

ADVISORY PANEL
ON
AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

APC Panel Meeting Report

February 17–18, 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.

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.

Michael D. Mills, Ph.D.

Agatha L. Nolen, M.S., D.Ph.

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.[®]

CMS STAFF PRESENT

E. L. Hambrick, M.D., J.D.	Medical Officer, Chair APC Panel
Shirl Ackerman-Ross, M.M.S.	Designated Federal Official (DFO) Federal Advisory Committee Act (FACA)
Jonathan Blum	Director Center for Medicare Management
Amy Bassano	Director Hospital & Ambulatory Policy Group
Marc Hartstein	Deputy Director Hospital & Ambulatory Policy Group
Christina Smith Ritter, Ph.D.	Acting Director Division of Outpatient Care (DOC)
Carrie Bullock, M.H.S.	Acting Deputy Director, DOC
Marjorie Baldo, LCDR, U.S.P.H.S., M.S., R.H.I.A.	Staff, DOC
Dana Burley, M.S.P.H., B.S.N.	Staff, DOC
Erick Chuang, M.S.	Staff, DOC
Rebecca Kane Cole, M.S.	Staff, DOC
Alberta Dwivedi	Staff, DOC
Anita Heygster	Staff, DOC
Heather Hostetler, J.D.	Staff, DOC
Alpha-Banu Huq, M.P.A.	Staff, DOC
Marina Kushnirova, M.S.	Staff, DOC
Barry Levi, M.B.A.	Staff, DOC
Paula Smith, M.Ed., J.D., C.P.H.I.T.	Staff, DOC
Gift Tee, M.P.H.	Staff, DOC

WELCOME AND CALL TO ORDER

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

Dr. Hambrick introduced Jonathan Blum, Director of the Center for Medicare Management, who welcomed the Panel members, particularly the five new members: Ruth L. Bush, M.D., M.P.H.; Dawn L. Francis, M.D., M.H.S.; David A. Halsey, 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.; and Gregory Przybylski, M.D.

Mr. Blum thanked the Panel and said the Panel's work underscores the commitment of CMS to continue to gather meaningful input and support transparency in decision-making. He noted that payment policy reform is a top priority for health care reform. Mr. Blum stated his appreciation and added that the Panel's work not only improves the Outpatient Prospective Payment System (OPPS) but also supports the broader goals of the next generation of payments for Medicare, which in turn affects and promotes good payment policy for all U.S. health care systems.

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 can be no more than two times the median cost of the least costly service).

OVERVIEW OF CHANGES TO THE OPPTS AND CALENDAR YEAR (CY) 2010 PAYMENT RATES

Christina Smith Ritter, Ph.D., Acting Director, DOC, summarized the CY 2010 OPPTS Final Rule, published in the *Federal Register* November 20, 2009. She noted that the market basket increase for CY 2010 is 2.1 percent, which increases the overall OPPTS payment to providers by approximately 1.9 percent. Significant changes of the CY 2010 OPPTS Final Rule include the following:

- **Drugs and Biologicals (Except Radiopharmaceuticals):** For CY 2010, CMS will pay for drugs and biologicals at a rate of the average sales price (ASP) plus 4 percent and increase the packaging threshold for drugs and biologicals to \$65 per day on the basis of the Producer Price Index. The rate of ASP plus 4 percent 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). (Dr. Ritter noted that the mean cost of separately payable drugs from hospital claims and cost reports was calculated at ASP minus 3 percent with no redistribution from packaged drugs.)
- **Drug Administration:** For CY 2010, CMS will maintain the five-level APC structure for drug administration established in CY 2009, which aligns payments with costs shown in hospital claims data and eliminates APCs used in CY 2008 that appeared to be unnecessary.
- **Radiopharmaceuticals:** For CY 2010, CMS will pay for therapeutic radiopharmaceuticals at a rate of ASP plus 4 percent. If ASP data are unavailable, payment will be based on mean unit cost. Diagnostic radiopharmaceuticals will remain packaged for CY 2010.
- **Brachytherapy Sources:** For CY 2010, CMS will pay for brachytherapy sources prospectively on the basis of median cost per source. Outlier payments will be available under the prospective payment methodology when outlier criteria are met.
- **Physician Supervision:** For CY 2010, CMS refined its supervision policies to allow nonphysician practitioners to supervise therapeutic services as appropriate, and to develop

further the definition of “direct” supervision. Dr. Ritter also noted that all hospital outpatient diagnostic services, whether provided in the hospital, provider-based department, or nonhospital location, follow the Medicare Physician Fee Schedule supervision requirements for individual tests. **Kidney Disease Education:** The CY 2010 OPPS Final Rule clarified provider qualifications, coverage criteria, and billing codes for kidney disease education, as mandated by the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

- **Pulmonary and Cardiac Rehabilitation:** The CY 2010 OPPS Final Rule describes the coverage of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. For CY 2010, existing American Medical Association (AMA) Current Procedural Terminology (CPT) codes for cardiac rehabilitation services are assigned to APC 0095, *Cardiac Rehabilitation*, at a payment rate of approximately \$38. In addition, CMS created HCPCS G codes for intensive cardiac rehabilitation to collect specific cost data. A new HCPCS G code for pulmonary rehabilitation is assigned to the newly created APC 0102, *Level II Pulmonary Treatment*, at a payment rate of \$50.
- **Type B Emergency Department (ED) Visits:** For CY 2010, CMS will base payment for Type B ED visits on costs derived from Type B ED claims data for all five levels of APCs.
- **Partial Hospitalization:** CMS will maintain two separate APCs for CY 2010: APC 0172, *Level I Partial Hospitalization (3 services)*, at a payment rate of approximately \$150 per day, and APC 0173, *Level II Partial Hospitalization (4 or more services)*, at a payment rate of approximately \$211 per day.
- **Quality Reporting:** For CY 2010, CMS continues to require hospitals to report the 11 existing quality measures to receive full payment in CY 2011. A validation effort beginning in CY 2011 will provide hospitals an opportunity to become familiar with the process but will not affect payment.. CMS is establishing mechanisms for making quality data publicly available.
- **Ambulatory Surgical Centers (ASCs):** Beginning in CY 2008, revised ASC payment system rates are based on OPPS payment weights and payment policies. The rates reflect the same relativity of resource use as under the OPPS while recognizing lower ASC costs. CY 2010 is the third year of a four-year transition to the revised payment system. A budget-neutral, ASC-specific conversion factor is used to determine ASC payments, but CMS has not been authorized to update that conversion factor before CY 2010. For CY 2010, the update factor is 1.2 percent. Total CY 2010 ASC payments are projected to be approximately \$3.4 billion.

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. For the CY 2010 OPPS, CMS made minor revisions to the revenue-code-to-cost-center crosswalk that CMS uses to match the charges on a claim to the cost-to-charge ratio for the applicable cost center, largely to update the CMS crosswalk to incorporate the National Uniform Billing Committee’s revenue codes.

To address payment for drugs and biologicals, CMS 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. Ms. Heygster explained that, to implement the CY 2010 proposal to redistribute \$150 million in claim costs from packaged to separately payable drugs and biologicals, CMS multiplied the cost of each packaged drug or biological with a HCPCS code and ASP pricing information in the CY 2008 claims data by 0.76. CMS also added the redistributed dollars to the total cost of separately payable drugs and biologicals in its CY 2008 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 4 percent—the final CY 2010 payment policy.

Ms. Heygster outlined how CMS categorizes claims for ratesetting, including the process of identifying “pseudo-single” claims with only one unit of one separately paid service that can be created from “natural” single claims, which is necessary to calculate a median cost for one unit of the separately paid service. About 99 million natural single and pseudo-single claims from CY 2008 were used to calculate the median costs on which the OPSS payment rates for 2010 are based. In addition, CMS evaluates claims data in slightly different ways to improve the accuracy of APC median costs (known as “offline” median calculations) to complement its standard methodology. Offline median calculations have become a standard means of determining median costs for device-dependent APCs, among others.

After determining a median cost for each APC and HCPCS code, CMS assesses APC assignments for violations of the two-times rule. Overall, 15 APCs continue to contain violations of the two-times rule in the CY 2010 OPSS Final Rule. Ms. Heygster reminded the Panel low-volume services are exempt from the two-times rule.

Data Subcommittee’s Report

Michael D. Mills, Ph.D., Chair of the Data Subcommittee, said that the Subcommittee heard presentations from CMS staff on the data process, APCs with notable changes in median costs between CY 2009 and CY 2010, the ratesetting methodology for drugs for CY 2010, changes to the frequency and payment of services that were packaged in CY 2008, and the status of composite APCs.

- **Recommendation:** The Panel recommends that CMS present to the Data Subcommittee an analysis of the effect of using a different lower-level threshold in the overall cost-to-charge-ratio error trim as part of the standard methodology.
- **Recommendation:** The Panel recommends that the work of the Data Subcommittee continue.

VISITS AND OBSERVATION ISSUES

Overview

CMS staff member Heather Hostetler explained the evolution of the five-level APC structure for Type A and B ED visits. Per the request of the Panel at its August 2009 meeting, CMS staff provided the following information to the Visits and Observation Subcommittee for review:

- Most common diagnoses and services associated with Type A and B ED visits;
- CY 2009 claims data for clinic and ED visits;
- Frequency and median costs for the extended assessment and management composite APCs; and

- Length-of-stay frequency distribution data for observation services, with additional detail for observation services over 24 hours by specific hospital characteristics.

For CY 2010, CMS will continue using the payment criteria and reporting requirements for the extended assessment and management composite APCs created in CY 2008. Payment was calculated using single and pseudo-single claims data from CY 2008.

Visits and Observation Subcommittee's Report

Michael Ross, M.D., Chair of the Visits and Observation Subcommittee, said the Subcommittee reviewed the CY 2010 OPPS payment policies for ED visits and extended assessment and management composite APCs as well as the data described by Ms. Hostetler. The Subcommittee discussed the feasibility of expanding extended assessment and management composite APCs to include common services and of using the same methodology for clinic and ED visits. It also discussed reporting critical care services.

- **Recommendation:** The Panel recommends that CMS study 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, electrocardiogram, and chest x-ray.
- **Recommendation:** The Panel recommends that CMS continue to report on clinic and emergency department visits and observation services in the claims data 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 information about the common diagnoses and services furnished with critical care services.
- **Recommendation:** The Panel recommends that the work of the Visits and Observation Subcommittee continue.

PACKAGING ISSUES

Overview

Carrie Bullock, Acting Deputy Director, DOC, described the implementation of composite APCs for multiple imaging procedures performed on the same date that went into effect in CY 2009. For CY 2010, payment rates for the five multiple imaging composite APCs are based on the CY 2008 claims that would have qualified for composite payment under the CY 2009 composite APC methodology.

Ms. Bullock provided the Panel with claims data from the first nine months of CY 2009 that reflect frequency and payments for services subject to the multiple imaging composite APC methodology. She summarized some of the changes in payment or volume from CY 2008 to CY 2009, noting that the ability of CMS to draw conclusions about the reasons for these changes is limited. Overall, CMS believes the composite methodology has not resulted in drastic changes in the practice patterns of providers. The overall volume of imaging services increased at a rate similar to the growth of OPPS services overall, and the data show no significant reduction in payment for imaging services overall. The data do show a very slight reduction across the board in the proportion of sessions involving more than one imaging service of the same modality. Ms. Bullock concluded that the data support CMS' belief that the composite APCs encourage efficiency among certain providers.

CMS staff member Gift Tee summarized the CMS rationale for packaging, noting that it provides an incentive for providers to deliver services in the most efficient, cost-effective manner possible and promotes stability of payments over time. He provided analyses requested by the Panel on packaging of radiation oncology services and diagnostic radiopharmaceuticals comparing claims data from the first nine months of CY 2007, CY 2008, and CY 2009. He also described data on other packaged services from the same periods that allow CMS to assess the overall impact of packaging on beneficiaries' access to services. Mr. Tee cautioned that the ability of CMS to draw specific conclusions about the reasons for changes in payment or frequency over time is limited.

The frequency of claims for contrast agents, guidance services, and imaging supervision and interpretation increased modestly (8–10 percent) from CY 2007 to CY 2009, while the frequency of claims for diagnostic radiopharmaceuticals increased only slightly (1 percent). Claims for specific image processing and intraoperative services claims decreased from CY 2007 to CY 2009, primarily because of coding changes. For all of the packaged services described, the percentage of hospitals reporting these services between CY 2007 and CY 2009 remained relatively steady, with the exception of image processing, for which 5 percent fewer hospitals reported image processing services from CY 2007 to CY 2009. Overall, Mr. Tee said, the data suggest that beneficiary access to these supporting and ancillary services has remained steady and that hospitals do not appear to have significantly changed their reporting patterns as a result of expanded packaging. Overall, according to Mr. Tee, there is not evidence from the analyses presented that hospitals have stopped offering these supportive and ancillary services with the primary services that they support. To explore further the impact of increased packaging on net payments for patient care, CMS evaluated data on cardiac catheterization and other percutaneous vascular procedures that would be accompanied by intravascular ultrasound, intracardiac echocardiography, or fractional flow reserve. From CY 2007 to CY 2009, instances in which these services were billed increased 26 percent, and payment increased 58 percent. Some of the increased payment may result from packaging, Mr. Tee said, while some may result from changes in practice patterns and the usual recalibration of payment rates.

Evaluating radiation oncology services that would be accompanied by guidance procedures, CMS data demonstrated a 6 percent decrease from CY 2007 to CY 2009 and a 2 percent increase in payment, likely attributable to higher APC payment rates. Mr. Tee also presented a table stratifying frequency and payment data for radiation oncology services that would be accompanied by radiation oncology guidance in the following categories: intensity-modulated radiation therapy, stereotactic radiosurgery, brachytherapy, and conventional radiation therapy. Finally, data on nuclear medicine procedures that would be accompanied by diagnostic radiopharmaceuticals demonstrated that frequency and payment for these procedures has remained fairly steady from CY 2007 to CY 2009.

Mr. Tee concluded that, although CMS cannot draw conclusions about the specific impact of our packaging proposal on the frequency, hospital availability, or payment for the associated primary services, the analyses presented suggest that, in aggregate, the CY 2008 packaging methodology has not had a negative impact on beneficiary access to hospital services.

Discussion

Deborah Williams of Baxter Health Care described an example of erroneous data used to calculate whether drug costs meet the packaging threshold. According to Ms. Williams, because hospital chargemasters do not sufficiently distinguish older, animal-derived hyaluronidase (J3470, *Injection*,

hyaluronidase, up to 150 units) from the newer, recombinant version (J3473, *Injection, hyaluronidase, recombinant, 1 USP unit*) and because the two products are coded using different units of measure, the older product is overpaid while the newer product is significantly underpaid. Ms. Williams believes the CMS claims data are wrong as a result of these coding problems, which AMA has declined to address.

Packaging Subcommittee's Report

Beverly Khnie Philip, M.D., Chair of the Packaging Subcommittee, said that the Subcommittee reviewed packaging issues identified by the public and others. She said the Subcommittee supports CMS' decision to package guidance procedures for chemodenervation.

- **Recommendation:** The Panel recommends that CMS conditionally package payment for the guidance procedures that would accompany breast needle placement (specifically CPT code 19290, *Preoperative placement of needle localization wire, breast*; CPT code 19291, *Preoperative placement of needle localization wire, breast; each additional lesion*((List separately in addition to code for primary procedure); CPT code 19295, *Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration* (List separately in addition to code for primary procedure); CPT code 77031, *Stereotactic localization guidance for breast biopsy or needle placement* (e.g., for wire localization or for injection)), each lesion, radiological supervision and interpretation; CPT code 77032, *Mammographic guidance for needle placement, breast* (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation; CPT code 76942, *Ultrasonic guidance for needle placement* (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation) when these guidance services are performed separately.
- **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 Packaging Subcommittee members.
- **Recommendation:** The Panel recommends that CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available.
- **Recommendation:** The Panel recommends that the work of the Packaging Subcommittee continue.

Electromagnetic Navigational Bronchoscopy (ENB)

Overview

Mr. Tee said the new CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation*, was assigned an interim payment status indicator of N. 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. Mr. Tee said CMS views ENB as similar to other computer-assisted navigational procedures.

Presentation

Thomas Gildea, M.D., Barb Peterson, Curtis Quinn, M.D., and Dan Sullivan, 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—essentially a catheter-based biopsy—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*. Dr. Quinn said ENB is paid separately in physician offices and inpatient settings and that all of the Medicare Administrative Carriers (MACs) cover it.

Discussion

Panel members asked the presenters for more specific detail about how and for whom ENB is used. Randall A. Oyer, M.D., and others indicated the procedure may be appropriately packaged as a guidance procedure ancillary to bronchoscopy. Dr. Quinn contended that ENB allows physicians to reach lesions they otherwise could not with conventional bronchoscopy, enabling them to diagnose and treat distal lesions sooner, in some cases treating patients who are otherwise untreatable. Patrick A. Grusenmeyer, Sc.D., F.A.C.H., noted that ENB requires additional skills and credentialing and that it represents a significantly different approach for treating lesions. Dr. Ross said ENB does not appear to fit in either APC 0076 or 0415. Initially, the Panel voted in favor of recommending that CPT code 31627 be placed in APC 0415 with a status indicator of T. However, upon further consideration, the Panel members said the procedure was not well described, and they asked CMS to further assess the decision to package ENB.

- **Recommendation:** The Panel recommends that CMS consider whether CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation*, should be packaged or paid separately; if it should be paid separately, CMS should investigate the appropriate APC assignment. The Panel suggests CMS use bronchoscopic ultrasonography as a clinical example for comparison.

Drug Administration Services

Overview

Mr. Tee explained the history of packaging drug administration codes. He said that CPT code 96376, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion*, and CPT code 96376, *Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular, each additional sequential intravenous push of the same substance/drug provided in the facility (List separately in addition to code for primary procedure)*, describe concurrent and sequential drug administration services that, per CPT guidelines, are always provided in association with an initial drug administration service and are thus appropriate for packaging.

Presentation

Jennifer Artigue, Kathy Dorale, and John Settlemeyer of the Provider Roundtable pointed out that CPT code 96361, *Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)*, and CPT code 96366, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)*, cannot be performed without the primary drug administration service but should be paid separately (Presentation B). They said hospitals are underpaid for CPT codes 96368 and 96376, and the true costs are not captured by CMS' ratesetting methodology, because these codes always appear as part of multiple procedure claims. They emphasized that concurrent infusions and

additional intravenous (IV) pushes require additional work, such as reassessment to ensure the correct patient is receiving the correct drug at the correct dose, evaluating the effects of the medication, and monitoring the patient. The presenters requested that CMS conduct a detailed analysis of the median costs of CPT codes 96368 and 96376, using the same methodology and rationale as for CPT codes 96361 and 96366. They requested that CPT codes 96368 and 96376 be paid separately in CY 2011.

Ms. Heygster noted that CMS' ratesetting methodology does capture the costs of these drug administration codes through its process of converting some multiple procedure claims to single procedure claims (i.e., pseudo-singles) for ratesetting. Mr. Settlemyer disagreed. Jugna Shah, representing the Alliance of Dedicated Cancer Centers (ADCC), said that if additional work is required for these infusions, they should be paid separately. CMS staff member Rebecca Cole said the additional work of concurrent infusions and IV pushes is taken into account and packaged into the payment for the primary procedure.

Judith T. Kelly, R.H.I.T., R.H.I.A., suggested that to ensure accurate coding, she would prefer that all the drug administration codes be paid at the lower rate rather than package similar codes. Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N., noted that with new mandates to ensure appropriate patient care, nurses must repeat nearly all of the assessments for an initial drug administration when they perform concurrent infusions or additional IV pushes. Dr. Grusenmeyer pointed out that paying separately for these drug administration codes moves Medicare further away from the tenets of a prospective payment system, and the result would be that payment for the primary service would decrease; Dr. Philip said the presenters believe that paying separately would yield more accurate data and thus more accurate payment.

- **Recommendation:** The Panel recommends that CMS make CPT codes 96368, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion*, and CPT code 96376, *Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular, each additional sequential intravenous push of the same substance/drug provided in the facility (List separately in addition to code for primary procedure)*, separately payable in the CY 2011 OPPS/ASC final rule at an appropriate payment rate as determined by CMS.

INPATIENT LIST

Overview

CMS staff member Dana Burley said that in the CY 2010 OPPS Final Rule, CMS removed seven procedures from the list of procedures that it believes may only be performed safely on a typical Medicare beneficiary in the inpatient setting (i.e., the inpatient list). She identified three procedures that CMS is considering proposing to remove from the inpatient list for CY 2011, which are described by CPT codes 21193, *Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft*, 21395, *Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)*, and 25909, *Amputation, forearm, through radius and ulna; re-amputation*. Ms. Burley noted that all three are fairly low-volume procedures that were performed on an inpatient basis less than 60 percent of the time in CY 2009.

Discussion

Panel members briefly discussed the clinical intensity of re-amputation. Ms. Burley described the CMS process for assessing the procedures on the inpatient list, noting that CMS uses all available information, including the expertise of its medical officers, to determine whether a procedure should only be paid when conducted in an inpatient setting.

- **Recommendation:** The Panel recommends that CMS remove the following procedures from the inpatient list:
 - HCPCS code 21193, *Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft*
 - HCPCS code 21395, *Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)*
 - HCPCS code 25909, *Amputation, forearm, through radius and ulna; re-amputation*

APC ASSIGNMENT ISSUES

Allogeneic Stem Cell Transplantation

Overview

Ms. Bullock explained CMS' payment policies for autologous and allogeneic stem cell transplantation. She pointed out that allogeneic stem cell harvesting procedures cannot be paid separately under the OPPI because the procedure to harvest stem cells from a healthy donor is not performed on the Medicare beneficiary whose illness is being treated. Rather, allogeneic stem cell acquisition services, including, harvesting and donor evaluation, are packaged into the payment for transplantation, and hospitals should report all allogeneic stem cell acquisition charges on the recipient's bill using revenue code 0819. CMS received very few claims including allogeneic stem cell transplant and harvesting services in CY 2009 based on the claims data that is currently available. Costs for HCPCS code 38205, *Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic*, are packaged.

Presentation

Ms. Shah of ADCC said none of the very few claims that CMS used for ratesetting for stem cell transplantation included HCPCS code 38205, and therefore hospitals are not paid for the donor-related services (Presentation F). Before the codes for this procedure were packaged, hospitals received from \$718 to \$759 for donor-related services, but that money is not included in the packaged rate for transplant procedures. In addition to donor evaluation and harvesting, donated cells must be thawed before transplantation. Therefore, claims for allogeneic stem cell transplantation will always involve multiple procedures and thus never be used for ratesetting, said Ms. Shah.

Discussion

Ms. Bullock said the problem of having very few claims identified by Ms. Shah is not unique to this procedure. She added that if hospitals included the cost of donor services on the recipient's bill using the designated revenue code, CMS would be able to identify that revenue code on the claims. Dr. Philip noted that the allogeneic approach is complicated because it involves procedures performed on different patients at different sites on different dates; she proposed developing a composite APC if all the different components of the transplant procedure could be captured adequately by CMS claims data. Ms. Bullock said hospitals only recently received guidance on billing revenue code 0819 for stem cell acquisition charges, so claims data reflecting that billing guidance would not be immediately

available for ratesetting. Ms. Shah suggested that CPT code 38205 be paid separately until CMS has sufficient claims data to set an appropriate rate for packaging payment.

- **Recommendation:** To support stem cell transplantation, the Panel recommends that CMS consider creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation and preparation of tissue.

Claims Data and APC Configurations

Presentation

Thomas Novelli of the Medical Device Manufacturers Association (MDMA) expressed concern that over time, expanded packaging and bundling may lead to artificial reductions in the complexity of services provided, with corresponding reductions in payment that, in turn, can cause access problems for beneficiaries (Presentation C). Mr. Novelli said packaging payment for outpatient services creates a financial incentive to admit patients to the hospital, where payment rates may be higher. Underpaying for services creates a disincentive for providers to order those services, even if the service may be cost-effective in the long term.

Mr. Novelli said that experience suggests hospitals do not submit codes for services that do not affect payment directly. He asked that CMS require complete and correct coding for packaged services and that it further study the effects of expanded packaging.

MDMA supports development of a composite APC for cardiac resynchronization therapy (CRT), as previously recommended by the Panel. Mr. Novelli said MDMA supports the methodology used by CMS to establish rates for device-dependent APCs. He asked that the Panel recommend—as it did in August 2009—that CMS study the claims for any APC facing a payment reduction of more than 10 percent and take action to avoid such drastic cuts.

Discussion

Dr. Oyer said that physicians, rather than hospitals, decide whether to admit patients to the hospital; he called Mr. Novelli's contention that such decisions are made on the basis of reimbursement a serious charge and requested data to support it. Mr. Novelli acknowledged that he had only anecdotal reports from members. Dr. Philip added that many presenters exaggerate the potential impact of APC payment rates by saying beneficiary access will be restricted. Ms. Kelly said she believes CMS provides good information about appropriate coding, and hospitals work hard to code claims correctly; manufacturers should do more to help hospitals with difficult device coding requirements, she said. Mr. Novelli responded that most biotechnology companies are small firms with limited resources, but they do benefit from correct coding and seek to support it.

Kathleen M. Graham, R.N., M.S.H.A., said CRT is costly, and she believes physicians determine the appropriate setting on the basis of individual patient factors. She suggested CMS create a separate APC to cover the high device cost for CRT or that CMS create a composite APC for CRT. Dr. Ritter noted that CMS accepted the Panel's August 2009 recommendation to create a composite APC for CRT and is in the process of collecting data that it will present to the Panel.

Ms. Graham suggested that the costs of devices should come down over time, but some vendors never lower their prices, leading to continually elevating payment rates. Dr. Ross noted that the changes in APC rates often represent correction of over- or underpayment. He felt CMS should determine when

a payment rate change merits evaluation. Dr. Ritter said that CMS routinely looks at payment increases or decreases of 10 percent or more when it evaluates data.

Presentation

DeChane L. Dorsey, Esq., of the Advanced Medical Technology Association (AdvaMed) asked that CMS continue to monitor the impact of the multiple imaging composite APCs on beneficiaries and evaluate whether its methodology for determining payment for these composites accurately reflects the resources they require (Presentation D). 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 CMS issue revised instructions to hospitals that clarify cost reporting changes and requirements. She requested that hospitals and MACs be fully educated about the new cost center reporting requirements and that CMS implement them in a timely fashion. Ms. Dorsey asked that the resulting data be validated by CMS.

Ms. Dorsey said AdvaMed supports mandatory reporting of all C codes to encourage hospitals to report costs accurately. She asked that CMS continue educating hospitals about the importance of accurate coding for devices and other technologies. Also, AdvaMed urges 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. Ms. Dorsey reiterated AdvaMed's support for the creation of a new composite APC for CRT.

Discussion

Dr. Ross asked Ms. Dorsey for suggestions on how to measure the impact of the multiple imaging composite APCs on trauma centers; Ms. Dorsey responded that CMS could work more closely with trauma centers to gather data. Dr. Przybylski pointed out that two years of data did not suggest that the composite APCs had resulted in changes in practice or utilization. Ms. Shah offered to provide the analysis her organization presented at a previous Panel meeting about the proportion of episodes that involve two imaging procedures as compared with three procedures. Ms. Bullock said a previous analysis of trauma diagnoses indicated that variability in the number of imaging procedures provided to trauma patients was the same as for patients with other diagnoses. Those with cancer diagnoses, however, were more likely to have three or more imaging procedures than patients not diagnosed with cancer, said Ms. Bullock, and CMS could reevaluate that analysis using updated claims.

Dr. Przybylski said the data CMS has provided should be sufficient to interpret the impact. Ms. Kelly reiterated that manufacturers should do more to assist hospitals with correct coding.

Skin Substitute Procedures

Overview

LCDR Marjorie Baldo summarized data requested by the Panel on the CPT codes and APC assignments for three skin repair products. She pointed out that CPT coding instructions indicate that Dermagraft application (HCPCS code 15365, *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children*, and HCPCS code 15366, *Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple*

digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof [List separately in addition to code for primary procedure]) should be reported separately from debridement and site preparation codes, while Apligraf application (HCPCS code 15340, *Tissue cultured allogeneic skin substitute; first 25 sq cm or less*, and HCPCS code 15341, *Tissue cultured allogeneic skin substitute; each additional 25 sq cm*) and Oasis application (HCPCS code 15430, *Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children*, and HCPCS code 15431, *Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)*) should not be reported separately from debridement and site preparation codes. For each of the three products, LCDR Baldo presented data (from the first nine months of CY 2009) on the frequency of reporting primary and add-on CPT application codes for Apligraf, Dermagraft, and Oasis; the frequency of site preparation and debridement CPT codes in relation to each of the products; and CPT and APC median costs for the CPT application codes and related procedures. For CY 2010, each skin repair product has a distinct Q code that is billed and paid separately from the application procedures.

Presentation

Antonio Montecalvo and David Hurley of Organogenesis asked that CMS reassign Apligraf application (HCPCS codes 15340 and 15341) to APC 0135, *Level III Skin Repair*, thus including in the same APC the two products for which site preparation and debridement are not reported separately (Presentation E). They described the history of reporting of Apligraf claims and of APC payment rates for the application of all three skin repair products before and after CPT revised the codes for the products. Mr. Hurley said the additional payment for site preparation and debridement procedures that may be reported separately with Dermagraft application can significantly affect the total payment for the procedure. He noted that in CY 2008 data, 54 percent of claims for Apligraf skin repair procedures still inappropriately report the cost for site preparation and debridement, so the real costs are underreported. Mr. Hurley also provided data on the use of each product in relation to the size of the wounds treated; he concluded that the size of the wound treated does not seem to affect the resources used.

Discussion

Dr. Philip pointed out that despite the information provided about wound size, it appears that when the product is packaged in a larger size, clinicians are much less likely to require additional applications. She concluded that the cost seems to be related to the product package size, not its APC assignment. The presenters disputed that conclusion, but Dr. Philip maintained the data support it.

Theresa Dixon of Advanced BioHealing said the MACs have clear, consistent policies for all three products, and debridement is not paid separately for any of them. Dr. Grusenmeyer said the data suggest only a few claims for Dermagraft application also include site preparation and debridement. Dr. Przybylski said the CPT median costs of Apligraf and Dermagraft application are the same, so he saw no need to move the codes.

- **Recommendation:** The Panel recommends to CMS that HCPCS code 15340, *Tissue cultured allogeneic skin substitute; first 25 sq cm or less* (Apligraf), and HCPCS code 15341, *Tissue cultured allogeneic skin substitute; each additional 25 sq cm* (Apligraf), remain in APC 0134, *Level II Skin Repair*.

Nuclear Medicine APCs

Overview

Ms. Cole presented data requested by the Panel at a previous meeting on diagnostic radiopharmaceuticals packaged with nuclear medicine procedures. She emphasized that comparison of data before and after packaging was implemented in CY 2008 is limited, because CMS now requires claims to pass through a procedure-to-radiolabeled-product edit. Prior to CY 2008, many claims for nuclear medicine procedures did not include charges for the associated diagnostic radiopharmaceutical. The data show the frequency of the most commonly used diagnostic radiopharmaceuticals by nuclear medicine procedure from CY 2007 to CY 2009.

Presentations

Gail Daubert of the Council on Radionuclides and Radiopharmaceuticals (CORAR) said she had not seen the data presented by Ms. Cole until this meeting but it appeared to show significant shifts and wide variations in use of radiopharmaceuticals from year to year, which illustrates CORAR's concerns about packaging (Presentation G). CORAR maintains that radiopharmaceuticals are drugs and therefore should be paid separately if the costs surpass the packaging threshold.

Ms. Daubert said that in structuring APCs, CMS only takes into account the costs of services when assessing for violations of the two-times rule; according to Federal statute, it should consider the costs of both items and services. If radiopharmaceuticals are not considered by CMS to be drugs and paid separately, then they should be considered items, and their costs taken into account in evaluating two-times rule violations. Ms. Daubert asked that CMS restructure the tumor/infection imaging APCs, as the costs of the radiopharmaceuticals alone are higher than the APC payment rates for these packaged codes.

Ms. Daubert suggested that CMS use ASP data for diagnostic radiopharmaceuticals, if available, to determine resource similarity. She also recommended that if the coefficient of variation for a diagnostic radiopharmaceutical's cost is higher than 70 percent, that CMS create an edit, move the procedure to another APC, or pay separately for the diagnostic radiopharmaceuticals. She asked that CMS continue to review the nuclear medicine APCs for clinical and resource homogeneity and refine them if variations in radiopharmaceutical costs exceed a designated threshold. In addition, CORAR recommends that CMS ensure, through claims edits, that only nuclear medicine procedures with radiopharmaceuticals reported be used to set payment rates.

Discussion

Dr. Oyer questioned the definition of radiopharmaceuticals as drugs, saying that some radiopharmaceuticals are used for both imaging and diagnosis. Ms. Daubert contended that CMS, the U.S. Food and Drug Administration, and Congress designated radiopharmaceuticals as drugs for the purpose of pass-through payments, and that the OPPS has always recognized them as drugs. Ms. Cole said that CMS has not always been consistent in its definition of radiopharmaceuticals; however, she pointed out that imaging agents are also packaged. Dr. Philip disagreed with Ms. Daubert's interpretation of the Federal statute, which states that in assessing two-times rule violations, CMS should take into account the costs of items *or* services, not items and services. Ms. Daubert responded that the high costs of radiopharmaceuticals should not be ignored. Ms. Cole said CMS evaluates two-times rule violations by looking at the dominant item or service; in this case, the nuclear

medicine procedure is the dominant service that drives APC payment rates, and diagnostic radiopharmaceuticals are supportive of and ancillary to that service.

Ms. Shah pointed out that initially, packaging focused on lower-cost items that could be substituted for one another, so that hospitals could select the most cost-efficient item for the service. She said nuclear medicine exemplifies the problem with the theory that packaging drives efficiency, because it is not clear that radiopharmaceuticals can be substituted for one another to achieve the same nuclear scan. Ms. Bullock noted that payment rates are averages and are not intended to match the hospital costs in all cases; the result of a prospective payment system is that payment will sometimes be more than, and other times be less than, the hospital's cost of providing a service. Dr. Oyer said the system is not working for this class of procedures, because physicians must select the right agent for the test, and he asked that CMS study the issue further. Dr. Ritter noted that data before and after packaging of diagnostic radiopharmaceuticals have shown no changes in hospital utilization or beneficiary access.

Ms. Cole stressed that the costs of diagnostic radiopharmaceuticals are taken into account in calculating APC median costs. Ms. Spencer-Cisek asked for more data from CMS looking specifically at the effects of packaging on the frequency of high-dollar radiopharmaceuticals. Denise Merlino of the Society for Nuclear Medicine suggested looking specifically at the tumor/infection imaging APCs, because they are the most problematic. Her organization's main concern is the shift over time from one type of radiopharmaceutical to another, which may force patients to travel from smaller, suburban hospitals to larger, urban hospitals to get needed treatment.

Ms. Daubert said ASP data would be a more reliable indicator of cost than hospital claims data. Ms. Merlino added that manufacturers are currently providing ASP data for therapeutic radiopharmaceuticals and would provide ASP data for diagnostic radiopharmaceuticals to CMS if requested. Tamar Thompson of Kendall and Associates agreed.

- **Recommendation:** The Panel recommends that CMS analyze claims data for the tumor imaging APCs in terms of the average, median, and range of costs of packaged diagnostic radiopharmaceuticals.

DRUGS, BIOLOGICALS, AND PHARMACY OVERHEAD

Overview

CMS staff member Alpha-Banu Huq explained that for CY 2010, CMS redistributed a portion of the total cost for packaged drugs and biologicals to separately payable drugs and biologicals, resulting in a payment rate for separately payable drugs without pass-through status of ASP plus 4 percent. Using the standard methodology of determining the total cost of separately payable drugs in the claims data compared to the ASP dollars for the same drugs, CMS determined that payment rates for separately payable drugs would be ASP minus 3 percent and the payment rate for packaged drugs would be ASP plus 258 percent without any adjustments. Because both rates appeared unlikely to represent real costs, CMS redistributed \$200 million of pharmacy overhead costs (\$150 million from 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 cost).

CMS acknowledges that improving reporting may require hospitals to change longstanding reporting practices, but notes that more complete data from hospitals will improve payment accuracy for separately payable drugs and biologicals. While CMS does not instruct hospitals on the appropriate revenue codes to use to charge for specific services, the accuracy of OPPS payment rates increases when hospitals report all HCPCS-coded items and services on claims, whether packaged or not. Ms. Huq pointed out that the CY 2011 preliminary APC cost data provided to the Panel in the two-times rule do not reflect the redistribution of pharmacy overhead costs from packaged to separately payable drugs.

Presentation

Matthew Farber of the Association of Community Cancer Centers (ACCC) urged CMS to do more to ensure appropriate payment rates for hospitals' drug acquisition and pharmacy service and handling costs (Presentation H). He suggested that CMS reallocate a larger portion of the pharmacy overhead costs associated with packaged drugs to separately payable drugs and reimburse hospitals for the acquisition costs of separately payable drugs at a rate of ASP plus 6 percent. If CMS does neither, Mr. Farber said that CMS should exclude 340B hospitals from its ASP ratesetting calculations and pay all hospitals at the same rate. In addition, CMS should pay separately for all drugs with HCPCS codes or, at a minimum, not increase the packaging threshold for drugs. Mr. Farber pointed out that survey data indicate pharmacy overhead accounts for about 25 percent of total drug costs, while CMS estimates that proportion to be less than 13 percent. In addition, new risk management requirements contribute to overhead costs but are not included in CMS' calculations.

Laurel Neff of the Biotechnology Industry Organization (BIO) said accurate payment is essential to ensuring beneficiary access and encouraging innovation, but separately payable drugs are still underpaid by CMS (Presentation J). She reiterated the recommendations to CMS made by ACCC, noting that despite CMS' redistribution, CMS still does not have the data necessary to ensure that its payment rates match the average acquisition costs. Ms. Neff said that Congress intended CMS to pay at a rate no less than ASP plus 6 percent, equivalent to the rate paid to physician offices. Regarding CMS' reallocation methodology, she noted that external analysis showed that packaged drugs with and without HCPCS codes are subject to the same markup, and Ms. Neff hoped CMS would consider that data in its analysis. If CMS continues its packaging of HCPCS-coded drugs, Ms. Neff asked that CMS reiterate its guidance that hospitals bill for them using HCPCS codes and revenue code 636. Finally, BIO asked that all anti-emetic drugs be paid separately to preserve beneficiary access.

Ms. Shah of ADCC said the redistribution of \$200 million was significant, but she questioned the rationale for reallocating 24 percent of the overhead costs from packaged drugs with HCPCS codes (\$150 million) but only 8 percent from those without HCPCS codes (\$50 million), given data showing the overhead costs for both are similar (Presentation I). She asked that CMS analyze separately the overhead costs for packaged drugs with and without HCPCS codes and use its findings to determine the amount that should be redistributed to separately payable drugs. Ms. Shah also asked that CMS describe its rationale for its redistribution dollar amount in the proposed rule.

Christopher Hogan, Ph.D., provided data from an analysis underwritten by Johnson and Johnson, Inc. (Presentation K). Dr. Hogan said the overhead costs for packaged drugs with and without HCPCS codes are similar. He concluded that treating all packaged drugs the same would bring the CMS estimate of the proportion of pharmacy overhead to total costs in line with data from cost reports and

other payers—that is, approximately ASP plus 25 percent. Doing so would result in a larger pool of overhead costs available for reallocation.

Stuart Yael Gordon of Safety Net Hospitals for Pharmacy Access said his organization supports the recommendations made by the presenters. Mr. Gordon described the 340B program, noting that the discounts participating programs receive enabled them to redirect scarce resources into other much-needed services. He pointed out that not all manufacturers participate in the 340B program and not all of those who do fully participate.

Discussion

Dr. Oyer asked why it is so difficult to get detailed data on the costs of drug handling from hospitals. Ms. Shah said hospitals are not reluctant to report data; she described some of the barriers hospitals face and some failed proposals to better capture acquisition costs. She noted that hospitals have been offered incentives to gather more data with the promise that doing so *might* result in better payment. Dr. Ross said the Panel has been discussing this topic for years without reaching a resolution; he suggested CMS determine whether its payment structure has a negative impact on providers and adjust accordingly.

Drs. Ross and Oyer both pointed out why removing 340B hospitals from the drug ratesetting methodology may be appropriate, but Dr. Ross raised concerns about the overall economic impact. Beth Roberts of Hogan and Hartson said 340B hospitals are not included in the ASP calculations but sales are included in the aggregate data used to calculate total drug cost under the OPPIs. She said the aggregate data are accurate, but the packaging threshold distorts the ASP. Ms. Roberts called for more stability in payment and a better ratesetting methodology for drugs.

In terms of hospital reporting, Ms. Graham said fiscal intermediaries stripped \$0 items out of hospital claims but MACs might not do that. Ms. Cole said no part of the CMS system strips out \$0 items from claims.

Ms. Williams of Baxter Health Care said Congress gave CMS the flexibility to define drug costs because it was concerned that ASP would not adequately reflect drug handling costs. Dr. Grusenmeyer said he was hesitant to ask hospitals to assign costs, especially given the arbitrary cutoff rate of the packaging threshold. Ms. Roberts said many studies show that pharmacy overhead costs are one quarter to one third of the acquisition cost. She said her organization would feel comfortable with ASP plus 6 percent at a minimum and suggested looking at the payment rates for physician offices. Dr. Hambrick said that CMS does not accept the contention that Congress intended CMS to use ASP plus 6 percent as a minimum rate. Ms. Williams reiterated the scenario she described earlier that contributed to errors in data that affect CMS methodology; she said CMS has flexibility in some cases and should use it.

Russ Ranallo, M.S., asked that CMS present the panel with an economic impact statement before it takes steps to reallocate a larger portion of pharmacy overhead costs from packaged to separately payable drugs, because it could have a detrimental effect on rural hospitals. Mary Jo Braid-Forbes of Forbes Health Research said that drugs are such a small part of overall payment that reallocation has no significant redistributive effect on hospitals.

Dr. Przybylski recommended removing 340B hospitals from the ratesetting methodology; Agatha L. Nolen, M.S., D.Ph., said she felt conflicted about doing so, because it would decrease the number of claims available for ratesetting. Dr. Philip said removing 340B hospitals from the calculation would not result in sufficient changes to fix the problem and raises too many competing issues. The Panel voted unanimously against the recommendation. Ms. Spencer-Cisek requested that CMS collect the background information on pharmacy overhead (e.g., analyses and proposals submitted, Panel discussions, recommendations) and send it to Panel members before the summer 2010 Panel meeting.

- **Recommendation:** The Panel recommends that CMS continue to look at the impact of its drugs and biologicals overhead payment policy on hospitals.
- **Recommendation:** The Panel recommends that CMS (1) reallocate a larger portion (relative to the CY 2010 final rule) of the pharmacy overhead costs from packaged drugs to separately payable drugs, and (2) evaluate the impact on hospitals (categorized by type and size) of such reallocation and present that analysis to the Panel at its next meeting.

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 1:45 p.m. on Thursday, February 18, 2010.

Appendix A



AGENDA

February 17 – 19, 2010

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

DAY 1 - Wednesday, February 17, 2010

Public registrants may enter the Centers for Medicare & Medicaid Services' (CMS) Central Office Building after 12:15 p.m.

AGENDA

01:00 Opening - Day 1

1. Welcome and Call to Order – E. L. Hambrick, M.D., J.D., Chair, APC Panel
2. Welcome New Members – E. L. Hambrick, M.D., J.D., Chair, APC Panel
 - a. Ruth L. Bush, M.D., M.P.H.
 - b. Dawn L. Francis, M.D., M.H.S.
 - c. David A. Halsey, M.D.
 - d. Daniel J. Pothan, M.S., RHIA, CHPS, CPHIMS, CCS, CCS-P, CHC
 - e. Gregory Przybylski, M.D.
3. Opening Remarks - TBA

01:30 Panel Organization and Housekeeping Issues

E. L. Hambrick, M.D., J.D., Chair, APC Panel

01:45 CMS-1414-FC: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates, et al, Federal Register

1. **Overview** – Christina Smith Ritter, Ph.D., Acting Director, Division of Outpatient Care (DOC)
2. Discussion
3. Panel's Comments

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TAB

02:00 **DATA**

1. **Overview** – Anita Heygster, CMS Staff
– Erick Chuang, M.S., CMS Staff
2. **Data Subcommittee’s Report** – Michael Mills, Ph.D., Chair
3. Discussion
4. Panel’s Comments/Recommendations

02:30 **VISITS AND OBSERVATION**

1. **Overview** – Heather Hostetler, J.D., CMS Staff
2. **Visit and Observation Subcommittee’s Report** – Michael Ross, M.D., Chair
3. Discussion
4. Panel’s Comments/Recommendations

03:00 *Break*

03:15 **PACKAGING**

1. **Overview** – Gift Tee, M.P.H., CMS Staff
– Carrie Bullock, M.H.S., Acting Deputy Director, DOC
2. **Packaging Subcommittee’s Report** – Beverly Khnie Philip, M.D., Chair
3. Discussion
4. Panel’s Comments/Recommendations

ELECTROMAGNETIC NAVIGATIONAL BRONCHOSCOPY (ENB)

1. **Overview** – Gift Tee, M.P.H., CMS Staff
2. **Presentation** – Thomas Gildea, M.D., Cleveland Clinic **A**
– Curtis Quinn, M.D., Waukesha Memorial
– Barb Peterson, Emerson Consultants, Inc., for superDimension, Inc.
3. Discussion
4. Panel’s Comments/Recommendations

DRUG ADMINISTRATION SERVICES

1. **Overview** – Rebecca Cole, M.S., CMS Staff
– Gift Tee, M.P.H., CMS Staff
2. **Presentation** – John Settlemeyer **B**
– Kathy Dorale
Provider Roundtable (PRT)
3. Discussion
4. Panel’s Comments/Recommendations

04:45 **Adjourn**



AGENDA

February 17 – 19, 2010

Advisory Panel on Ambulatory Payment Classification (APC) Groups Meeting

DAY 2 - Thursday, February 18, 2010

TAB

Public registrants may enter the CMS Central Office Building after 7:45 a.m.

09:00 **Opening** - Day 2

Welcome and Call to Order

E. L. Hambrick, M.D., J.D., Chair, APC Panel

09:15 **INPATIENT LIST**

1. **Overview** - Dana Burley, M.S.P.H., CMS Staff

2. Discussion

3. Panel's Comments/Recommendations

09:45 **APC ISSUES**

USE OF CLAIMS DATA AND APC CONFIGURATIONS

1. **Presentations**

a. Thomas C. Novelli

Medical Device Manufacturers Association

b. DeChane L. Dorsey, Esq.

Advanced Medical Technology Association

2. Discussion

3. Panel's Comments/Recommendations

C

D

10:15 *Break*

Page 2 - Day 2 - Thursday, February 18, 2010

TAB

10:30 **APC ISSUES** (*continued*)

SKIN SUBSTITUTE PROCEDURES

- 1. **Overview** – LCDR Marjorie Baldo, USPHS, M.S., CMS Staff
- 2. **Presentation** – David Hurley
– Antonio Montecalvo
Organogenesis
- 3. Discussion
- 4. Panel’s Comments/Recommendations

E

ALLOGENEIC STEM CELL TRANSPLANTATION

- 1. **Overview** – Carrie Bullock, M.H.S., Acting Deputy Director
- 2. **Presentation** – Jugna Shah, Consultant
Alliance of Dedicated Cancer Centers (ADCC)
- 3. Discussion
- 4. Panel’s Comments/Recommendations

F

NUCLEAR MEDICINE APCs

- 1. **Overview** – Rebecca Cole, M.S., CMS Staff
- 2. **Presentation** – Gail Daubert
Council on Radionuclides & Radiopharmaceuticals (CORAR)
- 3. Discussion
- 4. Panel’s Comments/Recommendations

G

11:20 **DRUGS, BIOLOGICALS, & PHARMACY OVERHEAD**

- 1. **Overview** – Rebecca Cole, M.S., CMS Staff
– Alpha-Banu Huq, M.P.A., CMS Staff

12:00 *Lunch*

01:00 **DRUGS, BIOLOGICALS & PHARMACY OVERHEAD** (*continued*)

2. Presentations

- a. Matthew Farber
Association of Community Cancer Centers (ACCC)
- b. Jugna Shah, Consultant
ADCC
- c. Lauren Neff
Biotechnology Industry Organization (BIO)
- d. Christopher Hogan, Ph.D.
Johnson and Johnson, Inc.

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- 3. Discussion
- 4. Panel’s Comments/Recommendations

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02:30 *Break* (Cumulative list of Panel's recommendations will be compiled.)

03:15 **Closing**

1. Summary of the Panel's Recommendations for 2011
2. Discussion
3. Final Remarks

04:00 **Adjourn**

NOTE: There will be no meeting tomorrow, Friday, February 19, 2010.

Appendix B

RECOMMENDATIONS

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

**Advisory Panel on Ambulatory Payment Classification (APC) Groups
February 17–18, 2010**

Recommendations

Visits and Observation Issues

1. The Panel recommends that CMS study 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, electrocardiogram, and chest x-ray.
2. The Panel recommends that CMS continue to report on clinic and emergency department visits and observation services in the claims data 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.
3. The Panel requests that CMS provide information about the common diagnoses and services furnished with critical care services.
4. The Panel recommends that the work of the Visits and Observation Subcommittee continue.

Packaging Issues

5. The Panel recommends that CMS consider whether CPT code 31627, *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation*, should be packaged or paid separately; if it should be paid separately, CMS should investigate the appropriate APC assignment. The Panel suggests CMS use bronchoscopic ultrasonography as a clinical example for comparison.
6. The Panel recommends that CMS make CPT codes 96368, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion*, and CPT code 96376, *Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular, each additional sequential intravenous push of the same substance/drug provided in the facility (List separately in addition to code for primary procedure)*, separately payable in the CY 2011 OPPS/ASC final rule at an appropriate payment rate as determined by CMS.

7. The Panel recommends that CMS conditionally package payment for the guidance procedures that would accompany breast needle placement (specifically CPT code 19290, *Preoperative placement of needle localization wire, breast*; CPT code 19291, *Preoperative placement of needle localization wire, breast; each additional lesion* ((List separately in addition to code for primary procedure); CPT code 19295, *Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration* (List separately in addition to code for primary procedure); CPT code 77031, *Stereotactic localization guidance for breast biopsy or needle placement* (e.g., for wire localization or for injection)), each lesion, radiological supervision and interpretation; CPT code 77032, *Mammographic guidance for needle placement, breast* (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation; CPT code 76942, *Ultrasonic guidance for needle placement* (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation) when these guidance services are performed separately.
8. 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 OPSS for review by the Packaging Subcommittee members.
9. The Panel recommends that CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available.
10. The Panel recommends that the work of the Packaging Subcommittee continue.

Data Issues

11. The Panel recommends that CMS present to the Data Subcommittee an analysis of the effect of using a different lower-level threshold in the overall cost-to-charge-ratio error trim as part of the standard methodology.
12. The Panel recommends that the work of the Data Subcommittee continue.

APC Placement Issues

13. The Panel recommends that CMS remove the following procedures from the inpatient list:
 - HCPCS code 21193, *Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft*
 - HCPCS code 21395, *Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)*
 - HCPCS code 25909, *Amputation, forearm, through radius and ulna; re-amputation*
14. To support stem cell transplantation, the Panel recommends that CMS consider creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation and preparation of tissue.

15. The Panel recommends to CMS that HCPCS code 15340, *Tissue cultured allogeneic skin substitute; first 25 sq cm or less* (Apligraf), and HCPCS code 15341, *Tissue cultured allogeneic skin substitute; each additional 25 sq cm* (Apligraf), remain in APC 0134, *Level II Skin Repair*.

Drugs, Biologicals, Radiopharmaceuticals, and Pharmacy Overhead

16. The Panel recommends that CMS analyze claims data for the tumor imaging APCs in terms of the average, median, and range of costs of packaged diagnostic radiopharmaceuticals.
17. The Panel recommends that CMS continue to evaluate the impact of its drugs and biologicals overhead payment policy on hospitals.
18. The Panel recommends that CMS (1) reallocate a larger portion (relative to the CY 2010 final rule) of the pharmacy overhead costs from packaged drugs to separately payable drugs, and (2) evaluate the impact on hospitals (categorized by type and size) of such reallocation and present that analysis to the Panel at its next meeting.

Appendix C

PRESENTATIONS

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting February 17–18, 2010:

- Presentation A: superDimension, Inc.
- Presentation B: The Provider Roundtable
- Presentation C: Medical Device Manufacturers Association
- Presentation D: Advance Medical Technology Association
- Presentation E: Organogenesis
- Presentation F: Alliance of Dedicated Cancer Centers
- Presentation G: Council on Radionuclides and Radiopharmaceuticals
- Presentation H: Association of Community Cancer Centers
- Presentation I: Alliance of Dedicated Cancer Centers
- Presentation J: Biotechnology Industry Organization
- Presentation K: Johnson and Johnson, Inc.