ADVISORY PANEL

ON

AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS

APC Panel Meeting Report

August 5–6, 2009

Centers for Medicare & Medicaid Services (CMS)

7500 Security Boulevard, Auditorium

Baltimore, MD 21244-1850

PANEL MEMBERS PRESENT AT THIS MEETING

Gloryanne Bryant, B.S., R.H.I.T.

Kathleen M. Graham, R.N., M.S.H.A.

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

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

Michael D. Mills, Ph.D.

Thomas M. Munger, M.D., F.A.C.C.

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

Randall A. Oyer, M.D.

Beverly Khnie Philip, M.D.

Russ Ranallo, M.S.

James Rawson, M.D.

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

Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.

Robert M. Zwolak, M.D., Ph.D.

CMS STAFF PRESENT

Amy Bassano, Director, Hospital and Ambulatory Policy Group (HAPG)

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

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

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

Christina Smith Ritter, Ph.D., Deputy Director, DOC

Sheila Roman, M.D., Medical Officer, HAPG

Marjorie Baldo, LCDR, U.S.P.H.S., M.S., Staff, DOC

Carrie Bullock, M.H.S., Staff, DOC

Dana Burley, M.S.P.H., B.S.N., Staff, DOC

Erick Chuang, M.S., Staff, DOC

Alberta Dwivedi, Staff, DOC

Heather Hostetler, J.D., Staff, DOC

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

Rebecca Cole, M.S., Staff, DOC

Barry Levi, M.B.A., 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; a listing of only the recommendations appears in Appendix B. A list of presentations appears in Appendix C.) Amy Bassano, Director of the Hospital and Ambulatory Policy Group, welcomed the Panel members and thanked them for their input as CMS continues to strengthen the connection between payment for Medicare services and efficient, high-quality care for beneficiaries. She gave special thanks and provided certificates of appreciation to five members of the Panel whose terms will expire in September: Gloryanne Bryant, B.S., R.H.I.T.; Thomas M. Munger, M.D., F.A.C.C.; James Rawson, M.D.; Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.; and Robert M. Zwolak, M.D., Ph.D.

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 CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND PROPOSED CALENDAR YEAR (CY) 2010 PAYMENT RATES

Carol Bazell, M.D., M.P.H., Director, DOC, briefly described the process CMS used to set the payment rates for CY 2010 in the Notice of Proposed Rulemaking (NPRM), which was published in the *Federal Register* July 20, 2009. She noted that the proposed market basket increase for CY 2010 is 2.1 percent and, taking into consideration the full proposal, CMS estimates that overall OPPS payment to providers in CY 2010 would increase by approximately 1.9 percent. Significant changes discussed in the CY 2010 proposed rule include the following:

- **Drugs and Biologicals (Except Radiopharmaceuticals)**: For CY 2010, CMS proposes to pay for separately payable drugs and biologicals at a rate of the average sales price (ASP) plus 4 percent for separately payable drugs and to increase the packaging threshold for drugs and biologicals to $65 per day as updated by the Producer Price Index for prescription preparations. The rate of ASP plus 4 percent includes a proposed redistribution to payment for separately payable drugs and biologicals of $150 million in pharmacy overhead cost currently attributed to packaged drugs. (Using the existing CMS methodology, Dr. Bazell said, the payment rate for CY 2010 would have been ASP minus 2 percent.)

- **Radiopharmaceuticals**: For CY 2010, CMS proposes to pay for separately payable therapeutic radiopharmaceuticals at a rate of ASP plus 4 percent. Diagnostic radiopharmaceuticals would remain packaged for CY 2010.

- **Brachytherapy Sources**: For CY 2010, CMS proposes to pay for brachytherapy sources prospectively on the basis of median cost per source.

- **Physician Supervision**: For CY 2010, CMS proposes to refine its physician supervision policies for hospital outpatient services to include nonphysician practitioners as appropriate, clarify "direct" supervision, and adopt the same supervision requirements for hospital outpatient diagnostic services across all sites of hospital outpatient care.

- **Kidney Disease Education**: The CMS proposal for VY 2010 would clarify provider qualifications, coverage criteria, and billing codes for kidney disease education, as coverage was mandated by the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

- **Pulmonary and Cardiac Rehabilitation**: For CY 2010, CMS proposes to continue recognizing existing American Medical Association (AMA) Current Procedural Terminology (CPT) codes for cardiac rehabilitation services and to create Healthcare Common Procedure Coding System (HCPCS) G codes for intensive cardiac rehabilitation to collect specific cost data. A new HCPCS G code for pulmonary rehabilitation would be assigned to a New Technology APC at a proposed payment rate of about $15.

- **Type B Emergency Department (ED) Visits**: For CY 2010, CMS proposes to base payment for Type B ED visits on costs derived from Type B ED claims data for all five levels.

- **Quality Reporting**: For CY 2010, CMS proposes to continue requiring hospitals to report the 11 designated quality measures to receive full payment in CY 2011. CMS is seeking public comment on 18 other potential quality measures for future years. The proposed validation effort would begin with the CY 2011 update, with results affecting hospital payment in CY 2012. CMS has also proposed mechanisms for making quality data publicly available.

- **Ambulatory Surgical Centers (ASCs)**: For CY 2010, the third year of a four-year transition in payment rates, ASC payments are based on a 25/75 blend of CY 2007 ASC rates and CY 2010 rates calculated according to the standard methodology. For CY 2010, CMS proposed covering 28 additional surgical procedures in ASCs.

DATA ISSUES

CMS staff member Anita Heygster described the data construction method CMS uses for setting median costs for APCs, focusing on changes to the process used for calculating rates for the CY 2010 proposed rule. 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 all of the National Uniform Billing Committee's revenue codes based on their specific definitions.

Ms. Heygster explained that, to implement the CY 2010 proposal to redistribute $150 million in claims cost from packaged drugs and biologicals 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 0.73. 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.

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. About 90 million "natural" single and "pseudo-single" claims from CY 2008 were used to calculate median costs for CY 2010. After determining median costs, CMS assesses APC assignments for violations of the two-times rule. Overall, 14 APCs continue to contain violations of the two-times rule in the proposed CY 2010 rule (the same number as in the CY 2009 final rule).

Ms. Heygster said that the medians for seven APCs decreased by 10 percent or more, and the medians for 63 APCs increased by 10 percent or more. She described some potential reasons for the variations, adding that CMS found nothing in its analysis that raised concern about the process CMS uses to calculate median costs.

Finally, Ms. Heygster clarified that the proposed rule imprecisely stated that CMS calculated "per unit" overhead costs for packaged drugs and biologicals when it should have stated that CMS calculated "per day" overhead costs for packaged drugs and biologicals as a proxy for "per administration" overhead costs. As a result of the misstatement, some data users may not be able to reproduce the CMS study results for Tables 27 and 28 in the proposed rule, and CMS is notifying those users affected.

Data Subcommittee's Report

Panel member Dr. Williams, Chair of the Data Subcommittee, said that many of the Subcommittee's requests for data from CMS are pending. The Subcommittee discussed the variation in median costs for certain APCs under the proposed CY 2010 rule, noting that a lot of APCs went up by 10 percent or more, while only a few went down by that 10 percent or more. The Subcommittee supported the proposal by CMS to maintain CPT code 76098, *Radiological examination, surgical specimen*, on the bypass list. The Subcommittee also discussed the APC assignments of neurostimulators and the proposed payment methodology for drugs, biologicals, and radiopharmaceuticals and pharmacy overhead in the proposed CY 2010 OPPS.

- **Recommendation**: The Panel recommends that the work of the Data Subcommittee continue.

- **Recommendation**: The Data Subcommittee deferred any further recommendations until after hearing the public presentations during the Panel's public session.

In response to a question from Valerie Rinkle of Asante Health System, Ms. Heygster noted that the use of cost report data by CMS typically lags about two years behind the claims year because of reporting requirements and timing of hospital submissions. Dr. Hambrick suggested Ms. Rinkle or others submit pertinent concerns related to OPPS cost estimation that would result from proposed changes to the cost report that are currently open for public comment and that would be appropriate for the Data Subcommittee to review (although it would be several years before those data are available).

PACKAGING ISSUES

Overview

CMS staff member Gift Tee reiterated the CMS rationale for packaging, noting that it provides an incentive for providers to deliver services in the most efficient, cost-effective manner possible. He said that CMS accepted the Panel's recommendations to continue exploring the impact on beneficiaries of increased packaging. Mr. Tee said that CMS will provide updated analyses that include CY 2007, CY 2008, and CY 2009 claims data at the Panel's 2010 winter meeting, but no new data were available for this meeting.

Packaging Subcommittee's Report

Dr. Rawson, Chair of the Packaging Subcommittee, said that the Subcommittee reviewed packaging issues identified by the public as well as past recommendations by the Panel that CMS evaluate the impact of packaging on beneficiaries.

- **Recommendation**: The Panel recommends that CMS submit to the Packaging Subcommittee, for its ongoing review, 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.

- **Recommendation**: The Panel recommends that CMS continue to study the impact of increased packaging on beneficiaries.

- **Recommendation**: The Panel recommends that the work of the Packaging Subcommittee continue.

VISITS AND OBSERVATION ISSUES

Overview

CMS staff member Heather Hostetler explained that in CY 2009, CMS established a five-level APC structure for Type B ED visits by creating four new APCs for care defined as levels 1–4 and paying for level-5 Type B ED visits using the same APC as level-5 Type A ED visits. For CY 2010, CMS proposes to continue the prospective payment method but to create a new APC specifically for level-5 Type B ED visits. Claims data indicate that the median costs of Type B ED visits are less than the median costs of Type A ED visits across all five levels of visits. For CY 2010, CMS proposes to continue using the current payment criteria, reporting requirements, and payment methodology for the extended assessment and management composite APCs created in CY 2008.

Visits and Observation Subcommittee's Report

Panel member Michael Ross, M.D., Chair of the Visits and Observation Subcommittee, said that the Subcommittee reviewed the proposed CY 2010 OPPS payment policies for ED visits and extended assessment and management composite APCs. The Subcommittee noted a need to further illuminate the structure, operations, and services provided by Type B EDs. The Subcommittee raised concerns that recovery audit contractor (RAC) examinations of hospital claims for inpatient services may result in increased volume of outpatient services, including observation. Dr. Ross said that members also discussed concerns about inconsistent interpretation of CMS payment policies for observation services by Medicare contractors and hoped CMS would work with contractors to improve consistency.

- **Recommendation**: The Panel recommends that CMS provide the Visits and Observation Subcommittee with analysis of the most common diagnoses and services associated with Type A and Type B ED visits at the next meeting of the APC Panel, including analysis by hospital-specific characteristics.

- **Recommendation**: The Panel recommends that CMS provide the Visits and Observation Subcommittee with analysis of CY 2009 claims data for clinic, ED (Type A and B), and extended assessment and management composite APCs at the next meeting of the Panel.

- **Recommendation**: The Panel recommends that CMS provide the Visits and Observation Subcommittee with continued analysis of observation services, as previously provided to the Panel, including data on frequency, length of stay, and common diagnoses, as well as RAC data on these subjects, if available.

- **Recommendation**: The Panel recommends that the work of the Visits and Observation Subcommittee continue.

APC ASSIGNMENT ISSUES

Radiofrequency Remodeling of the Bladder Neck

Overview

CMS staff member, LCDR Marjorie Baldo, said that for CY 2010, CMS proposes to continue to assign CPT code 0193T, *Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence*, to APC 0165, *Level IV Urinary and Anal Procedures*, with a proposed payment rate of about $1,353.

Presentation

Charles Carignan, M.D., of Novasys Medical, Inc., asked that CMS move CPT code 0193T to either APC 0202, *Level VII Female Reproductive Procedures*, or APC 0168, *Level II Urethral Procedures*, on the basis of better clinical and resource homogeneity (Presentation A). He described the use of his company's product, Renessa®, as a minimally invasive approach to treat stress urinary incontinence and noted that other procedures in APC 0165 are less complex and do not treat the underlying condition. He cautioned that insufficient payment for CPT code 0193T creates a barrier to Medicare beneficiaries' access to the procedure.

Discussion

Panel members discussed the clinical procedures assigned to the three APCs described and concluded that radiofrequency remodeling did not appear to require the same level of clinical resources as other procedures described in APCs 0202 or 0168.

- **Recommendation**: The Panel recommends that CPT code 0193T, *Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence*, remain in APC 0165, *Level IV Urinary and Anal Procedures*.

Low-Frequency, Non-Contact, Non-Thermal Ultrasound

Overview

CMS staff member Barry Levi said that CPT code 0183T, *Low-frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*, has been assigned to APC 0015, *Level III Debridement & Destruction*, with

a status indicator of "T," since its inception in CY 2008. (A status indicator of "T" means that the payment rate for the procedure will be reduced by 50 percent when it is billed with another procedure that is paid at an equal or higher payment rate.) From its OPPS CY 2008 claims data, CMS determined that the median cost of CPT code 0183T is approximately $72, based on 8,531 single claims out of a total of 12,752 claims. For CY 2010, CMS proposes to reassign CPT code 0183T to APC 0013, *Level II Debridement & Destruction*, which has a median cost of about $59. APC 0015 has a median cost of about $102.

Presentation

Pamela Unger of Celleration, Inc., explained the use of her company's non-contact ultrasound device in wound healing (Presentation B). She said that the number of claims CMS used to determine the median cost of CPT code 0183T does not correlate with her company's data, which estimate that over 2,600 Medicare beneficiaries received 12 treatments each of non-contact ultrasonography in the hospital outpatient department, which should have yielded over 31,000 Medicare OPPS claims. Ms. Unger outlined several reasons why she believed that CMS had inadequate data on which to determine the median cost of CPT code 0183T. She requested that CMS continue to assign CPT 0183T to APC 0015, where the actual costs would still be underpaid, but the underpayment would be less severe than if it were moved to APC 0013.

Discussion

Panel members noted that if Celleration succeeds in its application to the AMA to convert CPT 0183T from a Category III code to a Category I code, the data reported to CMS are likely to improve, thereby addressing some of the concerns raised by Ms. Unger. Others noted that the CMS proposal is based on a substantial number of claims, and that leaving CPT 0183T in APC 0015 would violate the two-times rule.

Reconfiguring APCs, Data, and Specific APC Assignments

Presentation

DeChane L. Dorsey, Esq., of the Advanced Medical Technology Association (AdvaMed) asked that CMS 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 C). She also asked that CMS make available to the public the data it uses to establish payment for packaged codes.

Ms. Dorsey asked that CMS ensure that hospitals are educated about the new cost center for implantable devices and that CMS implement it in a timely fashion. Ms. Dorsey asked that CMS exclude claims with the –FC modifier from ratesetting calculations.

Ms. Dorsey requested that CMS create two new composite APCs for cardiac resynchronization therapy (CRT): one for CRT with a defibrillator and one for CRT with a pacemaker. AdvaMed supports the request that CPT 0193T be reassigned to either APC 0202 or APC 0168. It also supports the request that CPT 0183T remain in APC 0015.

- **Recommendation:** The Panel recommends that CMS reconsider creating a new composite APC or group of composite APCs for cardiac resynchronization therapy (CRT) procedures.

Device-Related APCs and Packaging

Presentation

Thomas Novelli of the Medical Device Manufacturers Association (MDMA) voiced concern that over time, expanded packaging and bundling may lead to artificial reductions in the complexity of services provided, with corresponding reductions in payment (Presentation D). Mr. Novelli asked that CMS require complete and correct coding for packaged services and that it further study the effects of expanded packaging.

Mr. Novelli asked that CMS limit the reduction in payment rate for any device-dependent APC to no more than 10 percent in one year and study the claims for any APC facing a payment reduction of more than 10 percent. MDMA supports the request that CPT 0193T be reassigned to either APC 0202 or APC 0168.

Neurostimulator Implantation APCs

Overview

CMS staff member Carrie Bullock explained that when CMS adopted the current assignment of neurostimulator implantation procedure into three APCs, the Agency stated that creating separate APCs for the same procedure on the basis of whether a rechargeable or non-rechargeable device was implanted would not be consistent with the principles of a prospective payment system. However, CMS did agree that procedures that do not typically involve rechargeable devices should not be included in the same APC as procedures that could involve either rechargeable or non-rechargeable devices. As recommended by the Panel at its February 2009 meeting, for CY 2010, CMS proposes combining APC 0039, *Level I Implantation of Neurostimulator*, and APC 0222, *Level II Implantation of Neurostimulator*, into a single APC because the median costs of both APCs and their CPT codes were similar. Ms. Bullock said that the device costs also appear to be similar, as the median line-item cost for HCPCS C1820, *Generator, neurostimulator (implantable), with rechargeable battery and charging system*, was $9,636, and the median line-item cost for C1767, *Generator, neurostimulator (implantable), non-rechargeable*, was $9,606. She added that in no cases for CY 2010 did CMS propose to provide differential payment for procedures reported with the same HCPCS code on the basis of the type of device or any other packaged item used.

Presentation

John Hernandez, representing Boston Scientific, Cyberonics, Medtronic, and St. Jude Medical, said that in neurostimulator implantation, the device selected affects the complexity of the procedure and the resources required (Presentation E). The companies he spoke for jointly recommended that CMS adopt a three-level APC configuration for neurostimulator implantation procedures, constructed as follows: peripheral and spinal neurostimulator implantation procedures involving non-rechargeable devices assigned to Level 1; single array cranial neurostimulator implantation procedures involving non-rechargeable devices assigned to Level 2; and dual array cranial neurostimulator implantation procedures (rechargeable and non-rechargeable) and any neurostimulator implantation procedure involving rechargeable devices assigned to Level 3. Mr. Hernandez added that, using CMS data, his company saw a $6,500 difference between the costs of rechargeable and non-rechargeable devices.

Discussion

Richard North, M.D., stressed that the biggest difference between the procedures, from a clinical perspective, is that the use of the rechargeable device eliminates the need for some patients to return frequently for surgery to replace non-rechargeable devices, which can fail in as little as six weeks but may last a few years, whereas the rechargeable device lasts much longer. Christine Jackson asked whether CMS' median line-item cost data include –FB modifier claims (in which no cost is assigned to the device code). Mr. Hernandez said that a published economic analysis found that use of the rechargeable device provided substantial savings to Medicare but offered no cost savings to hospitals, which lose money because they no longer perform so many device replacement procedures. Panel members agreed that the issues involved were complex and decided to table the discussion until the following day.

Resuming the discussion, Ms. Bullock said that no –FB modifiers (device provided at no cost or with full credit) appeared on claims that were included in the median line-item cost calculations, and approximately 10 claims with –FC modifiers (partial credit of 50 percent or more) were included, concluding that no cost and partial credit cases would have a negligible impact on the line-item device costs determined by CMS. She added that the figures she provided were median costs and provided CMS determinations of the cost of the devices at the 25^{th} and 75^{th} cost percentiles.

Ms. Bullock noted that in CY 2003, CMS created a G code to enable hospitals to specifically bill for procedures involving drug-eluting coronary stents while using a CPT code to bill for procedures involving non-drug-eluting stents, and the codes were assigned to different APCs. However, at the time, CMS indicated that the decision to allow two APCs for one procedure on the basis of the choice of device was an exceptional case in which CMS was unable to assign pass-through status to the new technology. To do so again would require an extremely unusual situation in which CMS has no other viable options to pay appropriately for a potentially revolutionary device.

Bonnie Handke of Medtronic said that she evaluated the same CMS claims data and found different medians, but she could not explain the discrepancy. She cited median costs of about $13,000 for non-rechargeable devices and about $19,000 for rechargeable devices. Mr. Hernandez felt that some hospitals may bill incorrectly for the neurostimulator devices, especially for encounters in which only the external recharger is replaced. Yvette Marcan of Health First said that her experience with her own hospital's billing procedures leads her to believe hospitals may report the wrong device codes for rechargeable devices. Stan Jackson of Cyberonics reiterated the proposal made by his company in February to the Panel that cranial and spinal procedures be assigned to one APC and peripheral and gastric procedures to another. Ms. Rinkle said that the CMS approach to charge compression distorts cost data. Ann Marie Williams offered a personal insight, noting that her husband received a non-rechargeable neurostimulator device to treat his Parkinson's disease, and the decision to use the non-rechargeable device was made by the hospital on the basis of cost. She spoke in favor of the devices for patients and said that a rechargeable device would save the hospital and patients much more money in immediate and long-term costs.

Panel member Randall Oyer, M.D., said that he believed the high cost of the device was related to the manufacturers' charges for the battery and should not be confused with resource allocation considerations.

- **Recommendation**: The Panel supports the neurostimulator generator implantation APC configurations for CY 2010 proposed by CMS: CPT code 61885, *Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array*; CPT code 64590, *Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling*; and CPT code 63685, *Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays* in APC 0039, *Level I Implantation of Neurostimulator Generator*, and CPT code 61886, *Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays*, in APC 0315, *Level II Implantation of Neurostimulator Generator*.

Cholangioscopy

Overview

Mr. Levi said that CPT code 43273, *Endoscopic cannulation of papilla with direct visualization of common bile duct(s) and/or pancreatic ducts (List separately in addition to code[s] for primary procedure)*, was assigned to APC 0151, *Endoscopic Retrograde Cholangio-Pancreatography (ERCP)*, in 2009, with a status indicator of "T." CPT instructions for CPT code 43273 are to use it in conjunction with ERCP procedure codes. For CY 2010, CMS proposes that CPT 43273 remain in APC 0151. Mr. Levi added that the APC placement of CPT code 43273 is consistent with CMS policies for assigning new CPT codes and that the assignment of a new CPT code is based upon a number of sources of information.

Presentation

Samuel Giday, M.D., of Johns Hopkins Hospital, said that cholangioscopy performed in conjunction with ERCP enables direct visualization, which improves detection of abnormalities (Presentation F). He said that it facilitates diagnosis, altering patient management decisions and improving patient outcomes. Maria Stewart of Boston Scientific asked that CMS change the name of APC 0151 from *Retrograde Cholangio-Pancreatography (ERCP)* to "Level I Hepatobiliary Procedures" and change the name of APC 0152, from *Level I Percutaneous Abdominal and Biliary Procedures*, to "Level II Hepatobiliary Procedures." Ms. Stewart also asked that CMS reassign CPT code 43273 to APC 0152. She said that CPT code 43273 fits better in APC 0152 because it requires more clinical effort and resources than procedures in APC 0151 and because the procedure adds to the procedure time for ERCP.

Discussion

Panel member Beverly Khnie Philip, M.D., pointed out that other procedures in APC 0151 also include special techniquess beyond ERCP itself, so cholangioscopy is not exceptional in that regard. Panel member Dr. Ross noted that all the procedures currently in APC 0152 are percutaneous procedures, and an endoscopic procedure would not fit well there.

- **Recommendation**: The Panel recommends that CPT code 43273, *Endoscopic cannulation of papilla with direct visualization of common bile duct(s) (List separately in addition to code[s] for primary procedure)*, remain in APC 0151, *Endoscopic Retrograde Cholangio-Pancreatography (ERCP)*.

Electronic Brachytherapy

Overview

LCDR Baldo said that CPT code 0182T, *High dose rate electronic brachytherapy, per fraction*, was implemented in July 2007 and placed in New Technology APC 1519, *Level IXX ($1,700–$1,800)*, through 2009. For CY 2010, CMS proposes to reassign CPT code 0182T to APC 0313, *Brachytherapy*, which has a median cost of $753 and a proposed payment rate of about $747. LCDR Baldo noted that the procedure does not appear to be performed frequently on Medicare beneficiaries. CMS' ratesetting is based on 21 claims from six months of 2007 (July–December) and fewer than 200 claims from CY 2008. As of January 2010, CPT code 0182T will have been assigned to New Technology APC 1519 for two and a half years.

Presentation

Jeff Rospert of Carl Zeiss Meditec said that CPT code 0182T describes both single-fraction and multi-fraction electronic brachytherapy; John McGinnis, M.D., said that he believes most of the claims on which CMS is basing its proposed rate are for multi-fraction electronic brachytherapy (Presentation G). Dr. McGinnis asked that CMS keep CPT code 0182T in APC 1519 until it has at least two full years of claims data on the code, and he proposed working with CMS to identify more single claims. He also added that, unlike the conventional brachytherapy procedures that make up APC 0313 now, for which brachytherapy sources are all paid separately, the brachytherapy source for electronic brachytherapy is packaged with the procedure payment.

Discussion

Panel member Dr. Zwolak said that leaving CPT code 0182T in APC 1519 would require CMS to pay for electronic brachytherapy at three times the median cost it has identified in its claims. He added that the problem of distinguishing single- from multi-fraction electronic brachytherapy is a coding problem that would not be resolved by additional claims data. Panel member Michael Mills, Ph.D., added that the device is reusable, and the brachytherapy source is not a huge portion of the cost.

Skin Substitute Procedures

Overview

LCDR Baldo explained the history of the CPT codes and APC assignments for three skin repair products. For CY 2010, CMS proposes to maintain the following APC assignments for the application procedures and to continue paying separately for the associated biological products:

APC 0134, *Level II Skin Repair*:

- HCPCS code 15340, *Tissue cultured allogeneic skin substitute; first 25 sq cm or less* (Apligraf)
- HCPCS code 15341, *Tissue cultured allogeneic skin substitute; each additional 25 sq cm* (Apligraf)
- 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* (Dermagraft)
- 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)* (Dermagraft)

APC 0135, *Level III Skin Repair*

- HCPCS code 15430, *Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children* (Oasis)
- 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)* (Oasis)

Presentation

Antonio Montecalvo and David Hurley of Organogenesis pointed out that site preparation and debridement are paid under a separate CPT code when Dermagraft is applied, but those procedures are not paid separately for procedures involving Apligraf or Oasis; therefore, a financial incentive favoring Dermagraft is created. (Presentation H). They asked that CMS reassign Apligraf (CPT codes 15340 and 15341) to APC 0135.

Discussion

LCDR Baldo clarified that all three application procedures had been assigned to one APC, but claims data showed a violation of the two-times rule, and the Oasis application procedures were moved to a higher-paying APC. Panel members discussed whether the size specifications in the HCPCS descriptors referred to the size of the wound or the amount of product used. Panel members voted to recommend that CMS reevaluate its claims data and combine the Apligraf and Oasis application procedures into one APC (either 0134 or 0135, whichever CMS deems appropriate). However, on further consideration, the Panel rescinded that recommendation because it could create an incentive to bill for multiple procedures using the smaller-sized product (Apligraf) rather than bill once using the larger-sized product (Oasis).

- **Recommendation**: The Panel requests that CMS provide data at the next Panel meeting on the frequency of primary and add-on CPT codes billed for Apligraf, Oasis, and Dermagraft application in order to assess the apparent variability in billing for the application of these products. In addition, the Panel requests median cost data for site preparation and debridement that may be separately reported in preparation for application of Dermagraft.

Allogeneic Stem Cell Transplantation

Overview

Ms. Bullock said that CMS recently stated that autologous stem cell transplantation may be performed on either an inpatient or outpatient basis, but based on its understanding that allogeneic stem cell transplantation is always performed on an inpatient basis, all services related to acquiring stem cells from a healthy donor (whether performed inpatient or outpatient) are paid through Medicare's Inpatient Prospective Payment System (IPPS). CMS believes its guidance reflects current clinical practices for allogeneic stem cell transplantation for Medicare beneficiaries. Therefore, for CY 2010, CMS proposes to revise the status indicator assignment for CPT code 38205, *Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic*, from "S" to "E" to reflect that payment for stem cell harvesting is made through the IPPS. CMS further proposes to change the status indicator for CPT code 38240, *Bone marrow or blood-derived peripheral stem cell transplantation; allogenic*, and CPT code 38242, *Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions*, from "S" to "C" to reflect that these codes are payable by Medicare as inpatient procedures only.

Presentation

Willis Navarro, M.D., and Michael Boo of the National Marrow Donor Program (NMDP) said that reduced-intensity conditioning regimens have made allogeneic hematopoietic cell transplantation more feasible on an outpatient basis (Presentation I). Dr. Navarro said that the outpatient approach decreases the overall cost, improves patient comfort, decreases the risk of nosocomial infection, and allows hospitals to optimize their use of beds and resources. The CMS proposal would limit

reimbursement for donor cell harvesting by tying it to an inpatient procedure, making it not viable financially. Dr. Navarro added that older patients generally tolerate the reduced-intensity conditioning regimens better than full-scale regimens, and the decreased toxicity makes treatment safe and effective in the outpatient setting. He asked that CMS maintain the current APC assignments and status indicators for CPT codes 38205, 38240, and 38242. Jugna Shah of the Alliance of Dedicated Cancer Centers (ADCC) said her organization supports NMDP's request (Presentation J).

Discussion

Panel member Patrick Grusenmeyer, Sc.D., F.A.C.H., said that CMS is mistaken in its assessment that current clinical practice is to perform allogeneic stem cell transplantation only on an inpatient basis.

- **Recommendation:** The Panel recommends that CMS maintain the CY 2009 APC assignments and status indicators for the following allogeneic stem cell transplantation procedures: CPT code 38205, *Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic*; and CPT code 38242, *Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions*, in APC 0111, *Blood Product Exchange*, and CPT code 38240, *Bone marrow or blood-derived peripheral stem cell transplantation; allogenic*, in APC 0112, *Apheresis and Stem Cell Procedures*. Therefore, the Panel recommends that CPT codes 38205, 38242, and 38240 not be placed on the inpatient list.

DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD

Radioimmunotherapy

Overview

CMS staff member Alpha-Banu Huq said that for CY 2009, CMS proposes to continue to package payment for diagnostic radiopharmaceuticals into payment for their associated nuclear medicine procedures. CMS also proposes to pay for pass-through diagnostic and therapeutic radiopharmaceuticals using the ASP methodology. For CY 2010, CMS proposes to continue paying separately (at a proposed rate of ASP plus 4 percent) for therapeutic radiopharmaceuticals with per-day costs above the packaging threshold, which CMS proposes raising from $60 per day to $65 per day.

Ms. Huq noted that CMS proposes to collect ASP data on a patient-specific dose or patient-ready form to accurately calculate the ASP for a given therapeutic radiopharmaceutical HCPCS code. If ASP data are not available, CMS would use mean unit costs derived from CY 2008 hospital claims. For CY 2010, CMS proposes a single payment (based either on ASP or, if ASP is unavailable, mean unit cost) for radiopharmaceuticals that includes acquisition, pharmacy handling, and compounding costs. Hospitals have been instructed to include these costs in their charge for the radiopharmaceutical. Ms. Huq added that radioimmunotherapy using BEXXAR® requires administration of unlabeled tositumomab, which receives a bundled payment for the product and its administration.

Presentation

Marci Mutti of GlaxoSmithKline, which manufactures BEXXAR, said that the BEXXAR therapeutic regimen differs from traditional chemotherapy in that the entire treatment takes place over seven to 14 days in several steps that comprise a single therapeutic intervention as opposed to multiple cycles of chemotherapy given over several months (Presentation K). She said that the current CMS payment methodology misclassifies therapeutic components of the BEXXAR regimen as diagnostic radiopharmaceuticals or supplies and therefore underpays significantly, resulting in decreased access for beneficiaries.

Regarding the proposal to collect ASP data in a patient-specific dose or patient-ready form, Ms. Mutti asked that CMS allow manufacturers to supply ASP information for the products they provide and create a HCPCS code for hospitals to report their pharmacy handling and compounding costs. If the proposal is finalized, Ms. Mutti said, she requested open dialogue with CMS on whether her company would be able to report the data as requested and a six-month delay in implementation of the new methodology to ease the administrative burden.

Discussion

Denise Merlino of the Society for Nuclear Medicine (SNM) said that her organization supports the suggestion that CMS work with individual manufacturers to determine how best to report ASP data on diagnostic and therapeutic radiopharmaceuticals. However, her organization does not support the concept of separate HCPCS codes for reporting the handling costs of radiopharmaceuticals. While SNM believes that diagnostic and therapeutic radiopharmaceuticals should be paid separately, said Ms. Merlino, it does not agree with Ms. Mutti's characterization that the dosimetric dose of the BEXXAR regimen is therapeutic, not diagnostic.

Panel member Dr. Oyer felt that the BEXXAR regimen is an important treatment that is underutilized not because of billing or coding problems but because of the high cost of the radiopharmaceutical. He maintained that the dosimetric dose is not therapeutic. Ms. Merlino said that SNM will submit comments on composite APCs for radiopharmaceuticals but remains very concerned about the inability to identify the real costs of tumor imaging because of packaging of diagnostic radiopharmaceuticals. Ann Marie Williams added that there is no way to calculate the ASP for the patient-ready form of some radiopharmaceuticals that accurately incorporates the cost of disposing of excess materials.

- **Recommendation**: The Panel applauds CMS for its effort to date to tailor the resource-based APC system to facilitate appropriate payment for diagnostic and therapeutic radiopharmaceuticals. The Panel recommends that CMS continue its dialogue with professional societies, vendors, and other stakeholders to improve the accuracy of APC payments for these complex items and services, including consideration of developing composite APCs.

Drug Packaging

Overview

Ms. Huq described CMS' packaging methodology and said that, for CY 2010, CMS proposes to increase the packaging threshold to $65 per day (i.e., payment for drugs that cost less than or equal to $65 per day is packaged into payment for their associated procedures). Since CY 2005, certain 5-HT3 antiemetics have been exempt from packaging, regardless of their per day cost, to ensure that Medicare beneficiaries have sufficient access to these drugs. However, despite significant changes in the payment for some of these antiemetics, CMS has seen no changes in billing patterns for 5-HT3 antiemetics. Therefore, for CY 2010, CMS proposes to apply the standard packaging methodology to all 5-HT3 antiemetics, which would result in packaged payment for all 5-HT3 antiemetics except palonosetron hydrochloride.

Presentation

Mark Coin of SanofiAventis reiterated his company's request that CMS pay separately for all anticoagulant therapies with unique HCPCS Level II codes, in addition to payment associated for their administration (Presentation L). He noted that CMS has not yet completed an analysis of the effects of packaging on beneficiary access. In addition, he called on CMS to work with hospitals to better document all treatments that utilize drugs described by specific HCPCS codes. He asked that CMS not package the 5-HT3 antiemetic drugs, pointing out that CMS did not provide data to support its contention that prescription patterns for these drugs have not been sensitive to price fluctuations.

Discussion

Panel members were split on whether CMS payment drives prescription patterns, with members citing contrasting experiences in their own institutions. Panel member Dr. Zwolak noted that as the packaging threshold increases, CMS' ability to track the use and costs of specific drugs will diminish. Laurel Todd of the Biotechnology Industry Organization (BIO) said that her organization suggests that CMS pay separately for all drugs and biologicals for which there is a separate HCPCS code. Panel member Dr. Rawson added that with higher packaging thresholds, CMS is likely to split payments for drugs that are members of the same class into packaged and unpackaged payments, a byproduct of prospective payment that cannot easily be addressed. Matthew Farber of the Association of Community Cancer Centers (ACCC) suggested that CMS either take up BIO's suggestion or freeze the packaging threshold at the current level. He added that ACCC asks that CMS continue to pay separately for all 5-HT3 antiemetics.

Ms. Rinkle also asked that CMS freeze the packaging threshold; she further suggested CMS require all hospitals to report HCPCS J codes for all drugs. Panel members noted that CMS strongly encourages hospitals to report J codes for all drugs but they were not willing to recommend that CMS require such reporting because of the associated hospital administrative burden. Denise Williams of Vanguard Health Systems said that Medicare contractors often require hospitals to remove J codes for packaged drugs before they will submit claims to CMS. Ms. Shah supported that contention.

- **Recommendation**: The Panel recommends that when CMS changes the dollar amount of the drug packaging threshold and determines that some drugs within a single therapeutic class fall on either side of the packaging threshold, CMS consider packaging all of the drugs within that class on the basis of feedback from providers, the APC Panel, and stakeholders.

Drugs, Biologicals, and Pharmacy Overhead

Overview

CMS staff member Rebecca Cole said that for CY 2010, CMS proposes a variation of the ASP methodology for determining payment rates that redistributes some portion of the total cost for packaged drugs and biologicals with an ASP to separately payable drugs and biologicals with an ASP as acquisition and pharmacy overhead and handling costs. The revised methodology would pay for separately payable drugs without pass-through status at a rate of ASP plus 4 percent.

The proposal partially reflects the recommendation made by the APC Panel at its February 2009 meeting that CMS package the costs of all drugs that are not paid separately at ASP plus 6 percent and use the difference between these costs and CMS' costs derived from charges to create a pool that funds payment for pharmacy services. The Panel also recommended that if CMS were not able to pay for all separately payable drugs at a rate of ASP plus 6 percent, that it exclude 340B hospitals from its ASP ratesetting calculations and pay 340B hospitals at the same rate as all other hospitals.

Using the standard ASP methodology, CMS determined that payment rates for separately payable drugs would be ASP minus 2 percent and the payment rate for packaged drugs would be ASP plus 247 percent. Because both rates appeared unlikely to represent real costs, CMS proposed to redistribute $150 million of pharmacy overhead cost currently included in the cost for packaged drugs into payment for separately payable drugs.

CMS estimates that the cost of packaged drugs with an ASP includes about $395 million in total overhead cost. Ms. Cole said that CMS concluded that about one third to one half of that total ($150 million) is a function of both hospital charging practices and CMS' choice of annual drug packaging threshold. The proposed redistribution of cost from packaged drugs with an ASP to separately payable drugs with an ASP would result in a payment rate of ASP plus 4 percent for separately payable drugs and a 27-percent reduction in the cost of packaged drugs, thereby maintaining payment for separately payable drugs at current levels.

CMS did not propose to exclude 340B hospital data from ratesetting for the ASP methodology because doing so would result in an inaccurate representation of the total cost of drugs for all hospitals in CMS claims data.

Presentation

The Pharmacy Stakeholder Group—represented by Ernest Anderson Jr., M.S., R.Ph., Immediate Past President of ACCC; Ms. Todd of BIO; Justine Coffey of the American Society of Health-System Pharmacists; Jay Greissing of the Plasma Protein Therapeutics Association; Ms. Shah of ADCC; and Stuart Yael Gordon of Safety Net Hospitals for Pharmacy Access—provided a joint presentation responding to the proposal for CY 2019 (Presentation R). Each presenter from the Pharmacy Stakeholder Group also provided a written presentation (Presentations M–Q).

Mr. Anderson said that the group appreciates that CMS recognizes the flaws in the current methodology and that CMS agrees with the need to reallocate a portion of pharmacy overhead costs from packaged to separately payable drugs. However, the proposed $150 million redistribution is insufficient to cover hospital costs. The group believes that CMS should pay at a rate of ASP plus 6 percent for drugs to establish parity across sites of service between hospital outpatient departments and physicians' offices. Mr. Anderson reiterated the request that CMS exclude data from 340B hospitals from drug payment calculations.

Ms. Todd said that Federal statute mandates that CMS calculate average acquisition costs for drugs and that the current method is not an adequate proxy. She presented calculations made using July 2008 ASP data because those data better align with underlying claims data than the April 2009 ASP data that were used by the CMS in the CY 2010 proposed rule. Ms. Todd said that the group believes CMS' estimate of $395 million in pharmacy overhead costs is wrong. She added that the CMS proposal would pay about 12.7 percent more than hospital drug acquisition cost as measured by ASP, while the Medicare Payment Advisory Commission (MedPAC) estimated that the magnitude of hospital pharmacy cost is about one third to one half of the acquisition cost of drugs. Finally, the CMS methodology does not account for packaged drugs without HCPCS codes or ASP data that have significant pharmacy handling costs that should be considered for redistribution.

Ms. Shah reiterated Ms. Todd's points. Her calculations indicate that the category of packaged drugs without ASP data includes both drugs that have no HCPCS codes and drugs for which HCPCS codes are not reported. She reminded the Panel that some Medicare contractors return to providers for correction claims that report packaged drugs with HCPCS codes under revenue code 0250.

Mr. Greissing pointed out that including data from 340B hospitals is a growing problem, as participation in the 340B program has increased dramatically over the past decade and is expected to climb further, especially with pending health care reform legislation. Under CMS' current ASP-plus methodology, excluding 340B hospital data from ratesetting would yield a payment rate of ASP plus 3 percent. Mr. Gordon emphasized that the 340B program was not intended to harm other hospitals' ability to provide care by reducing Medicare reimbursement rates. Reducing Medicare payments to 340B hospitals for separately payable drugs would undermine the purpose of the 340B program to ensure that hospitals have funds available to reach more patients. Ms. Coffey recapped the recommendations of the Pharmacy Stakeholders Group.

Discussion

Ms. Shah acknowledged that the lack of reported data on drugs contributes to confusion about pharmacy overhead costs. Jennifer Artigue said that hospitals might be more inclined to report drug data if they saw that it affected payment rates. Beth Roberts of ACCC pointed out that the data are easily manipulated and reconfigured, so questions remain about how much of the pool of money in the packaged drug cost should be reallocated. Dr. Rawson raised concerns that none of the methods suggested could provide the long-term stability needed to ensure drugs are paid at a reasonable rate in years to come. Ms. Todd and Ms. Roberts both said that Congress contemplated that concern and suggested CMS pay at a rate of ASP plus 6 percent if it had no other firm basis for the rate. John Settlemyer of the Provider's Roundtable suggested fixing payment at ASP plus 6 percent until all applicable HCPCS codes are appropriately reported on claims.

Panel member Agatha L. Nolen, M.S., D.Ph., noted the complexities of revising the methodology, pointing out that paying at a rate of ASP plus 6 percent for separately payable drugs would mean redistributing another $50 million from the pharmacy overhead pool of $395 million. Ms. Shah said that both ASP data and claims data constantly fluctuate. Panel member Dr. Philip said that stakeholders and providers had some responsibility to negotiate with pharmaceutical manufacturers to get better prices. Panel members, Drs. Munger and Rawson, wondered how much of pharmacy overhead costs are fixed and how much vary. Dr. Hambrick noted that CMS has evaluated applicable Federal statutes and determined that it is not required to pay at a rate of ASP plus 6 percent, as some commenters claim.

Given the complexity of the system and the number of variables involved, the Panel members initially voted to recommend that CMS pay for all separately payable drugs at a rate of ASP plus 6 percent. After further consideration, the Panel amended its recommendation as follows:

- **Recommendation**: The Panel recommends that CMS pay for all separately payable drugs at a rate of ASP plus 6 percent. To provide payment at this level, which exceeds the cost of separately payable drugs in the claims data, the Panel recommends that CMS redistribute costs from packaged drugs to separately payable drugs, as outlined in the NPRM for CY 2010.

Panel members also called for continued analysis by CMS of the impact of proposed payment rates. Panel member Dr. Mills asked that CMS provide data on drugs with and without HCPCS numbers, if possible.

- **Recommendation**: The Panel requests that CMS analyze the impact on different classes of hospitals of paying ASP plus 6 percent for separately payable drugs compared with CY 2009 payment at ASP plus 4 percent.

- **Recommendation**: The Panel requests that CMS provide an impact analysis of payment for separately payable drugs at ASP plus 6 percent on payment rates for other services that use packaged drugs compared with CY 2009 payment at ASP plus 4 percent.

- **Recommendation**: The Panel recommends that CMS and stakeholders continue to refine their analysis of payment for drugs, biologicals, and radiopharmaceuticals to assess the infrastructure costs associated with the preparation and handling of these products.

CLOSING

Panel members reviewed the collective 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 4:30 p.m. on Thursday, August 6, 2009.

Appendix A

AGENDA

August 5 – 6, 2009

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

DAY 1 - Wednesday, August 5, 2009

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
Welcome and Call to Order – E. L. Hambrick, M.D., J.D., Chair, APC Panel
Opening Remarks – Amy Bassano
Director, Hospital and Ambulatory Policy Group

01:15 **Panel Organization and Housekeeping Issues**
E. L. Hambrick, M.D., J.D., Chair, APC Panel

01:30 **CMS-1414-P:** Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates, et al., **Federal Register**

1. **Overview –** Carol Bazell, M.D., M.P.H., Director, Division of Outpatient Care (DOC)
2. Discussion
3. Panel's Comments

TAB

01:45 **DATA**

1. **Overview** – Anita Heygster, CMS Staff
   – Erick Chuang, M.S., CMS Staff
2. **Data Subcommittee's Report –** Kim Allan Williams, M.D., F.A.C.C., F.A.B.C., Chair

1. Discussion
2. Panel's Comments/Recommendations

02:15 **PACKAGING**

1. **Overview** – Gift Tee, M.P.H., CMS Staff
2. **Packaging Subcommittee's Report –** James V. Rawson, M.D., Chair
3. Discussion
4. Panel's Comments/Recommendations

02:35 **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

02:55 *Break*

03:15 **APC ISSUES**

Public Presentations

RADIOFREQUENCY REMODELING OF BLADDER NECK

1. **Overview** – LCDR Marjorie Baldo, USPHS, M.S., CMS Staff
2. **Presentation** – Dr. Charles Carignan **A**
   Novasys Medical Inc.
3. Discussion
4. Panel's Comments/ Recommendations

LOW FREQUENCY, NON-CONTACT, NON-THERMAL ULTRASOUND

1. **Overview** – Barry Levi, M.B.A., CMS Staff
2. **Presentation** – Pamela Unger, Celleration **B**
3. Discussion
4. Panel's Comments/ Recommendations

RECONFIGURING APCS, DATA, AND SPECIFIC APC ASSIGNMENTS

1. **Presentation** – DeChane L. Dorsey, Esq. **C**
   Advanced Medical Technology Association
2. Discussion
3. Panel's Comments/Recommendations

APC ISSUES (*continued)*
Public Presentations
DEVICE-RELATED APCS AND PACKAGING

1. **Presentation** – Thomas C. Novelli **D**
   Medical Device Manufacturers Association
2. Discussion
3. Panel's Comments/Recommendations

NEUROSTIMULATOR IMPLANTATION

1. **Overview** – Carrie Bullock, M.H.S., CMS Staff
2. **Presentation** – John Hernandez **E**
   Cyberonics, Boston Scientific, Medtronic, and St. Jude
3. Discussion
4. Panel's Comments/Recommendations

CHOLANGIOSCOPY

1. **Overview** – Barry Levi, M.B.A., CMS Staff
2. **Presentation** – Maria Stewart **F**
   – Dr. Samuel Giday
   Boston Scientific
3. Discussion
4. Panel's Comments/ Recommendations

05:00 **Adjourn**

AGENDA

August 5 – 6, 2009

Advisory Panel on Ambulatory Payment Classification (APC) Groups' Meeting

DAY 2 - Thursday, August 6, 2009 TAB

Public registrants may enter the CMS Central Office Building <u>after</u> 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 **APC ISSUES (*continued*)**
Public Presentations

ELECTRONIC BRACHYTHERAPY

1. **Overview** – LCDR Marjorie Baldo, USPHS, M.S., CMS Staff
2. **Presentation** – John McGinnis, M.D., Arnold & Porter, LLP **G**
   – Jeff Rospect, Carl Zeiss Meditec
3. Discussion
4. Panel's Comments/Recommendations

SKIN SUBSTITUTE PROCEDURES

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

APC ISSUES (*continued*)
Public Presentations
ALLOGENEIC STEM CELL TRANSPLANTATION

1. **Overview** – Carrie Bullock, M.H.S., CMS Staff
2. **Presentations** – Dr. Willis Navarro and Michael Boo **I**
   National Marrow Donor Program
   – Jugna Shah, Consultant **J**
   Alliance of Dedicated Cancer Centers (ADCC)
3. Discussion
4. Panel's Comments/Recommendations

10:30 *Break*

10:45 **DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD**
Public Presentations
RADIOIMMUNOTHERAPY

1. **Overview** – Rebecca Cole, M.S., CMS Staff
   – Alpha-Banu Huq, M.P.A., CMS Staff
2. **Presentation** – Marci Mutti, GlaxoSmithKline **K**
3. Discussion
4. Panel's Comments/Recommendations

DRUG PACKAGING

1. **Overview** – Rebecca Cole, M.S., CMS Staff
   – Alpha-Banu Huq, M.P.A., CMS Staff
2. **Presentation** – Marc Coin, SanofiAventis US **L**
3. Discussion
4. Panel's Comments/Recommendations

DRUGS & PHARMACY OVERHEAD
Public Presentations

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

11:45 *Lunch*

1:00 **DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND PHARMACY OVERHEAD (*continued*)**
DRUGS & PHARMACY OVERHEAD (*continued*)
Public Presentations

2. **Presentations**
   - Justine Coffey **M**
     American Society of Health-System Pharmacists (ASHSP)
   - Laurel Todd **N**
     Biotechnology Industry Organization (BIO)
   - Ernest R. Anderson, Jr., M.S., R.Ph. **O**
     Caritas Christi Health Care System (Caritas)
   - Jugna Shah, Consultant, ADCC **P**
   - Jay Greissing **Q**
     Plasma Protein Therapeutics Association **(**PPTA)

   Pharmacy Stakeholders **R**
   - Ernest R. Anderson, Jr., M.S., R.Ph., Caritas
   - Justine Coffey, ASHSP
   - Jay Greissing, PPTA
   - Jugna Shah, Consultant, ADCC
   - Laurel Todd, BIO
   - Stuart Yael Gordon
     Safety Net Hospitals for Pharmacy Access

3. Discussion
4. Panel's Comments/Recommendations

02:15 *Break* (Cumulative list of Panel's recommendations will be compiled.)

03:00 **Closing**

1. Summary of the Panel's Recommendations for 2010
2. Discussion
3. Final Remarks

04:00 **Adjourn**

NOTE: There will be no meeting tomorrow, Friday, August 7, 2009.

Appendix B

Advisory Panel on Ambulatory Payment Classification (APC) Groups
August 5–6, 2009

Recommendations

APC Placement Issues

1. The Panel recommends that CPT code 0193T, *Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence*, remain in APC 0165, *Level IV Urinary and Anal Procedures*.

2. The Panel recommends that CPT code 43273, *Endoscopic cannulation of papilla with direct visualization of common bile duct(s) (List separately in addition to code[s] for primary procedure)*, remain in APC 0151, *Endoscopic Retrograde Cholangio-Pancreatography (ERCP).*

3. The Panel recommends that CMS reconsider creating a new composite APC or group of composite APCs for cardiac resynchronization therapy procedures.

4. The Panel supports the neurostimulator generator implantation APC configurations for calendar year 2010 proposed by CMS: CPT code 61885, *Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array*; CPT code 64590, *Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling*; and CPT code 63685, *Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays*, in APC 0039, Level I Implantation of Neurostimulator Generator; and CPT code 61886, *Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays*, in APC 0315, Level II *Implantation of Neurostimulator Generator.*

5. The Panel requests that CMS provide data at the next Panel meeting on the frequency of primary and add-on CPT codes billed for Apligraf, Oasis, and Dermagraft application in order to assess the apparent variability in billing for the application of these products. In addition, the Panel requests median cost data for site preparation and debridement that may be separately reported in preparation for application of Dermagraft.

6. The Panel recommends that CMS maintain the calendar year 2009 APC assignments and status indicators for the following allogeneic stem cell transplantation procedures: CPT code 38205, *Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic*; and CPT code 38242, *Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions,* in APC 0111, Blood Product Exchange, and CPT code 38240, *Bone marrow or blood-derived peripheral stem cell transplantation; allogenic,* in APC 0112, *Apheresis and Stem Cell Procedures*. Therefore, the Panel recommends that CPT codes 38205, 38242, and 38240 not be placed on the inpatient list.

Data Issues

7. The Panel recommends that the work of the Data Subcommittee continue.

Packaging Issues

8. The Panel recommends that CMS submit to the Packaging Subcommittee, for its ongoing review, 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.

9. The Panel recommends that when CMS changes the dollar amount of the drug packaging threshold and determines that some drugs within a single therapeutic class fall on either side of the packaging threshold, CMS consider packaging all of the drugs within that class on the basis of feedback from providers, the APC Panel, and stakeholders.

10. The Panel recommends that CMS continue to study the impact of increased packaging on beneficiaries.

11. The Panel recommends that the work of the Packaging Subcommittee continue.

Visits and Observation Issues

12. The Panel recommends that CMS provide the Visits and Observation Subcommittee with analysis of the most common diagnoses and services associated with Type A and Type B emergency department (ED) visits at the next meeting of the APC Panel, including analysis by hospital-specific characteristics.

13. The Panel recommends that CMS provide the Visits and Observation Subcommittee with analysis of calendar year 2009 claims data for clinic, ED (Type A and B), and extended assessment and management composite APCs at the next meeting of the Panel.

14. The Panel recommends that CMS provide the Visits and Observation Subcommittee with continued analysis of observation services, as previously provided to the Panel, including data on frequency, length of stay, and common diagnoses, as well as recovery audit contractor (RAC) data on these subjects if available.

15. The Panel recommends that the work of the Visits and Observation Subcommittee continue.

Drugs, Biologicals, Radiopharmaceuticals, and Pharmacy Overhead

16. The Panel applauds CMS for its effort to date to tailor the resource-based APC system to facilitate appropriate payment for diagnostic and therapeutic radiopharmaceuticals. The Panel recommends that CMS continue its dialogue with professional societies, vendors, and other stakeholders to improve the accuracy of APC payments for these complex items and services, including consideration of developing composite APCs.

17. The Panel recommends that CMS pay for all separately payable drugs at a rate of the average sales price (ASP) plus 6 percent. To provide payment at this level, which exceeds the cost of separately payable drugs in the claims data, the Panel recommends that CMS redistribute costs from packaged drugs to separately payable drugs, as outlined in the Notice of Proposed Rulemaking for calendar year 2010.

18. The Panel requests that CMS analyze the impact on different classes of hospitals of paying ASP plus 6 percent for separately payable drugs compared with calendar year 2009 payment at ASP plus 4 percent.

19. The Panel requests that CMS provide an impact analysis of payment for separately payable drugs at ASP plus 6 percent on payment rates for other services that use packaged drugs compared with calendar year 2009 payment at ASP plus 4 percent.

20. The Panel recommends that CMS and stakeholders continue to refine their analysis of payment for drugs, biologicals, and radiopharmaceuticals to assess the infrastructure costs associated with the preparation and handling of these products.

Appendix C

PRESENTATIONS

The following organizations provided written testimony for the Advisory Panel on Ambulatory Payment Classification Groups meeting August 5–6, 2009:

Presentation A:	Novasys Medical, Inc.
Presentation B:	Celleration, Inc.
Presentation C:	Advance Medical Technology Association
Presentation D:	Medical Device Manufacturers Association
Presentation E:	Cyberonics, Boston Scientific, Medtronic, and St. Jude Medical
Presentation F:	Boston Scientific Corp.
Presentation G:	Carl Zeiss Meditec
Presentation H:	Organogenesis
Presentation I:	National Marrow Donor Program
Presentation J:	Alliance of Dedicated Cancer Centers
Presentation K:	GlaxoSmithKline
Presentation L:	SanofiAventis
Presentation M:	American Society of Health-System Pharmacists
Presentation N:	Biotechnology Industry Organization
Presentation O:	Association of Community Cancer Centers
Presentation P:	Alliance of Dedicated Cancer Centers
Presentation Q:	Plasma Protein Therapeutics Association
Presentation R:	The Pharmacy Stakeholder Group