

Report
of the
Advisory Panel
On
Ambulatory Payment
Classification (APC)
Groups
Biannual Meeting

February 18-20, 2004

Centers for Medicare & Medicaid Services
Multipurpose Room

Baltimore, Maryland

APC ADVISORY PANEL MEMBERS PRESENT AT THIS MEETING:

Geneva Craig, RN, MA
Lora DeWald, MEd
Albert E. Einstein, Jr., MD
Edith Hambrick, MD, Acting Chairperson
Robert E. Henkin, MD
Lee H. Hillborne, MD, MPH
Stephen T. House, MD
Katherine Kinslow, CRNA, EdD

Mike Metro, RN, BS
Gerald V. Nacarelli, MD
Frank G. Opelka, MD, FACS
Beverly K. Philip, MD
Lynn R. Tomascik, RN, MSN, CNA
Timothy Gene Tyler, PharmD
William A. VanDecker, MD

CMS STAFF PRESENT:

Shirl Ackerman-Ross; Sabrina Ahmed; Carol Bazell, MD; Dana Burley; Edith Hambrick, M.D., J.D.; Anita Heygster; Deborah Hunter; Joseph Kelly, M.D.; Barry Levi; Cindy Read; Elizabeth Richter; Ken Simon, MD; Tamar Spolter; Cindy Yen

WELCOME AND INTRODUCTIONS

Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, called the meeting to order and thanked the members of the panel for their input and guidance. Dr. Edith Hambrick, Acting Chairperson, welcomed the Panel and introduced the newest member, Dr. Albert Einstein, Jr. (The proceedings of the APC Panel meeting follow. A listing of only the recommendations may be found in Appendix B.) Dr. Hambrick pointed out assessment of violations of the two-times rule (the highest median cost of an item in a given APC should not be more than twice that of the lowest-paying item in that APC) were based on data collected from January through September 2003. Therefore, APCs new in 2004 are not included, and some extinct codes may be included.

OLD BUSINESS

No old business was presented.

NEW BUSINESS

Agenda Item A: Payment of Packaged Codes

CMS Staffer Tamar Spolter discussed reimbursement of 11 packaged Current Procedural Terminology (CPT) codes (36540, 36600, 51701 through 51703, 77790, 90471, 90472, 94760 through 94762, and 97602). She asked the Panel to consider whether these codes should be paid separately in some cases. In particular, the Agency received numerous comments requesting clarification of appropriate billing for CPT code 97602, low-level wound care.

The Panel recommends a new subcommittee be created to discuss the issue of packaged codes that currently receive no additional payment; among issues to be considered are 1) all packaged CPT codes, not just those presented for discussion

at the meeting, 2) instructions for consistency of billing throughout regions and fiscal intermediaries, 3) appropriate status indicators for procedures, and 4) whether CPT code 97602, low-level wound care, should be assigned to its own APC or incorporated into an existing APC. The subcommittee should prepare a report for the Panel's August 2004 meeting.

Ms. DeWald, Mr. Metro, and Dr. VanDecker agreed to serve on the subcommittee.

Agenda Item B: Removal of Four Codes from the Inpatient-Only List

CMS Staffer Cindy Yen reported the Agency received requests that CPT codes 44901, 49021, 49041, and 49061—all of which are percutaneous abscess drainage procedures—be removed from the inpatient-only list. Panel members and commenters agreed that the inpatient-only list is obsolete.

The Panel recommends CPT codes 44901, 49021, 49041, and 49061 be removed from the inpatient-only list. The Panel further recommends the inpatient-only list be eliminated: CMS should review the list with professional specialty societies and hospital associations and—through Congressional action if necessary—reallocate funds from inpatient to outpatient reimbursement consistent with clinical practice. This should include, but not be limited to, those procedures moving off the inpatient-only list. Reimbursement for procedures transitioning from primarily inpatient to primarily outpatient performance should be reviewed in an ongoing manner. If a process for eliminating the inpatient-only list cannot be established in a timely manner (e.g., within 1 year), in the interim, the Panel should evaluate the inpatient-only list with the help of professional societies and hospitals to recommend specific changes via the APC Panel.

Agenda Item C: Brachytherapy

CMS Staffer Barry Levi updated the panel on changes to the brachytherapy codes in the 2004 Final Rule and noted that two new categories of brachytherapy sources had been brought to the Agency's attention since the publication of the Final Rule: high-activity iodine 125 and high-activity palladium 103. Kathy Francisco and Ray Horn from the Coalition for the Advancement of Brachytherapy testified that the cost difference between high-activity and low-activity iodine was significant (Presentation 1). They requested new APCs and HCPCS codes be developed for the high-activity sources. Similar requests were made by the American College of Radiology and Theragenics Corporation via written testimony (Presentations 2 and 3).

The Panel recommends CMS establish new HCPCS codes and new APCs per source for the brachytherapy sources high-activity iodine 125 and high-activity palladium 103.

Agenda Item D: Radiation Oncology APCs and CPTs

Tim Nelson and Jennifer McPeck, representing the freestanding Cancer Centers, presented a proposal to reconfigure the radiation oncology APCs for better clinical homogeneity, which, they said, would improve the accuracy of coding (Presentation 4).

The Panel recommends the freestanding Cancer Centers work with professional societies and other stakeholders to further develop the proposal to reconfigure radiation oncology APCs and provide data for discussion at the August 2004 meeting of the APC Advisory Panel.

Bill Thorwarth and Pam Kassing of the American College of Radiology requested that CPT code 77418, intensity-modulated radiation therapy (IMRT), remain in a new technology APC for 2004 so further cost data can be gathered (see Presentation 2). They also asked that dampening methodology be applied to APC 302 (level-2 radiation therapy); that CMS support more education of hospitals on coding for high-dose brachytherapy; that CMS work to identify more claims that can offer useful data; and that CMS accept external data in evaluating costs. Dr. Hambrick said CMS has received approximately 150,000 claims for IMRT and therefore has robust data from which to determine reimbursement. Beth Roberts of the Association of Community Cancer Centers said her organization is concerned that not all of those claims in fact represent IMRT. Ms. Roberts also pointed out that the corresponding planning code for IMRT remains in a new technology APC. Nelly Lee of the American Hospital Association (AHA) said hospitals continue to grapple with appropriate coding for IMRT.

Written testimony was provided by the Association of Community Cancer Centers (Presentation 5).

The Panel recommends CPT code 77418 for intensity-modulated radiation therapy be returned to the new technology APC 1510 for 1 year.

The Panel recommends when CMS applies a dampening formula, CMS highlight the adjustment in the published rule so providers understand the reimbursement amount and can plan for future years.

Agenda Item F: Radiosurgery

CMS Staffer Deborah Hunter described coding changes that separated planning from treatment delivery codes for cobalt-60-based multisource (also called Gamma Knife) stereotactic radiosurgery (SRS) and image-guided robotic (also called Cyber Knife) SRS. Rebecca Emerick of the International RadioSurgery Association asked the Panel to recommend a new code for cobalt-60-based multisource SRS because so many claims are being denied inappropriately under the current coding (see Presentation 6). Trisha Crishock of the American Society for Therapeutic Radiology and Oncology, Inc., (ASTRO) said her organization does not believe the claim denials are related to the use of revenue codes and does not support the recommendations of the International RadioSurgery Association (Presentation 7). Paul Loflin, Jr., of the San Diego Gamma Knife Center said payers are confused about the difference between radiation therapy and

radiosurgery and asked that a new APC be created to better distinguish the two (Presentation 8).

The Panel recommends CMS evaluate concerns about denials of appropriate reimbursement for cobalt-60 SRS and determine whether there are impediments between the Central Office and the fiscal intermediaries.

Lawrence L. Chin, MD, Associate Professor of Neurosurgery at the University of Maryland and Medical Director of the Gamma Knife Suite, described the procedure for cobalt-60-based multisource SRS and emphasized that planning and treatment delivery always take place on the same day (Presentation 9). Tricia Hill, a nurse from the Washington (DC) Hospital Center, described the procedure from the nurse's point of view (Presentation 10).

Soren Johansson of Elekta, Inc., said his company considers radiosurgery to be neurologic surgery and supports separate codes for radiosurgery delivery and planning. He asked that CMS reclassify codes G0251 and G0340 into an appropriate radiation therapy APC, revising the descriptors to "hypofractionated radiation therapy," and reimbursing as appropriate (Presentation 11).

Gail Daubert, representing BrainLAB, asked the Panel to recommend a G code for stereoscopic K_v x-ray guidance and localization of target volume for SRS. She asked that CMS provide a HCPCS code for the guidance procedure and assign it to an appropriate CPT code. She said the company's application to the American Medical Association for a CPT code some time ago was denied because there were not enough supporting data available at the time (Presentation 12).

The MidMichigan Medical Center and the International Stereotactic Radiosurgery Society provided written testimony (Presentations 13 and 14).

Agenda Item H: Assignment of HCPCS to APCs

CMS Staffer Dana Burley said the Agency received requests to move CPT 29827 (arthroscopy, shoulder, with rotator cuff repair) from APC 41 to APC 42 based on its similarity to CPT 29826 (arthroscopy, shoulder decompression of subacromial space with partial acromioplasty with or without coracoacromial release). Cindy Vandebosch of Strategic Reimbursement Consulting, Inc., said the change would result in better clinical homogeneity for these APCs (Presentation 15).

The Panel recommends CMS staff reevaluate the codes in APCs 41 and 42 and propose restructuring that would improve the homogeneity of codes within these APCs.

Ms. Burley noted that APC 97 violates the two-times rule.

The Panel recommends no changes to APC 97.

Ms. Burley noted that despite changes to APC 99, it continues to violate the two-times rule.

The Panel recommends no changes to APC 99.

Ms. Burley said the Agency received requests to move CPT 75978 from APC 668 to APC 280 and CPT 75774 from APC 668 to APC 279, but this change would leave no CPT codes in the category of level-1 angiography. The staff recommended a restructuring that preserves three levels of angiography.

The Panel accepts the recommendations of the CMS staff that preserve three levels of angiographic coding (currently APCs 668, 279, and 280) and recommends CMS adopt the proposed new configuration for the 2005 rule.

Ms. Burley provided an overview of new venous access codes at the request of the Panel at a previous meeting. Larry Yost of Vasca asked that CPT 36582 be assigned to the new technology APC 1522 (Presentation 16).

The Panel recommends CPT codes 36568 and 36569 be moved to APC 187.

The Panel recommends CPT code 36582 be moved to new technology APC 1522, which has an S status indicator.

David Parr of C.R. Bard asked that CPT codes 36557 and 36558, insertion of central venous access line in pediatric patients, be moved from APC 32 to APC 115 (Presentation 17).

The Panel recommends moving CPT codes 36557 and 36558 to APC 115.

Dan Trodden of Cytoc asked that CPT codes 0046T and 0047T in APC 18 be 1) removed from the Outpatient Prospective Payment System; 2) moved to APC 28, 31, or 37; or 3) be moved to a new technology APC (Presentation 18).

The Panel recommends moving CPT codes 0046T and 0047T to APC 21.

Mr. Parr of C.R. Bard asked that the N status indicator for CPT 76937 be changed to an S or T status indicator and that the code be paid separately (Presentation 19).

The Panel recommends no changes to CPT code 76937 but asks that the status indicator for this code be reevaluated at a later meeting. This code should also be reviewed by the new subcommittee on packaged codes.

Ms. Spolter noted that APC 19 violates the two-times rule.

The Panel recommends moving CPT code 27041 to APC 20.

The Panel recommends no changes to APC 19.

Ms. Spolter noted that APC 235 minimally violates the two-times rule.

The Panel recommends no changes to APC 235.

Ms. Spolter suggested moving CPT 44970 to APC 131.

The Panel recommends moving CPT code 44970 to APC 131.

Ms. Spolter asked the Panel for recommendations on restructuring APCs 203 and 207.

The Panel recommends moving CPT codes 46020 and 46706 to APC 150 and CPT codes 45005 and 45020 to APC 155.

The Panel recommends moving CPT codes 64420, 64630, 64640, and 62280 to APC 206 and CPT code 62282 to APC 203.

Ms. Spolter suggested moving CPT codes 65286, 66030, and 66625 to APC 232.

The Panel recommends moving CPT codes 65286, 66030, and 66625 to APC 232.

Ms. Spolter suggested moving CPT code 88346 TO APC 344.

The Panel recommends moving CPT code 88346 to APC 344.

Ms. Spolter suggested moving CPT code 90636 to APC 356 and CPT codes 90375, 90740, 90723, 90693 to APC 355. Additional information on APCs 355 and 356 will be sent to Panel members after the meeting for further consideration.

The Panel recommends moving CPT code 90636 to APC 356.

The Panel recommends moving CPT codes 90740, 90723, and 90693 to APC 355 and awaits information on the costs related to CPT code 90375.

Ms. Spolter suggested moving CPT code 94015 to APC 367.

The Panel recommends moving CPT code 94015 to APC 367.

Discussion of APCs 385 and 386 was held over for consideration with agenda item M on devices.

Ms. Spolter suggested moving CPT code G0264 to a higher level clinic visit code.

The Panel recommends no changes to APC 600.

Peggy Dotson and Laura Bolton, MD, of the Association for the Advancement of Wound Care requested a temporary code for sustained graduated compression techniques used for chronic wound care, because the existing code (CPT 29580 with modifier 22) is being rejected by payers as a miscoding (Presentation 20). Panel members suggested CMS provide clarification to the fiscal intermediaries about the appropriate use of evaluation and management codes in combination with procedure codes.

Agenda Item I: Assignment of HCPCS to APCs

Ms. Spolter noted that APC 148 violates the two-times rule. Written testimony was provided by Hogan & Hartson, LLP (Presentation 21).

Agenda Item J: Observation Issues

The Panel's Subcommittee on Observation reported its findings after evaluating separately payable observation APCs, as well as observation codes for surgical short stays and medical short stays. The Panel discussed the Subcommittee's recommendations. The Panel noted legislative changes may be needed to provide other routes to qualify for skilled nursing facility care.

CMS guidelines allow for reimbursement when a patient is admitted as an inpatient and subsequently needs observation status; the *Panel recommends* CMS clarify this issue definitively for all quality improvement organizations, regional offices, and fiscal intermediaries.

The Panel recommends CMS eliminate mandatory use of diagnostic, condition-specific tests as criteria for payment under observation codes.

The Panel recommends the category of observation services be expanded beyond the three clinical conditions of congestive heart failure, chest pain, and asthma to include all clinical conditions for which observation status is appropriate based on medical necessity.

The Panel recommends CMS clearly define appropriate categorization and billing instructions for 24–48-hour observation stays.

The Panel recommends when a postinterventional patient experiences unanticipated need for extended care based on medical necessity, the patient should be given observation status and receive additional reimbursement under the appropriate APC code. The Panel requests CMS monitor these claims and report findings back to the APC Panel.

The Panel recommends when a procedure has an anticipated recovery time that exceeds the 4–6 hours already built in to the procedure's APC, the additional cost be reported using revenue code 71x. This information should be clarified specifically to fiscal intermediaries.

The Panel recommends CMS allow observation hours to count toward the 3-day requirement for admission to a skilled nursing facility.

The Panel recommends CMS evaluate alternative criteria for qualifying for admission to a skilled nursing facility care.

Jennifer Artigue and Marion Kruse, representing the Provider Roundtable, a coalition of hospitals, asked that CMS revise its criteria for documenting start and stop times of observation to better correlate with computerized documentation systems and eliminate the need for manual record review (Presentation 22).

To eliminate the need for manual evaluation of charts to record start and stop times for admission and discharge, *the Panel recommends* CMS consider the following changes: the start time for observation should be the time after a physician has ordered observation based on medical necessity and the patient is placed in a bed for the purpose of observation; stop time should be the time the patient is discharged from the hospital.

Agenda Item K: Evaluation and Management Services

Ms. Hunter described a joint proposal from the AHA and the American Health Information Management Association (AHIMA) to better define emergency department and clinical visits. Panel members were divided on the question of whether a three-level system would be preferable to a five-level system; a majority felt a five-level system was appropriate.

The Panel supports the proposed definitions of an emergency department visit and a clinic visit put forth by the AHA and AHIMA in their model.

The Panel recommends CMS work to develop a national definition of levels of emergency department and outpatient clinical services.

The Panel recommends categorization of the level of discharge instructions be commensurate with the level of service provided for an emergency department or clinic encounter.

Agenda Item L: Single/Multiple-Claim Issues

CMS Staffer Anita Heygster said the Agency requested comments on the methodology established to identify median costs. Commenters suggested various APCs and codes for inclusion on the “bypass” list, and staff is reviewing those suggestions. A commenter requested that APC 313 be considered for the bypass list. Ms. Heygster said the Agency may contact specialty societies for their input, e.g., ASTRO for comments on the radiotherapy codes.

The Panel recommends CMS proceed with evaluation of the APCs and codes identified in Tab L for possible placement on the bypass list. The Panel also

suggests claims from APC 313 be evaluated closely.

Jugna Shah, representing the freestanding Cancer Centers, outlined some proposals on increasing the number of single claims for use in establishing costs and asked CMS to release more details on how its methodology is applied (Presentation 23).

The Panel recommends CMS continue to evaluate ways to increase the amount of useful data from single claims.

Agenda Item M: Device-Related APC Issues

Ms. Heygster explained that in 2004, CMS reinstated the use of device (C) codes, although hospitals are not required to use them. She said the Agency is using partial-year 2003 data on median costs for APCs associated with devices, which appears to result in underpayment.

Stephanie Mensch of AdvaMed asked that CMS consider external data on device costs for certain APCs (see Presentation 24). Valerie Rinkle, on behalf of the Provider Roundtable, outlined barriers hospitals face in using C codes and identifying actual device costs (Presentation 25). Ms. Rinkle suggested the Agency allow hospitals to report acquisition costs voluntarily using form UB 92.

The Panel recommends CMS work with professional societies and hospital associations to identify the hospital acquisition costs of high-cost devices for use as an additional parameter in validating cost data.

The Panel asks CMS to devise a methodology that reasonably collects data on the costs of medical devices.

Until a better methodology for collecting device cost data is in place, *the Panel recommends* rates for 2005 be set using the 2002 claims data that were used to create the 2004 Outpatient Prospective Payment System, with the addition of an appropriate adjustment for inflation.

Until a better methodology for collecting device cost data is in place, *the Panel recommends* the use of C codes be mandatory, not voluntary.

Russ Miller of American Medical Systems offered several suggestions for CMS to collect more accurate device cost data for APCs 385 and 386, levels I and II prosthetic urology, including use of external data (Presentation 26). John Mulcahy, MD, of the Coalition for the Advancement of Prosthetic Urology, reiterated that external data would provide much-needed cost data; he claimed some hospitals no longer offer prosthetic urology devices because the reimbursement is so low.

The Panel recommends CMS accept and consider external data on costs of devices, particularly high-cost devices.

Jay Straicke, representing Guidant, Medtronic, and St. Jude, asked that CPT 33225, insertion of left ventricular lead into the coronary sinus, which is in new technology APC 1550 with a T status indicator, be given an S status indicator (see written testimony provided by Cynthia Tracy, MD, Presentation 28).

The Panel recommends CMS move CPT code 33225 to APC 1513, which has an S status indicator.

Eva Snitkin of American Medical Systems Gynecology, Inc., requested that CPT 009T, endometrial cryoablation with ultrasound guidance, be moved from new technology APC 1557 to APC 1523 or a new APC (Presentation 29).

Written testimony was provided by the Medical Device Manufacturers Association (Presentation 30) and Organogenesis (Presentation 31).

Members of the Panel suggested device manufacturers and suppliers take a more active role in educating hospitals about proper coding to ensure appropriate reimbursement for devices. Grant Bagley of the Pharmaceutical Research and Manufacturers of America commented that concerns about fraud make suppliers reticent to get involved in coding education and hospitals reluctant to take suppliers' advice; recommendations from the Agency on coding are preferable.

Agenda Item N: Other APC Issues

James Archetto of Radi Medical Systems requested that CPT codes 93571 and 93572 for fractionated flow reserve measurement be moved to APC 670 (Presentation 32).

A commenter requested CPTs 93571 and 93572 be moved to APC 670. The Panel asks CMS to review the data submitted in relation to the request; if the data support such a move, *the Panel recommends* CMS move CPTs 93571 and 93572 to APC 670.

David Charles, MD, of Vanderbilt University and representing Medtronic, requested the status indicator for APC 223, catheter implantation, be changed from T to S or that CMS create a new APC that includes both the catheter and the infusion pump (Presentation 33).

The Alliance for Orthopedic Solutions provided written testimony (Presentation 34).

Agenda Item O: Drug Administration Coding

Ms. Heygster explained that staff evaluated a proposal by the AHA and AHIMA that crosswalks CPT codes with Q codes for drug administration; the Agency is considering substituting CPT codes for Q codes. However, Q code data will remain the basis for reimbursement levels through 2006.

The Panel recommends CMS continue to evaluate the possible use of CPT codes in place of Q codes for chemotherapy and nonchemotherapy infusions; the Panel

supports the use of CPT codes.

Jugna Shah, on behalf of the freestanding Cancer Centers, asked that CMS maintain its current mechanism to allow payment for multiple drug infusion visits that occur on a single day (Presentation 35). Jennifer McPeck of the freestanding Cancer Centers supported the move to CPT codes. Judith Baker of Resource Group, Ltd., requested use of CPT codes for nonchemotherapy infusions to allow the Agency to track such infusions (Presentation 36).

The Panel recommends CMS clarify its billing instructions regarding infusions in different outpatient settings, e.g., operating rooms, observation areas, and emergency departments.

Agenda Item P: Overview of Payment for Drugs, Biologicals, and Radiopharmaceuticals under the Medicare Modernization Act of 2003

CMS Staffer Sabrina Ahmed explained that the Medicare Modernization Act classifies drugs, biologicals, and radiopharmaceuticals as either sole-source, innovator multisource, or non-innovator multisource and sets different reimbursement rates accordingly. The comment period for this aspect of the act extends to March 8, 2004, and hospitals will be allowed to resubmit claims for January 1 through March 31, 2004, when the new rule is finalized.

Denise Merlino, representing the Nuclear Medicine APC Task Force, asked that CMS instruct hospitals on the use of the new revenue codes for diagnostic and therapeutic radiopharmaceuticals APCs that become effective in October 2004 (Presentation 37).

Shannon Penberthy of the National Hemophilia Foundation asked that all clotting factor products be categorized as sole-source drugs because they have no generic equivalents (Presentation 38).

Stuart Langbein, on behalf of the Plasma Protein Therapeutics Association, asked that all plasma-based therapies be categorized as sole-source drugs because they are biological products and that the General Accounting Office's (GAO's) survey of hospital acquisition costs collect data on separately branded products with different clinical effects (Presentation 39).

Gordon Schatz of the Council on Radionuclides and Radiopharmaceuticals, Inc., asked CMS to continue evaluating and modifying code descriptors for radiopharmaceuticals to ensure consistency, i.e., use of "per dose" as the standard unit, and that radiopharmaceuticals that qualify for separate payment be recognized as such by April 1, 2004 (Presentation 40).

Ms. Kassing of the American College of Radiology asked that CMS continue working with the American College of Radiology on a mechanism to account for cost increases in low osmolar contrast material agents (see Presentation 2).

Grant Bagley of the Pharmaceutical Research and Manufacturers of America asked that delays in assigning a HCPCS code not result in a delay in payment for use of a drug newly approved by the Food and Drug Administration (FDA), that radiopharmaceuticals be recognized as drugs, and that drugs that fall below the \$50 threshold be tracked (Presentation 41).

Wendy Resnick of the Association of Community Cancer Centers urged CMS to work with the GAO on the hospital acquisition cost survey to capture all categories of drugs, and made several suggestions for ensuring chemotherapy drugs are adequately reimbursed (see Presentation 5).

The Panel recommends CMS work swiftly and diligently to implement a methodology to enable filing and payment of claims for drugs newly approved by the FDA.

The Panel recommends CMS consider temporary or placeholder codes that can be assigned rapidly after FDA drug approval to allow providers to file claims on new drugs.

The Panel recommends CMS consider biologics, plasma-derived products and their recombinant analogs, and radiopharmaceuticals as sole-source drugs. The Panel further recommends CMS use the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the *Orange Book*, as a resource to determine whether other drugs fall into the category of sole-source or multiple source.

The Panel recommends providers use the revenue codes 343 and 344 for diagnostic and therapeutic radiopharmaceuticals when they become effective later this year.

The Panel recommends CMS work with the GAO to expand the list of drugs included on the hospital acquisition cost survey, subject to the mandates of the Medicare Modernization Act.

The Panel recommends CMS revisit the issue of low-osmolar contrast media, including, but not limited to, codes noted by the American College of Radiology, and gather data on changing the reimbursement as appropriate.

Agenda Item Q: Blood and Blood Products

Ms. Yen explained that the reimbursement for blood and blood products for 2004 remains frozen at 2003 levels. However, commenters feel the reimbursement still falls below acquisition costs, and hospitals have asked for further clarification on billing.

Peter Page of the American Red Cross requested that reimbursement rates be raised by 2005 in light of increasing costs related to compliance with federal regulations and use of technological advancements to safeguard the blood supply, as well as need for more

aggressive recruitment efforts (Presentation 42).

Paul Ness, representing the American Association of Blood Banks, said his organization can provide the Agency with cost data. He requested that blood and blood products be reimbursed on a cost-based system, as is brachytherapy, which would allow for better tracking of claims (Presentation 43).

The College of American Pathologists provided written testimony (Presentation 44).

The Panel recommends CMS use recent external data to derive reasonable costs of blood products for reimbursement purposes and adjust payments accordingly.

Closing

The Panel reviewed the recommendations from the meeting. Dr. Hambrick thanked the outgoing Panel members for their service and the CMS and support staff for their hard work. Dr. Hambrick adjourned the meeting at noon on Friday, February 20, 2004.

Appendix A
AGENDA

February 18, 19, and 20, 2004

APC Panel Meeting

DAY 1 - Wednesday, February 18, 2004

TAB

08:30 Opening - Day 1

- a. Welcome, Call to Order, and Introduction of New Member
(Elizabeth Richter, Director, Hospital and Ambulatory Policy Group)
- b. Opening Remarks (Elizabeth Richter)
- c. Swearing-in of New Member (Elizabeth Richter)
- d. Group Photo

09:00 Panel Organization and Housekeeping Issues
(Edith Hambrick, M.D., Acting Chair)

09:15 Payment for Packaged Codes **A**
(36540, 36600, 51701 thru 51703, 77790, 90471, 90472, 94760 thru 94762,
and 97602)

- a. Tamar Spolter, CMS Staff
- b. Comments
- c. Panel's Recommendations

09:45 Removal of four codes from the inpatient-only list **B**
(44901, 49021, 49041, and 49061—all abscess drainage procedures)

- a. Cindy Yen, CMS Staff
- b. Comments
- c. Panel's Recommendations

10:15 *Break*

DAY 1 - Wednesday, February 18, 2004 *(continued)*

TAB

10:30 Brachytherapy

C

- a. Barry Levi, CMS Staff
- b. Comments
 - Theragenics's Written Comments
 - CAB's Written Comments
 - ACR's Written Comments (See Tabs D & P)
- c. Panel's Recommendations

11:00 Radiation Oncology APCs and CPTs

D

Presentations/Comments

- Tim Nelson, Arthur James Cancer Hospital (ACCC)
- Jennifer McPeck, Arthur James Cancer Hospital (ACCC)
- Panel's Recommendations

- Pam Kassing, ACR (See Tabs C & P)
- William T. Thorwarth, Jr., M.D., ACR
- Panel's Recommendations

- Wendy Resnick, ACCC
- Panel's Recommendations

12:00 *Lunch*

VACANT

E

01:00 Radiosurgery

F

- a. Deborah Hunter, CMS Staff
- b. Presentations/Comments
 - Rebecca Emerick, IRSA
 - ASTRO's Written Comments
 - Panel's Recommendations

 - Paul H. Loflin, Jr., Gamma Knife Center
 - Lawrence L. Chin, M.D., UMAB, Gamma Knife® Suite
 - Tim Laugh's (Director, Gamma Knife) Comments
 - Panel's Recommendations

 - Tricia Hill, R.N., Washington Hospital Center
 - Panel's Recommendations

DAY 1 - Wednesday, February 18, 2004 (continued)

TAB

- Soren Johansson, Elekta, Inc.
- Panel's Recommendations

- Gail Daubert, BrainLab
- Panel's Recommendations

- International RadioSurgery Association's Written Comments
- Panel's Recommendations

VACANT

G

02:00 Assignment of HCPCS to APCs

H and I

(The afternoon break will be at the discretion of the Chair.)

- a. APCs 0041-0042
 - Dana Burley, CMS
 - Cindy Vandebosch, Strategic Reimbursement Consulting, Inc.
 - Panel's Recommendations
- b. APCs 0097-0099, 0668, 0279, 0280, 0032, 0109, 0115, 0187, 1541, and 1564
 - Dana Burley, CMS
 - Larry Yost, VASCA
 - David Parr, C.R. Bard
 - Panel's Recommendations
- c. APC 0018
 - Dana Burley, CMS
 - Dan Trodden, Cytoc Corporation
 - Panel's Recommendations
- d. APCs 0019, 0020, and 0021
 - Tamar Spolter, CMS
 - Panel's Recommendations
- e. APC 0235
 - Tamar Spolter, CMS
 - Panel's Recommendations
- f. APC 0130
 - Tamar Spolter, CMS
 - Panel's Recommendations

DAY 1 - Wednesday, February 18, 2004 *(continued)*

TAB

Assignment of HCPCS to APCs *(continued)*

H

- g. APC 0148
 - Tamar Spolter, CMS
 - Stuart Langbein, Written Comments
 - Panel's Recommendations
- h. APCs 0203 and 0207
 - Tamar Spolter, CMS
 - Panel's Recommendations
- i. APC 0233
 - Tamar Spolter, CMS
 - Panel's Recommendations
- j. APC 0343
 - Tamar Spolter, CMS
 - Panel's Recommendations
- k. APC 0355 and 0356
 - Tamar Spolter, CMS
 - Panel's Recommendations
- l. APC 0369
 - Tamar Spolter, CMS
 - Panel's Recommendations
- m. APC 0385
 - Tamar Spolter, CMS
 - Panel's Recommendation
- n. APC 0600
 - Tamar Spolter, CMS
 - Panel's Recommendations

05:00 Adjourn

REMINDER: Tomorrow, the APC Panel meeting starts at 10:30 a.m.; consequently, attendees may not enter the CMS complex until 9:45–10:00 a.m. Thanks for your cooperation.

DAY 2 – Thursday, February 19, 2004

TAB

10:30 Opening (**The public may not enter the building until 9:45 – 10:00 a.m.**)

10:35 Observation Issues

J

- a. Report of the Observation Subcommittee to the Full Committee
- b. Discussion of Issues Raised by Observation Subcommittee Report
- c. Presentations/Comments
 - Jennifer . Artigue, RHIT – Our Lady of Lourdes Regional MC (PRT)
 - Marion G. Kruse, BSN, RN, MBA – OhioHealth Corp. (PRT)
- d. Panel’s Recommendations

12:00 *Lunch*

01:00 Evaluation & Management Services

K

- a. Deborah Hunter, CMS Staff
- b. Comments
- b. Panel’s Recommendations

02:15 Single/Multiple-Claim Issues

L

- a. Anita Heygster, CMS Staff
- b. Presentation/Comments
 - Jugna Shah, MPH, Nimitt Consulting Inc. (ACC)
- c. Panel’s Recommendations

03:00 *Break*

03:15 Device-Related APC Issues

M

Effect of Absence of Device Coding on Median Costs

- a. Anita Heygster, CMS Staff
- b. Presentations/Comments
 - Shannon Penberthy, National Hemophilia Foundation
 - Panel’s Recommendations

 - Valerie Rinkle, Asante Health System (PRT)
 - Panel’s Recommendations

DAY 2 – Thursday, February 19, 2004 *(continued)*

TAB

Device-Related APC Issues *(continued)*

M

- Cynthia Tracy, M.D., Professor of Medicine & Chief of Cardiology
Georgetown University Hospital
- Panel's Recommendations

- Russ Miller, American Medical Systems (CAPU)
- AMS's Written Comments
- Panel's Recommendations

- Eva Snikin, American Medical Systems Gynecology, Inc.
- Panel's Recommendations

- The Medical Device Manufacturers Association's Written Comments
- Panel's Recommendations

- Organogenesis Inc.'s Written Comments
- Panel's Recommendations

- AdvaMed's Written Comments
- Panel's Recommendations

Other APC Issues

N

- Jim Archetto, Radi Medical Systems, Inc.
- Panel's Recommendations

- David Charles, M.D., Movement Disorders Clinic, Vanderbilt U.
- Panel's Recommendations

- Jenna Kappel, Alliance for Orthopedic Solutions
- Panel's Recommendations

05:00 Adjourn

DAY 3 – Friday, February 20, 2004

08:30 Opening

08:35 Drug Administration Coding **O**

a. Anita Heygster, CMS Staff

b. Presentations/Comments

- Judith Baker, Resource Group, Inc.
- Panel's Recommendations

- Jugna Shah, Nimit Consulting Inc. (ACCC)
- Jennifer McPeck, R.N., Arthur G. James Cancer Hospital & Richard J. Solove Research Institute (ACCC)
- Panel's Recommendations

09:15 Overview of Payment for Drugs, Biologicals, and Radiopharmaceuticals under MMA 2003 **P**

a. Sabrina Ahmed, CMS Staff

b. Presentations/Comments

- Denise Merlino, Society of Nuclear Medicine
- Panel's Recommendations

- Stuart Langbein (Hogan & Hartson, LLP) for the Plasma Protein Therapeutics Association
- Panel's Recommendations

- Gordon Schatz, CORAR
- Panel's Recommendations

- Pam Kassing, ACR (See Tabs C & D)
- William T. Thorwarth, Jr., M.D., ACR
- Panel's Recommendations

- Grant P. Bagley, M.D., J.D. (PhRMA)
- Panel's Recommendations

10:00 *Break*

DAY 3 – Friday, February 20, 2004 *(continued)*

- 10:15 Blood & Blood Products Q
- a. Cindy Yen, CMS Staff
 - b. Presentations/Comments
 - Peter L. Page, M.D., ARC
 - Panel's Recommendations

 - Susan Spires, M.D., College of American Pathologists
 - Panel's Recommendations

 - Paul Ness, M.D., Johns Hopkins (AABB)
 - Panel's Recommendations
- 11:15 Closing
- a. Summary of the Panel's Recommendations for 2004
 - b. Final Remarks
- 12:30 Adjourn*

NOTE: * (If there are more issues than we can address on Wednesday and/or Thursday, the meeting may be extended until 2 p.m. on Friday.)

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|---|----------|
| Interim Final Rule and Correction Notice | X |
| APC Cost Comparisons (2003 – 2005) | Y |
| 2 Times Tables – Median Costs by APC | Z |

Appendix B

Collected Recommendations of the APC Advisory Panel, February 18-20, 2004

Payment for Packaged Codes

The Panel recommends a new subcommittee be created to discuss the issue of packaged codes that currently receive no additional payment; among issues to be considered are 1) all packaged CPT codes, not just those presented for discussion at the meeting, 2) instructions for consistency of billing throughout regions and fiscal intermediaries, 3) appropriate status indicators for procedures, and 4) whether CPT code 97602, low-level wound care, should be assigned to its own APC or incorporated into an existing APC. The subcommittee should prepare a report for the Panel's August 2004 meeting.

Removal of Four Codes from the Inpatient-Only List

The Panel recommends CPT codes 44901, 49021, 49041, and 49061 be removed from the inpatient-only list. The Panel further recommends the inpatient-only list be eliminated: CMS should review the list with professional specialty societies and hospital associations and—through Congressional action if necessary—reallocate funds from inpatient to outpatient reimbursement consistent with clinical practice. This should include, but not be limited to, those procedures moving off the inpatient-only list. Reimbursement for procedures transitioning from primarily inpatient to primarily outpatient performance should be reviewed in an ongoing manner. If a process for eliminating the inpatient-only list cannot be established in a timely manner (e.g., within 1 year), in the interim, the Panel should evaluate the inpatient-only list with the help of professional societies and hospitals to recommend specific changes via the APC Panel.

Brachytherapy

The Panel recommends CMS establish new HCPCS codes and new APCs per source for the brachytherapy sources high-activity iodine 125 and high-activity palladium 103.

Radiation Oncology APCs and CPTs

The Panel recommends the freestanding Cancer Centers work with professional societies and other stakeholders to further develop the proposal to reconfigure radiation oncology APCs and provide data for discussion at the August 2004 meeting of the APC Advisory Panel.

The Panel recommends CPT code 77418 for intensity-modulated radiation therapy (IMRT) be returned to the new technology APC 1510 for 1 year.

The Panel recommends when CMS applies a dampening formula, CMS highlight the adjustment in the published rule so providers understand the reimbursement amount and can plan for future years.

Radiosurgery

The Panel recommends CMS evaluate concerns about denials of appropriate reimbursement for cobalt-60 stereotactic radiosurgery and determine whether there are impediments between the Central Office and the fiscal intermediaries.

Assignment of HCPCS to APCs

The Panel recommends CMS staff reevaluate the codes in APCs 41 and 42 and propose restructuring that would improve the homogeneity of codes within these APCs.

The Panel recommends no changes to APC 97.

The Panel recommends no changes to APC 99.

The Panel accepts the recommendations of the CMS staff that preserve three levels of angiographic coding (currently APCs 668, 279, and 280) and recommends CMS adopt the proposed new configuration for the 2005 rule.

The Panel recommends CPT codes 36568 and 36569 be moved to APC 187.

The Panel recommends CPT code 36582 be moved to new technology APC 1522, which has an S status indicator.

The Panel recommends moving CPT codes 36557 and 36558 to APC 115.

The Panel recommends moving CPT codes 0046T and 0047T to APC 21.

The Panel recommends no changes to CPT code 76937 but asks that the status indicator for this code be reevaluated at a later meeting. This code should also be reviewed by the new subcommittee on packaged codes.

The Panel recommends moving CPT code 27041 to APC 20.

The Panel recommends no changes to APC 19.

The Panel recommends no changes to APC 235.

The Panel recommends moving CPT code 44970 to APC 131.

The Panel recommends moving CPT codes 46020 and 46706 to APC 150 and CPT codes 45005 and 45020 to APC 155.

The Panel recommends moving CPT codes 64420, 64630, 64640, and 62280 to APC 206 and CPT code 62282 to APC 203.

The Panel recommends moving CPT codes 65286, 66030, and 66625 to APC 232.

The Panel recommends moving CPT code 88346 to APC 344.

The Panel recommends moving CPT code 90636 to APC 356.

The Panel recommends moving CPT codes 90740, 90723, and 90693 to APC 355 and awaits information on the costs related to CPT code 90375.

The Panel recommends moving CPT code 94015 to APC 367.

The Panel recommends no changes to APC 600.

Observation Issues

CMS guidelines allow for reimbursement when a patient is admitted as an inpatient and subsequently needs observation status; the Panel recommends CMS clarify this issue definitively for all quality improvement organizations, regional offices, and fiscal intermediaries.

The Panel recommends CMS eliminate mandatory use of diagnostic, condition-specific tests as criteria for payment under observation codes.

The Panel recommends the category of observation services be expanded beyond the three clinical conditions of congestive heart failure, chest pain, and asthma to include all clinical conditions for which observation status is appropriate based on medical necessity.

The Panel recommends CMS clearly define appropriate categorization and billing instructions for 24–48-hour observation stays.

The Panel recommends when a postinterventional patient experiences unanticipated need for extended care based on medical necessity, the patient should be given observation status and receive additional reimbursement under the appropriate APC code. The Panel requests CMS monitor these claims and report findings back to the APC Panel.

When a procedure has an anticipated recovery time that exceeds the 4–6 hours already built in to the procedure's APC, the additional cost be reported using revenue code 71x. This information should be clarified specifically to fiscal intermediaries.

The Panel recommends CMS allow observation hours to count toward the 3-day requirement for admission to a skilled nursing facility.

The Panel recommends CMS evaluate alternative criteria for qualifying for admission to a skilled nursing facility care.

To eliminate the need for manual evaluation of charts to record start and stop times for

admission and discharge, the Panel recommends CMS consider the following changes: the start time for observation should be the time after a physician has ordered observation based on medical necessity and the patient is placed in a bed for the purpose of observation; stop time should be the time the patient is discharged from the hospital.

Evaluation and Management Services

The Panel supports the proposed definitions of an emergency department visit and a clinic visit put forth by the American Hospital Association and American Health Information Management Association in their model.

The Panel recommends CMS work to develop a national definition of levels of emergency department and outpatient clinical services.

The Panel recommends categorization of the level of discharge instructions be commensurate with the level of service provided for an emergency department or clinic encounter.

Single/Multiple Claims Issues

The Panel recommends CMS proceed with evaluation of the APCs and codes identified in Tab L for possible placement on the bypass list. The Panel also suggests claims from APC 313 be evaluated closely.

The Panel recommends CMS continue to evaluate ways to increase the amount of useful data from single claims.

Device-Related APC Issues

The Panel recommends CMS work with professional societies and hospital associations to identify the hospital acquisition costs of high-cost devices for use as an additional parameter in validating cost data.

The Panel asks CMS to devise a methodology that reasonably collects data on the costs of medical devices.

Until a better methodology for collecting device cost data is in place, the Panel recommends rates for 2005 be set using the 2002 claims data that were used to create the 2004 Outpatient Prospective Payment System, with the addition of an appropriate adjustment for inflation.

Until a better methodology for collecting device cost data is in place, the Panel recommends the use of C codes be mandatory, not voluntary.

The Panel recommends CMS accept and consider external data on costs of devices, particularly high-cost devices.

The Panel recommends CMS move CPT code 33225 to APC 1513, which has an S status indicator.

Other APC Issues

A commenter requested that CPTs 93571 and 93572 be moved to APC 670. The Panel asks CMS to review the data submitted in relation to the request; if the data support such a move, the Panel recommends CMS move CPTs 93571 and 93572 to APC 670.

Drug Administration Coding

The Panel recommends CMS continue to evaluate the possible use of CPT codes in place of Q codes for chemotherapy and nonchemotherapy infusions; the Panel supports the use of CPT codes.

The Panel recommends CMS clarify its billing instructions regarding infusions in different outpatient settings, e.g., operating rooms, observation areas, and emergency departments.

Overview of Payment for Drugs, Biologicals, and Radiopharmaceuticals Under MMA 2003

The Panel recommends CMS work swiftly and diligently to implement a methodology to enable filing and payment of claims for drugs newly approved by the Food and Drug Administration (FDA).

The Panel recommends CMS consider temporary or placeholder codes that can be assigned rapidly after FDA drug approval to allow providers to file claims on new drugs.

The Panel recommends CMS consider biologics, plasma-derived products and their recombinant analogs, and radiopharmaceuticals as sole-source drugs. The Panel further recommends CMS use the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the *Orange Book*, as a resource to determine whether other drugs fall into the category of sole-source or multiple source.

The Panel recommends providers use the revenue codes 343 and 344 for diagnostic and therapeutic radiopharmaceuticals when they become effective later this year.

The Panel recommends CMS work with the General Accounting Office to expand the list of drugs included on the hospital acquisition cost survey, subject to the mandates of the Medicare Modernization Act.

The Panel recommends CMS revisit the issue of low-osmolar contrast media, including but not limited to codes noted by the American College of Radiology, and gather data on changing the reimbursement as appropriate.

Blood and Blood Products

The Panel recommends CMS use recent external data to derive reasonable costs of blood products for reimbursement purposes and adjust payments accordingly.

Appendix C
Presentations

The following documents were presented at or submitted for the APC Panel meeting, February 18-20, 2004, and are appended here for the record:

- Presentation 1: Coalition for the Advancement of Brachytherapy
- Presentation 2: American College of Radiology
- Presentation 3: Theragenics Corporation
- Presentation 4: Freestanding Cancer Centers
- Presentation 5: Association of Community Cancer Centers
- Presentation 6: International RadioSurgery Association
- Presentation 7: American Society for Therapeutic Radiology and Oncology, Inc.
- Presentation 8: San Diego Gamma Knife Center
- Presentation 9: Lawrence L. Chin, MD, University of Maryland
- Presentation 10: Tricia Hill, RN, Washington Hospital Center
- Presentation 11: Elekta, Inc.
- Presentation 12: BrainLAB
- Presentation 13: MidMichigan Medical Center
- Presentation 14: International Stereotactic Radiosurgery Society
- Presentation 15: Strategic Reimbursement Consulting, Inc.
- Presentation 16: Vasca, Inc.
- Presentation 17: C.R. Bard, Inc.
- Presentation 18: Cytoc Corporation
- Presentation 19: C.R. Bard, Inc.
- Presentation 20: Association for the Advancement of Wound Care
- Presentation 21: Hogan & Hartson, LLP
- Presentation 22: Provider Roundtable
- Presentation 23: Freestanding Cancer Centers
- Presentation 24: AdvaMed
- Presentation 25: Provider Roundtable
- Presentation 26: American Medical Systems
- Presentation 27: Coalition for the Advancement of Prosthetic Urology
- Presentation 28: Cynthia M. Tracy, MD, Georgetown University Hospital
- Presentation 29: American Medical Systems Gynecology
- Presentation 30: Medical Device Manufacturers Association
- Presentation 31: Organogenesis
- Presentation 32: Radi Medical Systems, Inc.
- Presentation 33: Medtronic
- Presentation 34: Alliance for Orthopedic Solutions
- Presentation 35: Freestanding Cancer Centers
- Presentation 36: Resource Group, Ltd.
- Presentation 37: Nuclear Medicine APC Task Force
- Presentation 38: National Hemophilia Foundation
- Presentation 39: Plasma Protein Therapeutics Association
- Presentation 40: Council on Radionuclides and Radiopharmaceuticals
- Presentation 41: Pharmaceutical Research and Manufacturers of America
- Presentation 42: American Red Cross
- Presentation 43: American Association of Blood Banks

Presentation 44: College of American Pathologists