the 646xx series. We were pleased to see that CMS assigned codes 64650 and 64653 to APC 0204 consistent with our recommendation. We encourage CMS to finalize this APC assignment.

³ Code 64612 and 64613 were implemented in 1992 and code 64614 was implemented in 2001.

2. Interim Ambulatory Payment Classification for New Code 46505

In addition to the two new codes for chemodenervation of eccrine glands, new code 46505 was adopted to report "chemodenervation of internal anal sphincter" (e.g., for treatment of anal fissure). We were pleased to see that this procedure was assigned to an appropriate APC classification—APC 0148 "Level I Anal/Rectal Procedures." We support this APC assignment.

3. Interim Ambulatory Payment Classification for New Codes 95873 and 95874

In addition to adopting new codes for chemodenervation procedures, the CPT Editorial Panel created two new codes to report electromyography or electrical stimulation as guidance for chemodenervation procedures. The new codes are:

95873 *Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)*

95874 *Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)*

These codes were assigned to the same APC as the limited single needle EMG procedure reported under code 95870⁴--APC 0215 "Level I Nerve and Muscle Tests." Although we believe it is appropriate to distinguish between the two new procedures because they involve different levels of resources, we understand CMS's assigning these to the same APC pending development of data to evaluate the differential costs for these two procedures. We would encourage CMS to look carefully at the relative cost data for these two procedures, as these become available over the next year, and adjust the APC assignment as appropriate.

* * * *

Finally, we would like to express our support for CMS's determination to pay for separately paid drugs and biologicals using the Average Sales Price methodology used in the physician office/other outpatient settings. However, we were disappointed to see that CMS did not finalize its proposal to provide an additional payment to cover pharmacy handling and overhead costs. As we indicated in our comments to the Proposed Rule, handling and overhead costs are over and above drug acquisition costs reflected by the ASP plus 6-percent payment amount. We would encourage CMS to reconsider this decision and to provide adequate payments to cover pharmacy handling and overhead in the future.

We appreciate having the opportunity to comment on the Final Rule with Comment Period and hope CMS will consider these recommendations in developing the Proposed Rules for 2007. If you have any questions about our comments, please contact Jim Hayes, Director, Reimbursement Strategy and Healthcare Policy, Neuroscience Division at 714-246-6401 or by e-mail at hayes_jim@allergan.com. Thank you.

Sincerely yours,

/s/ Jim Hayes

Director, Reimbursement Strategy and Healthcare Policy
Neuroscience Division
Allergan Inc.

⁴ 95870: "Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters."

CMS-1501-FC-15

Submitter : Mr. Brian McGinty

Date: 01/09/2006

Organization : Biogen Idec

Category : Drug Industry

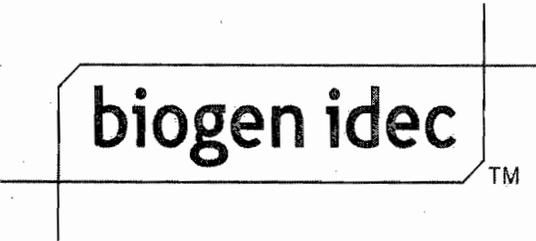
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-FC-15-Attach-1.DOC

The logo for Biogen Idec, featuring the company name in a bold, lowercase sans-serif font. The text is enclosed within a rectangular frame that has a slightly irregular, hand-drawn appearance. A small "TM" trademark symbol is located to the right of the text.

biogen idec™

January 5, 2006

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1501-FC (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Dr. McClellan:

Biogen Idec appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Final Rule with Comment implementing portions of the Medicare Modernization, Prescription Drug and Improvement Act of 2003 (MMA), and revising payment rates and policies under the Hospital Outpatient Prospective Payment System (HOPPS). Biogen Idec is a global leader in biotechnology headquartered in Cambridge, Massachusetts. Our products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology.

Biogen Idec's pipeline and existing products are infused or injected in a variety of settings, including hospital outpatient departments. Biogen Idec views the revisions in payment policies from the Proposed Rule to those articulated in the Final Rule as a clear improvement toward ensuring that the hospital outpatient setting presents a viable care alternative for Medicare beneficiaries seeking access to critical therapies. Specifically, Biogen Idec:

- Generally supports Medicare hospital outpatient department payment for radiopharmaceuticals based upon hospital costs

converted to costs utilizing each hospital's overall cost-to-charge ratio;

- Supports continued pass-through status for Natalizumab in 2006;
- Supports CMS incorporation of changes in Zevalin HCPCS codes effective for 2006 into the hospital outpatient payment system to ensure consistency between payment settings;
- Supports CMS use of the new Current Procedural Terminology (CPT) codes and descriptors for drug administration services under HOPPS, and urges CMS to ensure that hospitals have sufficient guidance to utilize the appropriate codes for complex biological therapies such as monoclonal antibodies and other biological response modifiers that are appropriately billed under chemotherapy administration codes; and
- Requests clarification on the interface between CAP payment and hospital outpatient payment for pass-through products.

I. Payment for Radiopharmaceuticals

Biogen Idec appreciates that CMS determined not to collect ASP data for radiopharmaceuticals for hospital outpatient department payment rate purposes. Biogen Idec appreciates that CMS faces significant challenges in creating a permanent payment methodology for radiopharmaceuticals in the hospital outpatient setting that does not threaten access through precipitous payment cuts. We generally support CMS in its efforts to derive actual acquisition cost data from hospital charges utilizing each hospital's overall cost-to-charge ratio.

As we stated in comment to the Proposed Rule, however, hospitals generally tend to set charges for higher cost therapies such as Zevalin at levels relatively close to acquisition cost. We noted that according to data acquired from the Moran Group, only 26% of hospitals currently charge sufficiently to recover costs for the imaging dose of Zevalin, while just 18% of hospitals set charges at a sufficient level for the therapeutic dose of the Zevalin regimen. We urge CMS and its Regional Offices to provide sufficient guidance to hospitals so that the interim methodology does not adversely impact access to Zevalin and similar therapies. Biogen Idec recognizes that CMS received comments urging the agency to create

a separate methodology for therapeutic radiopharmaceuticals such as Zevalin and Bexxar. We request that CMS engage Biogen Idec in any discussions regarding the propriety of separating Zevalin and Bexxar from more traditional radiopharmaceuticals for hospital outpatient payment purposes so that any methodology applied to these products does not create a financial incentive for use of one product over another.

Finally, Biogen Idec urges CMS to continue working with hospitals, manufacturers, and other stakeholders, including manufacturers of therapeutic products within the radiopharmaceutical classification, to ensure that both short and long-term payment methodologies sufficiently reimburse providers for medically necessary therapies. We also request that CMS provide sufficient guidance to hospitals so that the interim payment methodology generates valid and reliable data from which CMS can set future payment rates.

II. Pass-through Status for Tysabri (natalizumab)

As stated in comment to the Proposed Rule, Biogen Idec supports continued pass-through status for Tysabri (natalizumab) in 2006. In those comments, however, we expressed concern that the continuation of the 1 mg unit descriptor will present confusion for providers and result in erroneously denied or underpaid claims. While CMS correctly stated in its Final Rule that permanent HCPCS codes fall within the jurisdiction of the HCPCS Committee, that Committee declined to issue a permanent Tysabri J code for 2006. We urge CMS to reconsider its decision and apply a 300 mg unit descriptor for Tysabri in the hospital outpatient setting beginning with the April 2006 update. Alternatively, we suggest that Tysabri claims experience during 2006 may be useful in ascertaining whether or not the 1 mg unit descriptor is appropriate in facilitating correct claims and their accurate processing. We hope that any claims processing difficulties would be communicated to the HCPCS Committee to inform its decision regarding the appropriate unit descriptor for Tysabri.

III. Drug Administration Codes and Payment

Biogen Idec appreciates CMS' decision to implement 20 of the 33 new CPT codes for drug administration services. We note that rather than utilizing the 13 new codes that require determinations of initial, sequential, and concurrent infusions or intravenous pushes, CMS created 6 new C-codes that describe these services. We concur with the comments of the Biotechnology Industry Organization (BIO) that these codes represent a significant improvement over the old codes because they

offer more specific descriptions of the types of services offered. We remain concerned that payment rates for these codes may not be sufficient for 2006 given the age of the data and lack of granularity in the former code set used to set payment rates, and anticipate that as charge data are collected on the new codes, CMS should be able to set more appropriate rates for these procedures in the future. We hope that CMS will monitor access to drug and biological therapies in the hospital outpatient setting and that it will adjust rates as needed to protect access.

We also appreciate the guidance recently issued by CMS on the use of the new codes in hospital outpatient departments, specifically with respect to the use of chemotherapy codes for complex biologicals such as monoclonal antibodies and other biological response modifiers. We suggest that CMS reiterate the guidance on use of these new codes that is contained in the Final Rule in its educational outreach efforts to hospitals, including any Open Door Forums and website resources.

IV. Interface Between CAP Payment Rate and Payment for Pass-Through Drugs

In the Final Rule, CMS noted the MMA provision setting HOPPS payment for pass-through drugs based upon payment rates under the Competitive Acquisition Program (CAP) for drugs and biologicals under Part B. CMS also released a separate rulemaking in which it exempted sales to CAP vendors from ASP calculations. Biogen Idec agrees with CMS in its interpretation of the MMA, but is concerned that this MMA provision may have the effect of either (1) discouraging CAP discounts for newer products that have pass-through status; or (2) disadvantaging newer therapies through application of the CAP payment amount to the hospital outpatient setting. As a practical matter, CMS may find that few products in the CAP for 2006 retain pass-through status for 2007, and that for effected products, the 2006 CAP payment is based upon the ASP rather than the bidding process.

Biogen Idec suggests that CMS evaluate whether the goals of CMS' public policy decision to exempt CAP sales from ASP calculations may be compromised by applying CAP payment amounts to newer products in the hospital outpatient setting. We recommend that CMS decline to apply non-ASP CAP payment amounts to the hospital outpatient setting in 2007 as part of its phase-in of the CAP. If the ASP exemption will likely be permanent, CMS should consider the

Mark B. McLellan
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desirability of legislative changes to eliminate any disadvantage to newer therapies.

Conclusion

Biogen Idec recognizes CMS' efforts to improve the HOPPS and to ensure that the payment reform provisions of the MMA are implemented with a careful eye on preserving patient access to valuable therapies. We appreciate the opportunity to comment on the payment policies contained in the Final Rule. If you have any questions or require further information, please do not hesitate to contact me.

Very truly yours,

Brian McGinty
Vice President
Managed Markets and Reimbursement

Submitter : Mr. E. Strode Weaver

Date: 01/09/2006

Organization : Association of Community Cancer Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-FC-16-Attach-1.PDF

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**Re: CMS-1501-FC (Medicare Program; Changes to
the Hospital Outpatient Prospective Payment
System and Calendar Year 2006 Payment Rates)**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on November 10, 2005 (the "Final Rule").¹ ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team

members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies in the most appropriate settings. Hospital outpatient departments are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses, and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. Our members also play an important role in the health care safety net. In some cases, hospital outpatient departments are the only sites available for Medicare and uninsured patients who need cancer care. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that only is available in that setting. Finally, hospital outpatient departments play an important role in the early adoption of new technologies and frequently serve patients who have recently completed participation in clinical trials.

Adequate OPPS payment rates for cancer drugs¹ and the services required to prepare and administer them are critical to ensuring patient access to care. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Medicare payments for cancer drugs have been reduced significantly. The combined effects of these reductions seem to be slowly dismantling multi-disciplinary cancer care, which is certainly not CMS' intent. We believe that it is critical to establish payment rates that will ensure hospitals are reimbursed appropriately for the services they provide. For example, in Palm Springs, California, a leading medical clinic known for treating cancer patients, expects to close its doors at the end of January 2006 due to physician departures and losses caused by "reductions in Medicare reimbursements (that) cut into the clinic's operating margin."² We have also heard from several members that the continued "hits" to the entire service line may lead to hospitals choosing to close their infusion units entirely. Indeed in the Tidewater area of Virginia, three

¹ We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

² Spillman, Benjamin. "Desert cancer clinic to close." The Desert Sun.com, December 2, 2005

outpatient infusion centers have closed, citing perceived reductions to reimbursement as a primary reason for their decision. At the same time, hospitals expect demand for care to increase at a rate of 35% to 40% each year as patients and therapies are shifted to outpatient departments. CMS must take care to ensure that Medicare beneficiaries are able to receive cancer care in the most appropriate settings.

ACCC is particularly troubled about the effect of CMS' decision not to make an additional payment for pharmacy handling costs. As we describe below, we are greatly concerned that this decision will threaten hospitals' ability to provide safe and effective cancer care and is inconsistent with CMS' goals of improving the quality of care provided to Medicare beneficiaries. We urge CMS to work with providers to ensure that hospitals are reimbursed appropriately for all of the costs of providing drugs and biologicals in 2006 and to develop a long-term methodology for measuring and reimbursing these costs.

We are also still concerned with the erratic changes in the price and availability of IVIG. We appreciate CMS's implementation of a \$75 add-on payment for the pre-administration related services associated with infusion of IVIG, but we advise CMS to closely monitor the cost and availability of IVIG and respond accordingly to ensure appropriate compensation to hospitals and continued patient access. We also recommend that CMS revise its guidance regarding payment for hydration and non-chemotherapy drug infusion services during a single visit and allow separate payment for additional hours of infusion services. CMS also should allow hospitals a one-month grace period in which they can submit drug administration claims using the 2005 codes while updating their chargemasters. We are pleased that CMS decided not to implement its proposed reduction in payment for multiple diagnostic imaging procedures. We remain concerned about the dramatic reductions in payment for brachytherapy services, however. Finally, we recommend that CMS expand the oncology demonstration program to apply to care provided in hospital outpatient departments as well as in physician offices.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

A. Payment for Pharmacy Handling Costs

In the Final Rule, CMS announced that it will reimburse separately payable drugs and biologicals administered in hospital outpatient departments at average sales price (ASP) plus 6%.³ CMS asserts that this payment rate "will serve

³ 70 Fed. Reg. at 68642.

as a proxy to make appropriate payment for both the acquisition cost and overhead cost of each of these products.”⁴ Based on an ACCC analysis that was recently shared with CMS staff, we estimate that this payment methodology will reduce hospital reimbursement for 115 drugs commonly used in cancer care by \$200 million from 2005 to 2006. We are deeply sceptical that these rates will be sufficient to reimburse hospitals adequately for their pharmacy handling costs. ACCC urges CMS to reconsider this decision and provide an additional payment to reimburse hospitals for the substantial costs associated with safely handling and preparing drugs and biologicals. We are greatly concerned that patient safety and access to quality care will be put at risk if Medicare does not reimburse hospitals for all of the costs of providing care.

1. Pharmacy Services Are Critical to Protecting Patient Safety

Medication safety is a pressing concern in health care and is especially important in oncology due to the complexity of medication regimens and the inherent risks of preparing and administering cancer drugs. To ensure that each patient receives the correct dosage of each drug, in the correct sequence, and through the safest administration method, hospitals employ complex medication use processes in which physicians, nurses, and pharmacists review drug choices at each step of their prescribing, dispensing, and administration. Pharmacists make essential contributions to these processes by using a sequence of activities commonly referred to as “safety through redundancy.” Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of drug, such as labelling, recording, and tracking mixed drugs for safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions.

Thanks to such safety measures, cancer hospitals have been able to keep their pharmacy error rates relatively low and reduce harm to patients that would have been caused by those errors. A recent study of more than 10,000 medication orders at one cancer center found a medication error rate of 3%, lower than the overall error rates found in inpatient or primary care settings. Approximately two-thirds of the errors had the potential to cause harm, however.⁵ Fortunately, none of

⁴ Id. at 68643.

⁵ Tejal K. Gandhi et al, Medication Safety in the Ambulatory Chemotherapy Setting, 104 Cancer 2477-83, October 24, 2005.

the errors identified in this study actually caused harm to patients because the hospital used a rigorous chemotherapy order review process in which pharmacists and nurses assess and verify physicians' orders at each step of the medication use process.⁶

These safety protocols are necessary to prevent harm to patients, but they are costly to provide, and discussed in greater detail below.

2. Pharmacy Handling Costs Are Significant

In its June 2005 report to Congress, the Medicare Payment Advisory Commission (MedPAC) cited studies that found pharmacy service overhead costs make up 26% to 33% of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs.⁷ Most of the overhead costs reflect ancillary supplies (gowns, booties, masks) and salaries and benefits of pharmacists and technicians. As described above, pharmacy professionals not only prepare drugs for administration, they also review the prescribed dosage and method of administration for potential errors and consult with physicians and nurses about recommended changes to drug selection, dosage, administration schedules, and route of administration. An ACCC member reported an average of 3.1 pharmacist interventions per hour over a 15 month period. Most interventions lasted 15 to 30 minutes, and the average pharmacist salary and benefits at that hospital was \$56 per hour, producing a per-intervention cost of \$14 to \$28. These costs are in addition to the time needed to prepare a drug when no intervention is required. Nationwide, the median hourly wage for pharmacists is \$54.14 (\$41.78⁸ plus benefit

⁶ Id. at 2482.

⁷ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

⁸ U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages, November 2004, Pharmacists, available at <http://www.bls.gov/oes/current/oes291051.htm>.

costs of 29.6%⁹), while the wage for pharmacy technicians is \$15.66 (\$12.09¹⁰ plus benefit costs of 29.6%¹¹).

Pharmacy service costs also include contract negotiations, building and information systems maintenance and upgrades, transportation of drugs within the hospital, and disposal of unused products (that typically involve the housekeeping department) to comply with Environmental Protection Agency (EPA) and National Institute for Occupational Safety and Health (NIOSH) regulations. Accordingly, costs for these items and services are affected by regulatory and accreditation standards and can increase dramatically when these standards change. For example, many hospitals currently bear the costs of renovating their facilities to comply with the new sterile compounding standards of the United States Pharmacopeia Chapter 797. A 2005 study commissioned by the National Patient Advocate Foundation found that the average cost per dose of chemotherapy administration, including all of the costs listed above, is \$36.03.¹² This is in addition to the acquisition cost of the drug.

3. Medicare's Payments for Drugs Do Not Compensate Hospitals for Their Pharmacy Handling Costs

Historically, Medicare' OPPS rates were intended to cover pharmacy handling costs in addition to drugs' acquisition costs. In 2006, the MMA requires Medicare to begin reimbursing separately payable drugs administered in hospital outpatient departments at acquisition cost.¹³ When Congress created this change in the law, it recognized that rates based on acquisition cost would not compensate hospitals for handling costs. To determine whether OPPS rates should be adjusted

⁹ U.S. Department of Labor, Bureau of Labor Statistics, Private Industry, Health Care and Social Assistance Workers, by Industry and Occupational Group, September 2005, Hospitals: Management, Professional, and Related, available at <http://www.bls.gov/news.release/ecec.t14.htm>.

¹⁰ U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages, November 2004, Pharmacy Technicians, available at <http://www.bls.gov/oes/current/oes292052.htm>.

¹¹ U.S. Department of Labor, Bureau of Labor Statistics, Private Industry, Health Care and Social Assistance Workers, by Industry and Occupational Group, September 2005, Hospitals: Management, Professional, and Related, available at <http://www.bls.gov/news.release/ecec.t14.htm>.

¹² Gary Oderda, Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices, available at <http://www.npaf.org/pdf/gap/utah.pdf>.

¹³ MMA, Pub. L. No. 108-173, § 621(a)(1), 117 Stat. 2066, 2307 (2003), amending Social Security Act § 1833(t)(14)(A)(iii), 42 U.S.C. § 1395l(t)(14)(A)(iii).

to reflect these costs, Congress instructed MedPAC to study pharmacy service and handling costs.¹⁴ MedPAC's report, described above, concluded that these costs are significant and that an adjustment is warranted.

In the OPPIs proposed rule for 2006, CMS announced its plans to pay an additional 2% of ASP for separately payable drugs, on top of an estimated acquisition cost of ASP plus 6%, to reimburse hospitals for pharmacy handling costs.¹⁵ Although many stakeholders, including ACCC, and the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) supported an additional payment, these groups also were concerned that 2% of ASP would not be adequate reimbursement for hospitals' significant pharmacy handling costs. The APC Panel recommended that CMS carefully consider this proposal to ensure that it was in line with hospital costs.¹⁶ ACCC supported this recommendation and suggested that CMS increase the add-on payment to 8% of ASP.

Against the advice of hospitals, provider groups, and its own advisory panels, including MedPAC and the APC Panel, CMS abandoned this proposal in the Final Rule. Instead, CMS concluded that reimbursement for all separately payable drugs at ASP plus 6% would be an appropriate payment for both the acquisition and overhead costs of these drugs.¹⁷ We are concerned that the methodology CMS used to reach this conclusion is flawed, and hospitals may not be able to continue to provide safe and effective cancer care as a result.

In reaching its decision to reimburse separately payable drugs at ASP plus 6%, CMS used an analysis of mean unit cost from hospitals' claims and relied on a MedPAC survey that found that hospitals generally set charges high enough to reflect handling costs as well as acquisition costs.¹⁸ MedPAC also reported that hospitals do not have precise information about the magnitude of their pharmacy expenses, however, and that drugs administered in outpatient departments generally require more preparation time than drugs administered to inpatients.¹⁹

¹⁴ Social Security Act § 1833(t)(14)(E)(i), 42 U.S.C. § 1395l(t)(14)(E)(i).

¹⁵ 70 Fed. Reg. 42673, 42730 (July 25, 2005).

¹⁶ Panel's Recommendations, APC Panel Biannual Meeting – August 2005, at 2, available at http://www.cms.hhs.gov/FACA/Downloads/0817_192005mtg.zip.

¹⁷ 70 Fed. Reg. at 68642-43.

¹⁸ *Id.* at 68642.

¹⁹ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

We are concerned that CMS' reliance on hospital charges converted to costs fails to capture hospitals' true costs of providing care. We urge CMS to work with providers to determine whether all of the pharmacy costs described above are represented accurately in CMS data.

Unless hospitals are reimbursed adequately for the substantial costs of safely handling advanced cancer therapies, they will not be able to continue to provide quality care. Although Medicare payments historically have been sufficient to cover both handling and acquisition costs,²⁰ we expect that many hospitals will struggle to provide critical pharmacy services under the reduced rates for 2006. In the past, hospitals were able to support their pharmacy safety protocols using their margins on drug reimbursement. This margin will be eliminated in 2006 as Medicare reimbursement for 115 separately payable drugs used in cancer care is reduced by \$200 million. Indeed, several ACCC members anticipate losses as high as \$1 million next year because of the payment changes and elimination of the pharmacy add-on adjustment. Faced with dramatic reductions in reimbursement, hospitals may have to reduce expenditures through lay offs of essential pharmacy, nursing, and social work staff who are critical to the preparation and delivery of medicine and associated support services, but whose services are not separately reimbursed by Medicare. This clearly is contrary to CMS' goals of improving patient care and enhancing quality.

CMS and providers must work together to develop a short-term transitional payment adjustment and develop a long-term payment methodology to ensure that hospitals are reimbursed appropriately for pharmacy handling costs. Because even low error rates present an unacceptable risk of serious harm to patients, Medicare must support hospitals' efforts to improve their error reduction programs through adequate reimbursement. We thank CMS for taking the time to discuss these concerns with us, and we look forward to working with the agency to develop a solution to this problem.

B. Payment for IVIG

ACCC thanks CMS for responding to hospitals' concerns about ensuring access to IVIG. IVIG is an important therapy for many cancer patients, including those who have had bone marrow transplants and certain kinds of leukemia. When Medicare began to reimburse IVIG in other settings at ASP plus 6%, many hospitals experienced significant increases in demand for this critical therapy but have not been able to obtain sufficient quantities of it for their patients. Hospitals' efforts to

²⁰ Id. at 139, 140.

acquire enough IVIG are complicated by the fact that IVIG products are not interchangeable. Each brand of IVIG is particularly suited for specific conditions, and patients who respond well to one brand may experience adverse effects if switched to another brand. We are pleased that CMS recognizes these concerns, and we support the add-on payment of \$75 for the pre-administration-related services associated with infusion of IVIG.²¹

Notwithstanding the above, we remain concerned with the erratic prices confronting hospitals when they purchase IVIG. An ACCC member estimates the cost of its monthly IVIG allotment has risen 30 percent with an additional 20 percent charge if the allotment is exceeded and additional supply is needed. This issue is compounded by the fact that the hospital has been notified by several private practices in the area that they can no longer obtain IVIG and will be sending patients needing IVIG treatment to the member hospital for treatment.

Such dramatic changes in the demand and costs of IVIG may require more frequent updates to IVIG reimbursement rates to reflect rapidly changing prices. Alternative solutions include possibly considering a "pass-thru" payment or increasing the amount of the \$75 add-on.

To ensure that this payment is sufficient to protect beneficiary access to IVIG, we recommend that CMS work with providers to determine whether the payment fully compensates hospitals for the costs of providing this critical therapy.

II. Drug Administration

ACCC supports CMS' decision to begin using 20 of the 33 new drug administration Current Procedural Terminology® (CPT) codes in the OPSS in 2006 and to create 6 new C-codes instead of using the 13 new codes that require determinations of initial, sequential, and concurrent infusions or intravenous pushes.²² We greatly appreciate that the agency addressed our concerns about the 13 CPT codes and believe the new codes, describing drug administration services in greater detail than the old codes, will help CMS collect the data it needs to set more appropriate payment rates in the future. We also appreciate CMS' recent transmittal clarifying how the new codes should be used.²³ According to this

²¹ 70 Fed. Reg. at 68648.

²² *Id.* at 68880.

²³ January 2006 Update of the Hospital OPSS Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, December 16, 2005.

guidance, hospitals may report a first hour for each different type of infusion provided when the infusions can be reported using different codes and they meet the requirements for billing an hour of each type of infusion.²⁴ This instruction permits hospitals to report and be paid for providing a hydration service and a chemotherapy service to a patient during a single visit.

We are concerned, however, that because CMS issued its guidance on the new drug administration codes in the middle of December, many hospitals have not been able to update their chargemasters before January 1. They also have not had sufficient time to educate their staff about the new codes. As a result, some hospitals have held their charges for both drug administration services and drugs until the chargemasters have been revised and the staff are fully trained. One ACCC member estimated the value of their delayed billings to be in the hundreds of thousands of dollars. Many hospitals simply cannot afford the costs of providing care if they do not receive timely reimbursement from Medicare.

We recommend that CMS allow hospitals a one-month grace period during which they can be reimbursed for using the 2005 drug administration codes if they desire. When CMS eliminated the 90-day grace period for discontinued codes effective January 1, 2005, it stated that information about new, revised, and discontinued CPT and Healthcare Common Procedure Coding System (HCPCS) codes is available in October of each year, giving providers time to implement any changes to their billing systems.²⁵ This year, however, CMS issued the new drug administration codes in November and did not release guidance on their use until December 16. Due to the late issuance of guidance on the new codes, we believe a brief extension is necessary to allow hospitals to be reimbursed in a timely manner while they update their systems.

Additionally, we urge CMS to make separate payment additional hours of infusion services. Under the Final Rule, payment for additional hours of infusion services is packaged into the rate for the first hour. Hospital outpatient departments frequently treat patients who require infusions administered over several hours. For example, one ACCC member indicated that in June of this year, her hospital treated 177 patients who required multiple hours of chemotherapy infusions. Due to the differences in reimbursement for drug administration services in the hospital outpatient department compared to physician offices, the hospital was reimbursed almost \$35,000, or \$200 per patient, less than a physician office

²⁴ Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

²⁵ CMS Transmittal 89, Change Request 3093, February 6, 2004, revising Medicare Claims Processing Manual (CMS Pub. 100-04), ch. 4, § 20.1.1.

would have been paid for treating the same patients. This payment inequity will continue in 2006 as hospitals will be paid \$87, or 31%, less than a physician's office for infusions lasting 4 hours.

As noted, these losses are not insignificant. Another member, for example, indicated that her hospital has been treating a patient who failed first line treatment for acute promyelocytic leukemia and now is undergoing second line treatment. An orphan drug is the best hope for patients with this rare form of leukemia who have not responded to other treatment. Because this drug must be administered seven days a week for six months, most patients with this condition must seek treatment in hospitals. Under the OPPS, however, hospitals would be reimbursed for only half the time involved in administering the drug, resulting in payment for the course of treatment that is \$2000 less than what a physician office would receive for the same regimen. If inadequate Medicare reimbursement leaves hospitals unable to provide these services, some patients may have nowhere else to go for care. Patients who require infusions administered over periods of 8 hours, seven days a week, or in other situations that are outside normal physician office hours depend on hospital outpatient departments to provide their critical cancer treatments.

We understand that CMS is collecting charge and cost data for all the CPT codes to determine appropriate payment rates for all drug administration services, including those that currently are packaged. It appears that the earliest CMS would implement separate payments for these services would be January 2007, however. Our review of 2004 OPPS claims data identified 4,069 claims for 90781 *IV infusion, add'l hour* and 719 claims for 96412 *Chemotherapy infusion, add'l hour* even though these codes are not recognized for payment. The average costs for the two services were \$70.28 and \$77.71, respectively. In addition to this data, there is partial year data from 2005 available to CMS for use in calculating payment rates for these packaged codes. We ask CMS to use this data to establish separate payments so that more equitable payments for prolonged drug administration services can be established immediately.

III. Multiple Diagnostic Imaging Procedures

ACCC is very pleased that CMS has not implemented its proposal to reduce payment by 50% for second and subsequent imaging procedures within the same family when performed in the same session.²⁶ We agree that further analysis is necessary before any payment reduction should be implemented. Imaging

²⁶ 70 Fed. Reg. at 68708.

services are critical to cancer care, both for the initial diagnosis and for assessing the effectiveness of treatment. ACCC is greatly concerned that a dramatic payment cut would harm patient access to these important services and could discourage hospitals from investing in new technologies. It also could incentivize hospitals to schedule imaging services over several days, increasing the patient's inconvenience and potential exposure to contrast media. Reduced payment also could lead to increased use of invasive diagnostic techniques that put the patient at greater risk for complications and ultimately may cost the patient and Medicare more. We appreciate CMS' willingness to explore these issues further before implementing reductions for critical imaging services.

IV. Brachytherapy

ACCC is dismayed that CMS finalized its proposal to reduce payments for brachytherapy APC 651. Payment for this code will drop from \$1248.93 in 2005 to \$666.21 in 2006, a reduction of 46%. This drastic reduction could jeopardize hospitals' ability to offer brachytherapy as a treatment option. We urge CMS to reconsider this decision and apply a dampening adjustment to stabilize payment for brachytherapy services.

V. Oncology Demonstration Program

In 2006, CMS will implement an oncology demonstration program to gather information on the quality of care provided to Medicare beneficiaries with cancer. Participating physicians will report the primary focus of the evaluation and management service provided to the patient, the patient's current disease state, and whether current management adheres to clinical guidelines.²⁷ We believe this program would be equally beneficial for evaluating the quality of care provided in hospital outpatient departments, too, and we strongly urge that CMS expand it to apply to in this setting. Indeed, MedPAC has urged Medicare to "pay the same amount for identical services regardless of the setting in which they are furnished."²⁸ To date, ACCC has not been provided a plausible explanation why physicians who treat patients in a hospital setting are denied equal consideration. Allowing hospital-based oncologists to participate also would improve the equality of Medicare's payments to physicians across treatment settings.

²⁷ 70 Fed. Reg. 70115, 70272 (November 21, 2005).

²⁸ MedPAC, Report to the Congress: Medicare Payment Policy, March 1999, at p. 6.

VI. Conclusion

ACCC urges CMS to protect cancer patients' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPPTS. Toward this end, we believe it is imperative for CMS to make an add-on payment for pharmacy handling costs. In addition, it is critical that CMS revise the coding and payment policies for drug administration services to make separate payment for additional hours of infusion services and to allow hospitals to be paid separately for administration of hydration and non-chemotherapy infusions in a single day. We recommend CMS work with providers to ensure proper compensation to hospitals for providing IVIG treatments and advise the agency to closely follow and appropriately respond to rapidly changing prices and availability of IVIG. We suggest that CMS permit hospitals to submit claims using the 2005 drug administration codes for one month while hospitals update their chargemasters and train their staff on the new codes. We also recommend that CMS apply a dampening mechanism to stabilize payments for brachytherapy APC 651 and protect beneficiary access to this treatment option. Finally, we suggest that CMS expand the oncology demonstration program to measure the quality of care provided in hospital outpatient departments as well as in physician offices.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact our staff person, Deborah Walter, at (301) 984-5067, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



E. Strode Weaver, FACHE, MBA, MHSA
President, Association of Community Cancer
Centers