

**ADVISORY PANEL**  
**ON**  
**AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS**

**APC Panel Meeting Report**

**August 23–24, 2010**

**Centers for Medicare & Medicaid Services (CMS)**

**7500 Security Boulevard, Auditorium**

**Baltimore, MD 21244-1850**

**PANEL MEMBERS PRESENT AT THIS MEETING**

Ruth L. Bush, M.D., M.P.H.

Dawn L. Francis, M.D., M.H.S.

Kathleen M. Graham, R.N., M.S.H.A., C.P.H.G., A.C.M.

Patrick A. Grusenmeyer, Sc.D., F.A.C.H.

David A. Halsey, M.D.

Judith T. Kelly, R.H.I.T., R.H.I.A., C.C.S.

Michael D. Mills, Ph.D.

Agatha L. Nolen, D.Ph., M.S., F.A.S.H.P.

Randall A. Oyer, M.D.

Beverly Khnie Philip, M.D.

Daniel J. Pothan, M.S., R.H.I.A., C.H.P.S., C.P.H.I.M.S., C.C.S., C.C.S.-P., C.H.C.

Gregory Przybylski, M.D.

Russ Ranallo, M.S.

Michael A. Ross, M.D., F.A.C.E.P.

Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.<sup>®</sup>

**CMS STAFF PRESENT**

E. L. Hambrick, M.D., J.D., CMS Medical Officer, *Chair*

Shirl Ackerman-Ross, M.M.S., *Designated Federal Official* (DFO)

Amy Bassano, Director, Hospital and Ambulatory Policy Group

Christina Smith Ritter, Ph.D., Acting Director, Division of Outpatient Care (DOC)

Carrie Bullock, M.H.S., Acting Deputy Director, DOC

LCDR Marjorie Baldo, LCDR, U.S.P.H.S., M.S., R.H.I.A., C.C.S., C.C.S.-P, Staff, DOC  
Erick Chuang, M.S., Staff, DOC

Charles Cowles, M.A., Staff DOC

Anita Heygster, Staff, DOC

Alpha-Banu Huq, M.P.A., Staff, DOC

Twi Jackson, Staff, DOC

Barry Levi, M.B.A., Staff, DOC

Ann Marshall, M.S.P.H., Staff, DOC

Paula Smith, M.Ed., J.D., Staff, DOC

Gift Tee, M.P.H., Staff DOC

Charlotte Thompson, M.S., Staff, DOC

### **WELCOME AND CALL TO ORDER**

E. L. Hambrick, M.D., J.D., Chair, CMS Medical Officer , welcomed the members, CMS staff, and the public. (The proceedings of the meeting follow. The agenda appears in Appendix A; a listing of only the recommendations appears in Appendix B. A list of presentations appears in Appendix C.)

Amy Bassano welcomed the Panel members, noting that advisory groups are an important part of ensuring that the public and experts are involved in rulemaking. She recognized five members whose terms expire at the end of September: Michael D. Mills, Ph.D.; Beverly Khnie Philip, M.D.; Russ Ranallo, M.S.; Michael A. Ross, M.D., F.A.C.E.P.; and Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.<sup>®</sup>

Dr. Hambrick briefly reviewed the Panel’s Charter and defined the scope of issues that the Panel can address. She summarized the “two-times rule” (i.e., in a given APC, the median cost of the most costly service should be no more than two times the median cost of the least costly service).

**OVERVIEW OF CALENDAR YEAR (CY) 2011 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS)/AMBULATORY SURGICAL CENTER (ASC) PROPOSED RULE**

Christina Smith Ritter, Ph.D., Acting Director, Division of Outpatient Care, CMS, summarized the CY 2011 proposed rule, published in the *Federal Register* August 3, 2010. She noted that the proposed CY 2011 payment rates reflect a 2.15-percent update (the market basket update of 2.4 percent less the 0.25-percentage-point reduction mandated by the Patient Protection and Affordable Care Act [PPACA]). The proposed rates also reflect a budget neutrality adjustment for adopting the proposed fiscal year (FY) 2010 Inpatient Prospective Payment System (IPPS) wage index values. The CY 2011 proposed full conversion factor is \$68.267 (up from 2010). The CY 2011 proposed conversion factor for hospitals that do not meet quality reporting requirements is \$66.930, and the reporting ratio would remain at 0.980. The proposed CY 2011 rule includes the following:

- **Physician Supervision:** For CY 2011, CMS proposes to define a limited set of therapeutic services that would require direct supervision for the initiation of the service, followed by general supervision for the remainder of the service. It would adopt the definition of general supervision recognized under the Medicare Physician Fee Schedule (MPFS). Direct supervision would continue to be required for other outpatient therapeutic services.
- **Partial Hospitalization:** For CY 2011, CMS proposes four separate APCs for partial

hospitalization program (PHP) services based on data from community mental health centers (CMHCs) and hospitals: APC 0172, *Level I Partial Hospitalization (3 services) for CMHCs*, at a payment rate of \$115.90 per day; APC 0173, *Level II Partial Hospitalization (4 or more services) for CMHCs*, at a payment rate of \$120.96 per day; APC 0175, *Level I Partial Hospitalization (3 services) for a Hospital-based PHP*, at a payment rate of \$180.89 per day; and APC 0176, *Level II Partial Hospitalization (4 or more services) for a Hospital-based PHP*, at a payment rate of \$231.00.

- **Drugs, Biologicals, and Radiopharmaceuticals:** For CY 2011, CMS proposes to pay a rate of the average sales price (ASP) plus 6 percent for separately payable drugs and increase the packaging threshold to \$70 per day. The proposal includes a redistribution of \$200 million currently attributed to packaged drugs (\$150 million from Healthcare Common Procedure Coding System [HCPCS]-coded packaged drugs and \$50 million from uncoded drugs). If ASP data are not available, CMS proposes to provide prospective payment based on the mean unit cost from hospital claims data.

Dr. Ritter explained that PPACA required CMS to study whether 11 designated cancer hospitals are more costly than other hospitals and, if so, to propose an appropriate adjustment. CMS determined that the cancer hospitals have a lower payment-to-cost ratio (PCR) than all other hospitals paid under the OPPS and proposes to adjust each cancer hospital's OPPS payment so that its individual PCR is equivalent to the average PCR of all other hospitals paid under the OPPS. By law, the adjustment will be budget-neutral and will be assessed periodically. PPACA also defined preventive services and required changes in payment for them. As a result, beneficiary cost-sharing will be waived for

services recommended by the United States Preventive Services Task Force (USPSTF). The annual wellness visit payment will be excluded from the OPPIs, and payment will be based on the MPFS.

Also under PPACA, beginning in CY 2011, the wage adjustment factor applicable to any hospital outpatient department in a “frontier” (i.e., low-population) State may not be less than 1. The adjustment is not budget-neutral. Dr. Ritter reported that the transitional outpatient payments for rural hospitals and sole community hospitals expire at the end of CY 2010, and CMS proposes to continue the rural sole community hospital adjustment of 7.1 percent in CY 2011. The Section 508 wage index adjustment expires September 30, 2010.

Finally, CMS began the transition of ASC payments to OPPI rates in CY 2008, and CY 2010 represents the first year of full implementation of ASC payment based on OPPI rates. Total CY 2010 ASC payments are projected to be approximately \$3.4 billion. Beginning in CY 2011, PPACA requires the ASC update to be reduced by a productivity adjustment. Currently, both the Consumer Price Index for All Urban Consumers (CPI-U) and the productivity adjustment are estimated to be 1.6 percent for CY 2011, resulting in a proposed 0-percent update to ASC payments for CY 2011.

## **DATA ISSUES**

### ***Overview***

CMS staff member Anita Heygster described the data construction method CMS uses for setting median costs for APCs, noting that the CMS Web site provides a detailed description of the ratesetting process. Ms. Heygster explained that CMS used claims data from CY 2009 to determine CY 2011

proposed rates. CMS also used Healthcare Cost Report Information Systems (HCRIS) data available as of December 31, 2009, to calculate cost-center-specific and overall hospital cost-to-charge ratios (CCRs), which it used to reduce the charges on the claims to estimated costs.

CMS excluded claims from hospitals for which the overall ancillary CCR exceeded the allowed tolerances, which have long been set at less than 0.0001 or greater than 90 or plus or minus three standard deviations from the geometric mean. Using these tolerances, the claims from 97 hospitals were excluded from median ratesetting. At the request of the Panel, CMS examined the effect of changing its tolerances and calculated the number of hospitals that would have been excluded using the IPPS tolerances (which exclude hospitals with an overall ancillary CCR less than 0.01 or greater than 10). Ms. Heygster said that if IPPS tolerances were used, CMS would use the claims of six fewer hospitals than it would under the current OPSS CCR tolerances.

Ms. Heygster outlined how CMS categorizes claims for ratesetting, including the process of identifying “pseudo-single” claims that can be assessed alongside “natural” single claims. Ms. Heygster noted that, in response to public comments, CMS reassessed conditionally packaged codes (with status indicators [SIs] Q1 or Q2), which yielded approximately 20,000 additional pseudo-single claims for ratesetting. About 95 million natural single and pseudo-single claims from CY 2009 were used to calculate median costs for 2011. The medians for composite APCs, “offline” APCs, and PHP APCs were calculated using claims that met specific criteria for those APCs.

Ms. Heygster explained that, to implement the CY 2011 proposal to redistribute \$150 million in claim costs from packaged to separately payable drugs and biologicals, CMS took each packaged drug or

biological with a HCPCS code and ASP pricing information in the CY 2009 claims data and multiplied its cost by 0.75. To redistribute another \$50 million in costs from packaged drugs and biologicals reported without a HCPCS code, CMS multiplied all other drug costs (excluding diagnostic radiopharmaceuticals) by 0.92. CMS also added the redistributed dollars to the total cost of separately payable drugs and biologicals in its CY 2009 claims data, which increased the relationship between the total cost for separately payable drugs and biologicals and ASP dollars for the same drugs and biologicals to ASP plus 6 percent—the proposed CY 2011 payment rate.

After determining median costs, CMS assesses APC assignments for violations of the two-times rule. For CY 2011, CMS proposed moving some HCPCS codes to resolve two-times rule violations and improve clinical and resource homogeneity, and those changes are identified in the Final Rule.

### ***Data Subcommittee's Report***

Dr. Mills, Chair of the Data Subcommittee, said that the Subcommittee heard a CMS staff report on the examination of OPPS CCR tolerances and an overview of payment for drugs and biologicals, including pharmacy overhead. The Subcommittee discussed changes in APC median costs between CY 2010 and CY 2011 and specifically the median cost of APC 0105, *Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices*. It also reviewed the Impact Table in the proposed rule.

- **Recommendation:** The Panel recommends that CMS retain the current CCR trim tolerances of 0.0001, 90, and plus or minus three standard deviations of the geometric mean for determining the hospitals whose claims are to be included in ratesetting.



- **Recommendation:** The Panel recommends that CMS investigate and report at a future Panel meeting on the reason for the decline in the median cost for APC 0307, *Myocardial Positron Emission Tomography (PET) Imaging*, from the CY 2010 OPPS to the proposed CY 2011 OPPS.
- **Recommendation:** The Panel recommends that CMS identify increases or decreases in APC median costs of 10 percent or greater and that CMS develop and present explanatory information on APCs with significant changes.
- **Recommendation:** The Panel commends CMS for providing data analyses requested by the Data Subcommittee.
- **Recommendation:** The Panel recommends that Patrick Grusenmeyer, Sc.D., be named Chair of the Data Subcommittee.
- **Recommendation:** The Panel recommends that the work of the Data Subcommittee continue.

## **VISITS AND OBSERVATION ISSUES**

### ***Overview***

CMS staff member Twi Jackson said that for CY 2011, CMS proposes to continue using the current five-level APC structure for Type A and B emergency department (ED) visits and the current definitions of new and established patients. Per the request of the Panel at its February 2010 meeting, CMS staff provided the Visits and Observation Subcommittee with clinic/ED visit and observation claims data, as well as information on common diagnoses and services furnished in association with critical care services.

CMS staff member Ann Marshall said that for CY 2011, CMS proposes to continue using the same criteria and reporting requirements for the extended assessment and management composite APCs. The proposed payment rates are as follows: APC 8002, *Level I Extended Assessment & Management Composite*, \$393.44; and APC 8003, *Level II Extended Assessment & Management Composite*, \$729.01. As requested by the Panel at its February 2010 meeting, CMS staff presented to the Visits and Observation Subcommittee the results of its study of the feasibility of expanding the extended assessment and management composite APC methodology to include services commonly furnished in conjunction with visits and observation services, such as drug infusion, electrocardiography, and chest x-ray.

### ***Visits and Observation Subcommittee's Report***

Dr. Ross, Chair of the Visits and Observation Subcommittee, said the Subcommittee reviewed the proposed CY 2011 OPPS payment policies and the data provided by CMS staff. It also discussed data specific to observation services, such as the distribution of hours reported on observation claims.

### ***Discussion***

Valerie Rinkle of Asante Health System cautioned against creating extended assessment and management composite APCs that include both diagnostic and therapeutic services.

- **Recommendation:** The Panel commends CMS for providing excellent, timely data for consideration. The Panel recommends that CMS continue to report claims data for clinic and ED visits and observation, critical care, and trauma activation services and, if CMS identifies

changes in patterns of utilization or cost, that it bring those issues before the Visits and Observation Subcommittee for future consideration.

- **Recommendation:** The Panel requests that CMS provide additional information about critical care patients with a primary diagnosis of unspecified chest pain or other chest pain, including the three most common secondary diagnoses and patient disposition.
- **Recommendation:** The Panel recommends that CMS consider including other services commonly provided with extended assessment and management in the extended assessment and management composite APC.
- **Recommendation:** The Panel recommends that Randall Oyer, M.D., be named Chair of the Visits and Observation Subcommittee beginning at the next meeting.
- **Recommendation:** The Panel recommends that the work of the Visits and Observation Subcommittee continue.

## **PACKAGING ISSUES**

### ***Overview***

Ms. Heygster reiterated the CMS rationale for packaging, noting that packaging promotes efficient use of resources and payment stability over time. For CY 2011, CMS proposes to continue using the approach it has developed for creating composite APCs. CMS welcomes suggestions for additional candidates for composite APCs.

***Packaging Subcommittee's Report***

Dr. Philip, Chair of the Packaging Subcommittee, said that the Subcommittee's charge has been expanded to include assessment of APC groupings and SI assignments. The Subcommittee reviewed suggestions from the public related to packaging Current Procedural Terminology (CPT) and HCPCS codes and specifically considered questions about packaging of electromagnetic navigational bronchoscopy (ENB) and an anterior segment aqueous device.

- **Recommendation:** The Panel recommends that the Packaging Subcommittee be renamed the Subcommittee for APC Groups and SI Assignments.
- **Recommendation:** The Panel requests that CMS provide data for all unconditionally packaged items and services that appear by themselves on separate bills in outpatient claims data to the Subcommittee for APC Groups and SI Assignments.
- **Recommendation:** The Panel encourages the public to submit common clinical scenarios involving currently packaged HCPCS codes and recommendations of specific services or procedures for which payment would be most appropriately packaged under the OPPS for review by the Subcommittee for APC Groups and SI Assignments.
- **Recommendation:** The Panel recommends that Judith T. Kelly, R.H.I.T., R.H.I.A., C.C.S., be named Chair of the Subcommittee for APC Groups and SI Assignments.

**Recommendation:** The Panel recommends that the work of the Subcommittee for APC Groups and SI Assignments continue.

***ENB***

Overview

Ms. Heygster said that CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])*, took effect in 2010 and that CMS assigned it an interim payment SI of N. The CPT code descriptor specifies that the code is an add-on. CMS believes the procedure is supportive of and ancillary to a primary diagnostic or therapeutic procedure and therefore packages payment into the costs of the separately paid primary service with which it is billed. For CY 2011, CMS proposes to continue packaging CPT code 31627.

Presentation

Kurt Ellis, Barb Peterson, Curtis Quinn, M.D., Dan Sullivan, and David Wilson, M.D., on behalf of superDimension, Inc., briefly described how ENB is used (Presentation A). They requested that CPT code 31627 be placed in APC 0415, *Level II Endoscopy Lower Airway*, with a status indicator of T. The presenters maintained that ENB is a primary diagnostic procedure that enables physicians to biopsy a distal lesion or lymph node for diagnosis. Ms. Peterson said the code would violate the two-times rule if it remained in APC 0076, *Level I Endoscopy Lower Airway*, and that ENB is paid separately in physician offices and inpatient settings. Mr. Ellis said his hospital loses about \$3,000 per case when ENB is used. Dr. Wilson said the American Thoracic Society and the American College of Chest Physicians support the use of ENB. Mr. Sullivan said ENB is the only treatment option for some Medicare beneficiaries.

Discussion

Gregory Przybylski, M.D., pointed out that, despite the presenters' contention that ENB is a stand-alone procedure, the CPT Panel—in the code description and in explanatory vignettes—views ENB as a navigational procedure supporting bronchoscopy. Dr. Oyer said the procedure fits the definition for packaging. The presenters added that ENB involves a steep learning curve; that the staff, supplies, and equipment required are costly; and that ENB could obviate the need for more costly inpatient procedures in some patients.

### Presentation

Leah Amir of the Institute for Quality Resource Management, speaking on behalf of Veran Medical Technologies and Barnes Jewish Hospital, supported moving CPT code 31627 to another APC, such as APC 0415, *Level II Endoscopy Lower Airway* (Presentation B). She said that ENB is performed as a stand-alone procedure by many physicians, but claims do not capture those data because the code is packaged. Ms. Amir requested that CMS assign CPT code 31627 an SI that allows CMS to collect information on the cost of the procedure.

### Discussion

Dr. Ross acknowledged that the current payment for CPT code 31627 may be inadequate but felt the procedure did not fit in APC 0415. Dr. Oyer said ENB should be viewed as a computer-assisted diagnostic technology, as it is portrayed in the current literature, and Daniel J. Pothan, M.S., R.H.I.A., reiterated that the CPT's advice to coders depicts ENB as a guidance technology. Dr. Hambrick noted that other codes are used to describe the biopsy of the lung and asked what codes would be applicable if ENB were used as a stand-alone procedure. Dr. Quinn said he did not feel ENB is a stand-alone procedure.

- **Recommendation:** The Panel recommends that CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])*, continue to be assigned an SI of “N.”
- **Recommendation:** The Panel recommends that CMS provide claims data at the Panel’s winter 2012 meeting about CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])*, for the Panel’s consideration.

### ***Glaucoma Drainage Devices***

#### Overview

CMS staff member Barry Levi described the background and rationale for assigning CPT code 0191T, *Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach*, to APC 0234, *Level III Anterior Segment Eye Procedures* (note that for CY 2011, APC 0234 is described as *Level IV Anterior Segment Eye Procedures*). APC 0234 contains several other surgical procedures to treat glaucoma, and the median cost of the APC is similar to the median cost calculated for CPT code 0191T. Medicare received only three single claims for CPT code 0191T in CY 2008, the year of claims data used for CY 2010 rates. Mr. Levi explained that the iStent device (manufactured by Glaukos Corporation) is not yet approved by the U.S. Food and Drug Administration (FDA) but is eligible for payment under the OPPTS as an FDA investigation device exemption (IDE) - Category B device. For CY 2011, CMS proposes that CPT code 0191T remain in APC 0234.

Presentations

Eric Donnenfeld, M.D., David Applegate, Kuo Tong, and Michael Beebe, representing Glaukos Corporation, requested that CMS move CPT code 0191T to APC 0673, *Level V Anterior Segment Eye Procedures*, to ensure clinical homogeneity of the APCs and adequate payment for the procedure (Presentation C). They noted that the iStent aqueous drainage device is a permanent implant that requires a more complex, invasive surgical procedure than the other devices in APC 0234. Dr. Donnenfeld said internal placement of the iStent is more difficult and requires more dexterity than placing an external device. Mr. Tong pointed out that current CMS claims data indicate that CPT code 0191T has a higher median cost than when it was initially assigned to APC 0234.

The Panel reviewed comments submitted jointly by the American Academy of Ophthalmology, the American Society of Cataract and Refractive Surgery, and the Outpatient Ophthalmic Surgery Society, which also requested that CMS move CPT code 0191T to APC 0673, *Level V Anterior Segment Eye Procedures* (Presentation D).

Discussion

Panel members were concerned about the paucity of claims data used to determine the median costs for CPT code 0191T. However, they agreed that it is clinically similar to the other codes in APC 0673.

- **Recommendation:** The Panel recommends that CMS assign CPT code 0191T, *Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach*,



to APC 0673, *Level V Anterior Segment Eye Procedures*, on the basis of its clinical similarity with both CPT code 0192T, *Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach*, and HCPCS code 66180, *Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)*.

## **GENERAL APC ISSUES**

### ***Use of Claims Data and APC Configurations***

#### **Presentation**

DeChane L. Dorsey, Esq., of the Advanced Medical Technology Association (AdvaMed) asked that CMS evaluate whether the methodology used to establish composite APCs results in payments that accurately reflect the resources required (Presentation E). She also asked that CMS make available to the public the data it uses to establish payment for packaged codes, including utilization rates and median costs.

Ms. Dorsey asked that hospitals and Medicare administrative contractors (MACs) be fully educated about the new cost center reporting requirements and that CMS implement them in a timely fashion. She asked that CMS focus education on supply codes. Ms. Dorsey urged CMS to give stronger consideration to criteria other than the two-times rule when assigning new technologies to APCs, such as changes in medical practice and technology, as outlined in statute.

Finally, Ms. Dorsey asked CMS to consider reassigning the new CPT codes 63661, *Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed*; 63662,

*Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed; 63663, Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed; and 63664, Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed; so that lead revisions are included in APC 0687, Revision/Removal of Neurostimulator Electrodes; percutaneous lead replacements in APC 0040, Percutaneous Implantation of Neurostimulator Electrodes, and surgical or paddle lead replacements in APC 0061, Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes. Otherwise, the cost of the devices associated with replacement procedures may not be recognized.*

### Discussion

Dr. Oyer asked what additional education about coding is needed. Ms. Dorsey said more clarification is needed at the hospital level about the appropriate use of supply codes to identify supplies and devices not captured in existing codes. Dr. Przybylski noted that revising a neurostimulator electrode may simply entail moving the device, while replacement requires a new device. If the proportion of replacements is much higher than the proportion of revisions, he said, AdvaMed's request to reassign the new neurostimulator codes would have more credence. Jeff Farkas of Medtronic offered to provide those data.

### Presentation

Beth Halpern of the Medical Device Manufacturers Association (MDMA) said that since CMS began packaging more services, CMS has noted increases in billing and reporting in several categories but a

decrease in the number of hospitals reporting certain services (Presentation F). Either hospitals are not providing these services, thus limiting beneficiary access, or they are not reporting them properly, which means the data CMS uses to establish rates are incomplete, said Ms. Halpern. MDMA requests that CMS pay separately for ancillary and supportive services or that, at a minimum, CMS require complete coding on all claims. Ms. Halpern asked that CMS report annually to the Panel on the impact of packaging on beneficiaries and that CMS continue to consult with stakeholders before it creates new service packages.

Ms. Halpern said that MDMA remains concerned about potentially severe reductions in payment for device-dependent APCs. She asked that CMS study the claims for any APC for which payment would be reduced by more than 10 percent and correct any issues that could cause artificial reduction in payments.

Finally, Ms. Halpern asked that HCPCS code 0193T, *Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence*, be moved to an APC that better reflects the clinical and resource requirements of the procedure (e.g., a device-dependent APC), such as APC 0202, *Level VII Female Reproductive Procedures*, or APC 0168, *Level II Urethral Procedures*.

### Discussion

Mr. Ranallo said that the Data Subcommittee reviews APCs for which payment increases or decreases 10 percent or more and plans to continue to doing so.

## ***Total Arthroplasty Procedures***

### Overview

LCDR Marjorie Baldo described the APC assignment of HCPCS codes 24363, *Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (e.g., total elbow)*; 25446, *Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)*; and 27446, *Arthroplasty, knee, condyle and plateau; medial or lateral compartment* to APC 0425, *Level II Arthroplasty or Implantation with Prosthesis*, for CY 2010. Before CY 2010, HCPCS code 27446 was the only procedure assigned to APC 0681, *Knee Arthroplasty*. Comments to the CY 2010 OPPS/ASC proposed rule on the reassignment of CPT code 27446 from APC 0681 to APC 0245 were mixed. While many supported the change, some commenters disagreed with the APC reassignment and stated that knee arthroplasty was not similar to the other procedures in APC 0425. CMS believes it is based on the procedure's clinical and resource characteristics, and proposes to maintain APC 0425 as currently constructed for CY 2011, with a median cost of \$8,341.

### Presentation

Paul Shieves of the Alliance for Orthopedic Solutions asked that CMS assign HCPCS codes 24363, 25446, and 27446 to a new APC to better reflect their clinical and resource requirements (Presentation G). While CMS was concerned about the low volume of claims for HCPCS code 27446 when it was assigned to APC 0681, knee arthroplasty is now the highest single frequency procedure in APC 0425, said Mr. Shieves. He said that APC 0425 violates the two-times rule and that the median payment for APC 0425 underpays for the median cost of HCPCS codes 24363, 25446, and 27446.

Discussion

Dr. Oyer asked about the wide range of costs on claims data, and Ms. Heygster and Dr. Ritter described some of the factors that can lead to such large ranges. Dr. Philip suggested that if the Panel decides to reassign the procedures in question, it should also consider HCPCS code 23470, *Arthroplasty, glenohumeral joint; hemiarthroplasty*, which is performed frequently in outpatient settings. Dawn L. Francis, M.D., M.H.S., suggested moving HCPCS code 61967, *Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy*, which had a median cost of \$3,510 in CY 2010, out of APC 0425. Dr. Philip agreed that the temporal bone procedures are not similar to joint arthroplasty. David A. Halsey, M.D., supported creating a new APC for HCPCS codes 24363, 25446, 27446, and 23470, but Panel members felt the impact of such a change would not be significant.

***Magnetoencephalography (MEG)***Overview

CMS staff member Charlotte Thompson said that APC 0067, *Level III Stereotactic Radiosurgery, MRgFUS [magnetic resonance guided focused ultrasound], and MEG*, includes HCPCS code 95965, *Magnetoencephalography (meg), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)*; HCPCS code G0173, *Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session*; and HCPCS code G0339, *Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment*. Ms. Thompson noted that the Panel recommended assigning HCPCS code 95965 to APC 0067 in 2007, and CMS proposes to maintain the APC as

currently constructed for CY 2011. She said the current payment for APC 0067 is 34 percent above the median cost for HCPCS code 95965.

### Presentation

Michael Funke, M.D., Ph.D., of the American Clinical MEG Society said that the cost data used to determine payment for MEG have been incorrect since the procedure was moved out of a new technology APC (Presentation H). He said it is impossible to distinguish the costs of MEG from those of electroencephalography (EEG) because the two procedures share the same cost line on the Medicare Cost Report and the same revenue code on the UB-04 form. The American Clinical MEG Society separated the costs of MEG and EEG and found that MEG is significantly more expensive than EEG.

Dr. Funke said the American Academy of Neurology submitted a letter to the Panel in support of the request to recognize the costs of MEG, but the Panel did not receive a copy of that letter. He asked that CMS either calculate the costs of MEG by hand (i.e., looking at individual claims) or establish a fixed payment rate that better reflects the real costs of the procedure.

### Discussion

In response to Dr. Oyer, Ms. Heygster said that the Panel recommended assigning HCPCS code 95965 to APC 0067, and CMS staff clinicians determined that the placement was appropriate.

## ***Nuclear Medicine APCs***

### Presentation

The Panel reviewed comments submitted by the Council on Radionuclides and Radiopharmaceuticals (CORAR) outlining concerns about the decrease in payment for the myocardial PET imaging APC and the composition of the tumor/infection imaging APCs (Presentation I).

### Discussion

Dr. Ritter noted that the Data Subcommittee reviewed the myocardial PET imaging APC.

## **DRUGS, BIOLOGICALS, AND PHARMACY OVERHEAD**

### *Overview*

CMS staff member Alpha-Banu Huq described the methodology for determining payment and packaging thresholds for drugs and biologicals and summarized the history of the ASP-plus payment policy. For CY 2011, CMS proposes to set the packaging threshold at \$70.

For CY 2010, CMS applied a variation of the ASP-plus methodology that redistributed a portion of the total cost for packaged drugs and biologicals to separately payable drugs and biologicals as acquisition and pharmacy overhead and handling costs. Using the standard ASP-plus methodology, CMS determined that payment rates for CY 2011 for separately payable drugs would be ASP plus 0 percent and the payment rate for packaged drugs would be ASP plus 283 percent. Because both rates appeared unlikely to represent real costs, CMS proposes to redistribute \$200 million of pharmacy overhead costs (\$150 million from HCPCS-coded packaged drug costs for drugs with ASP data and \$50 million from packaged drug costs without ASP data for which CMS lacked specific acquisition costs).

Ms. Huq said CMS believes that \$50 million in cost from uncoded drug costs is a conservative and appropriate estimate of the pharmacy overhead cost that could be associated with payment for separately payable drugs. At the February 2010 Panel meeting, the Panel suggested that CMS redistribute a larger portion of the pharmacy overhead costs from packaged drugs, specifically uncoded packaged drug costs, to separately payable drugs, and presenters argued that more overhead costs could be attributed to uncoded packaged drugs. CMS believes that hospitals should provide more drug-specific information so that CMS can better determine the proportion of overhead costs attributable to uncoded packaged drugs.

At the request of the Panel, CMS evaluated the impact of the redistribution by comparing the CY 2010 relative weights with those proposed for CY 2011 under two methods: 1) no redistribution and a payment rate of ASP plus 0 percent and 2) proposed redistribution of \$200 million in packaged drug costs and payment for separately payable drugs at a rate of ASP plus 6 percent. CMS found the following:

- Small rural hospitals and small urban hospitals lose up to 0.5 percent of their total payment when drug costs are redistributed from packaged drugs to separately payable drugs.
- Large rural, large urban, and teaching hospitals gain up to 0.3 percent of their total payment under a redistribution policy.
- New England hospitals benefit from a redistribution policy, as do rural hospitals in the Mountain and Pacific regions. Most other regions of the country and Puerto Rico lose up to a few tenths of a percent.



***Presentation***

Laurel Todd of the Biotechnology Industry Organization (BIO) requested that CMS:

1. Pay for separately payable drugs and biologicals at a rate no less than ASP plus 6 percent;
2. Implement a more stable methodology for payment of separately payable drugs and biologicals;
3. Pay separately for all drugs and biologicals with HCPCS codes, as it does in the physician office setting, or not increase the packaging threshold; and
4. Require hospitals to bill using HCPCS codes and Revenue Code 636 if CMS continues its packaging of HCPCS-coded drugs (Presentation L).

Ms. Todd said that the methodology CMS uses to determine the ASP-plus payment rates is not consistent with Federal statute and results in a reduction of at least one percentage point when CMS updates the ASP data, claims data, and cost report data for the Final Rule. To improve stability of payment, Ms. Todd asked that CMS use ASP file data that are better aligned with the claims data it uses (rather than applying current ASP data to claims that are two years old). She asked that CMS reallocate a larger portion of pharmacy overhead costs from packaged drugs to separately payable drugs and that it remove data from hospitals that participate in the 340B program from its ratesetting calculations.

Ms. Todd noted that, in response to comments that packaged and unpackaged drugs with HCPCS codes are likely subject to the same markup by pharmacies, CMS wrote in the proposed rule that its

own analysis found that uncoded packaged drugs tend to be reported with surgical services, while coded packaged drugs tend to be reported with medical services.

Ernie Anderson Jr. said the Association of Community Cancer Centers (ACCC) supports the requests made by BIO (Presentation J). He said that even with the ASP-plus-6-percent payment, his hospital's pharmacy is upside-down (i.e., spending more than it is reimbursed) on 44 percent of drugs and biologicals. He emphasized the importance of setting payment at no less than ASP plus 6 percent. Regarding the hospital markup of coded and uncoded packaged drugs, Mr. Anderson said pharmacies tend to apply one of two markup methods (acquisition cost times a set multiplier, or a tiered method based on the cost of the drug), but pharmacies do not apply different methodologies on the basis of the drug's use for medical or surgical procedures.

Jugna Shah said the Alliance of Dedicated Cancer Centers (ADCC) also supports the requests made by BIO (Presentation K). She asked that CMS publish the details of the methodology it used to determine that uncoded packaged drugs tend to be reported with surgical services, while coded packaged drugs tend to be reported with medical services. Ms. Shah questioned the rationale for reallocating only 8 percent of the overhead costs from packaged drugs without HCPCS codes to separately payable drugs and requested that CMS use the same redistribution percentage (25 percent) for both coded and uncoded packaged drugs.

### *Discussion*

Mr. Ranallo pointed out that CCRs are for periods that precede the claims data used by CMS. Dr. Ritter noted that CMS has considered the time frames in which claims data and ASP data are gathered;

the agency concluded that its standard methodology is sufficient. Dr. Ritter said CMS welcomes public comment on how to assess cost trending within the context of budget neutrality. Agatha L. Nolen, M.S., D.Ph., said that using old ASP data would result in Medicare paying for drugs at proprietary drug prices long after a generic equivalent is available. Dr. Nolen said CMS should use the most current ASP data, which are updated quarterly.

Ms. Rinkle said CMS does not yet have a good understanding of the impact of its drug payment methodology and therefore should freeze the packaging threshold and pay at a minimum of ASP plus 6 percent. She said that health care reform will affect participation in the 340B program, ultimately driving costs down. Ms. Rinkle added that hospitals already have mechanisms for documenting drug HCPCS codes on claims to get rebates, so it would not be an additional burden for them to provide HCPCS codes for drugs; hospitals that do not use HCPCS codes could use J codes.

Dr. Nolen suggested that CMS continue to include the 340B hospitals in its calculations. Eliminating them would result in fewer claims available for ratesetting.

Mr. Ranallo said that pharmacies could provide more consistent data and reduce variations in payment if they applied a uniform markup methodology and educated their hospitals about that methodology, and Mr. Anderson agreed. Dr. Nolen said her hospital is trying to use Revenue Code 636 consistently but it's a burden for some institutions, and there's no financial incentive to justify the extra work. She suggested that all HCPCS codes be reported with Revenue Code 636. Kathi Austin of Sisters of Mercy Health System described the complexities of drug billing her system faces and urged the Panel to recommend using Revenue Code 636 for all drugs with an identifiable J code.

Kathryn J. Noorbakhsh of the University of Pittsburgh agreed. Mr. Ranallo said the change would be easier for larger hospitals than smaller ones, and without a mandate, smaller hospitals will choose not to make the change. Ms. Shah suggested redistributing more of the uncoded packaged costs to separately payable drugs and letting provider practices catch up. John Settlemyer of the Provider Roundtable said that setting the payment rate at no less than ASP plus 6 percent would help achieve stability.

- **Recommendation:** The Panel recommends that CMS require hospitals to report all drugs with a HCPCS code using Revenue Code 0636, regardless of payment status.
- **Recommendation:** The Panel recommends that CMS pay for the acquisition and pharmacy overhead costs of all separately payable drugs at no less than ASP plus 6 percent for CY 2011.

Dr. Ross asked CMS to clarify its findings about coded and uncoded packaged drugs. Beth Roberts of the ACCC said that it may be true that more uncoded packaged drugs are associated with surgical procedures, but the proportions don't matter, as lower-cost drugs are subject to a higher markup. She reiterated the request that CMS redistribute 25 percent of both coded and uncoded packaged drugs to separately payable drugs.

Ms. Shah asked that CMS include in the Medicare cost files that it releases to the public all CPT and HCPCS codes for which Medicare makes separate payment regardless of whether the claims are used for ratesetting. Dr. Ritter said the data are currently available for purchase but because they are not part of the median cost data used to set APC rates, they are not included in the files that CMS posts on

the web. However, Dr. Ritter said CMS would provide the data requested with the HCPCS median file CMS makes available with each proposed and final rule.

### **CLOSING**

Panel members reviewed the collected recommendations and refined them following further discussion.

Dr. Hambrick thanked the Panel members for their service and the CMS support staff for their hard work. She gave special thanks to Shirl Ackerman-Ross (DFO for the Panel) and to contractors John O’Leary (audio specialist) and Dana Trevas (reporter) for their assistance.

The meeting adjourned at approximately noon on Tuesday, August 24, 2010.

**Appendix A**

The Advisory Panel on Ambulatory Payment Classification (APC) Group agenda is accessible on the Centers for Medicare and Medicaid Services (CMS) web site at [http://www.cms.gov/faca/05\\_advisorypanelonambulatorypaymentclassificationgroups.asp](http://www.cms.gov/faca/05_advisorypanelonambulatorypaymentclassificationgroups.asp) in the “Downloads” section.

**Appendix B****CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)****Advisory Panel on Ambulatory Payment Classification (APC) Groups  
August 23–24, 2010*****Recommendations*****Visits and Observation Issues**

1. The Panel commends CMS for providing excellent, timely data for consideration. The Panel recommends that CMS continue to report claims data for clinic and emergency department visits and observation, critical care, and trauma activation services and, if CMS identifies changes in patterns of utilization or cost, that it bring those issues before the Visits and Observation Subcommittee for future consideration.
2. The Panel requests that CMS provide additional information about critical care patients with a primary diagnosis of unspecified chest pain or other chest pain, including the three most common secondary diagnoses and patient disposition.
3. The Panel recommends that CMS consider including other services commonly provided with extended assessment and management in the extended assessment and management composite APC.
4. The Panel recommends that Randall Oyer, M.D., be named chair of the Visits and Observation Subcommittee beginning at the next meeting.
5. The Panel recommends that the work of the Visits and Observation Subcommittee continue.

**Packaging Issues**

6. The Panel recommends that Current Procedural Terminology (CPT) code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])*, continue to be assigned a status indicator of “N.”
7. The Panel recommends that CMS provide claims data at the Panel’s winter 2012 meeting about CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])*, for the Panel’s consideration.
8. The Panel recommends that CMS assign CPT 0191T, *Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach*, to APC 0673, *Level V Anterior Segment Eye Procedures*, on the basis of its clinical similarity with both CPT 0192T, *Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external*

*approach*, and HCPCS code 66180, *Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)*.

9. The Panel recommends that the Packaging Subcommittee be renamed the Subcommittee for APC Groups and Status Indicator (SI) Assignments.
10. The Panel requests that CMS provide data for all unconditionally packaged items and services that appear by themselves on separate bills in outpatient claims data to the Subcommittee for APC Groups and SI Assignments.
11. The Panel encourages the public to submit common clinical scenarios involving currently packaged HCPCS codes and recommendations of specific services or procedures for which payment would be most appropriately packaged under the Outpatient Prospective Payment System (OPPS) for review by the Subcommittee for APC Groups and SI Assignments.
12. The Panel recommends that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., be named chair of the Subcommittee for APC Groups and SI Assignments.
13. The Panel recommends that the work of the Subcommittee for APC Groups and SI Assignments continue.

#### **Data Issues**

14. The Panel recommends that CMS retain the current cost-to-charge ratio (CCR) trim tolerances of 0.0001, 90, and +/- three standard deviations of the geometric mean for determining the hospitals whose claims are to be included in ratesetting.
15. The Panel recommends that CMS investigate and report at a future Panel meeting on the reason for the decline in median cost for APC 0307, *Myocardial Positron Emission Tomography (PET) Imaging*, from the calendar year (CY) 2010 OPPS to the proposed CY 2011 OPPS.
16. The Panel recommends that CMS identify increases or decreases in APC median costs of 10 percent or greater and that CMS develop and present explanatory information on APCs with significant changes.
17. The Panel commends CMS for providing data analyses requested by the Data Subcommittee.
18. The Panel recommends that Patrick Grusenmeyer, Sc.D., be named chair of the Data Subcommittee.
19. The Panel recommends that the work of the Data Subcommittee continue.

#### **Drugs, Biologicals, Radiopharmaceuticals, and Pharmacy Overhead**

20. The Panel recommends that CMS require hospitals to report all drugs with a HCPCS code using Revenue Code 0636, regardless of payment status.



21. The Panel recommends that CMS pay for the acquisition and pharmacy overhead costs of all separately payable drugs at no less than average sales price plus 6 percent for CY 2011.

### **Appendix C**

#### **PRESENTATIONS**

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting August 23–24, 2010:

- Presentation A: superDimension, Inc.
- Presentation B: Institute for Quality Resource Management/Veran Medical Technologies/Barnes Jewish Hospital
- Presentation C: Glaukos Corporation
- Presentation D: American Academy of Ophthalmology, American Society of Cataract and Refractive Surgery, and Outpatient Ophthalmic Surgery Society
- Presentation E: Advance Medical Technology Association
- Presentation F: Medical Device Manufacturers Association
- Presentation G: Alliance for Orthopedic Solutions
- Presentation H: American Clinical MEG Society
- Presentation I: Council on Radionuclides and Radiopharmaceuticals
- Presentation J: Association of Community Cancer Centers
- Presentation K: Alliance of Dedicated Cancer Centers
- Presentation L: Biotechnology Industry Organization