Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents Public Meeting
June 14, 2006

Public Meeting Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 75 people attended. The agenda included 33 items.

Cindy Hake provided an overview of the public meeting process and the overall HCPCS process. She also discussed the survey of stakeholders regarding needed changes to the HCPCS process, the nature of responses to the survey, and the nature of changes already made, as well as pending changes, included in the reformation of the HCPCS process. Monitor the HCPCS world-wide website for announcement of changes to the HCPCS coding process at www.cms.hhs.gov/medicare/hcpcs.

Amy Bassano presented an educational overview of the variety of methods used for setting the payment amount for items, and when the different methods are used. This overview was also provided as a written attachment to the agenda. For additional information, the DME payment rules are located at Section 1834(a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http://cms.hhs.gov/providers/pufdownload/default.asp#dme.

CMS HCPCS Public Meetings provide an opportunity for CMS to share its preliminary coding decisions and payment recommendations, and an opportunity for interested parties to make oral presentations and submit written comments in reaction to CMS' these coding and pricing recommendations.

Prior to the Public Meetings the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding decision. CMS also makes preliminary decisions regarding the applicable payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are included in the public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding decisions based on the input heard at the Public Meetings. Afterwards, the workgroup will decide on its final recommendations. CMS maintains the permanent HCPCS level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment

determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

HCPCS Public Meetings are not workgroup meetings. No final decisions are made at the public meetings. All requestors will be notified in writing, in early November, of the workgroup's final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings for new supplies are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medicare/hcpcs/default.asp. The standard application form for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Public Meeting Summary

The following information includes a detailed summary of each request on the Public Meeting Agenda, along with CMS' preliminary decisions and rationale, and summaries of presentations made by primary speakers.

Meeting Agenda Item #1
June 14, 2005
HCPCS Request #05.34

Background/Discussion:

David I. Bell of Grifols Biologicals, Inc. has submitted a request to establish a code for an immune globulin intravenous (human) liquid, pasteurized, Trade Name: Flebogamma 5%, used to replace immunoglobulins in patients who have congenital or hereditary lack or deficiency of IgG. According to the requester, Flebogamma 5% is a liquid pasteurized intravenous immunoglobulin solution obtained from the plasma of normal U.S. donors. According to the requester, Flebogamma 5% is the only sorbitol stabilized immunoglobulin product available in the marketplace. The requester claims that it is manufactured using a proprietary process utilizing a stabilizer and other components which give rise to a significantly different risk profiles, including incidence of renal failure, stroke and myocardial infarction, by virtue of using sorbitol as a stabilizing agent which has not been associated with renal damage due to hyper-osmotic overload, or stroke or M.I. due to increased blood viscosity. Flebogamma is administered intravenously and dosed by weight. Most patients receive monthly infusions, although some require infusions on a more frequent basis. The usual dose of Flebogamma 5% for replacement therapy in primary humoral immunodeficiency diseases is 300 to 600 mg/kg body weight administered every 3 to 4 weeks. Doses may be adjusted over time to achieve the desired trough IgG levels and clinical response. It is supplied in single dose vials containing 0.5, 2.5, 5 or 10 gram vials of IgG as a 5% liquid solution. The requester claims that existing codes J1563 and J1564 do not allow for accurate billing according to dose by weight and claims that Medicare reimbursement is less than the cost of the product.

CMS HCPCS Workgroup Preliminary Decision:

1) Establish 4 new "Q" codes effective 4/1/2005:

Q9941 Injection, immune globulin, intravenous, lyophilized, 1 G.
Q9942 Injection, immune globulin, intravenous, lyophilized, 10 mg.
Q9943 Injection, immune globulin, intravenous, non-lyophilized, 1 G.
Q9944 Injection, immune globulin, intravenous, non-lyophilized, 10 mg.

2) Change coverage indicator to "not valid for Medicare" for J1563 and J1564, effective 4/1/2005.

3) Discontinue codes J1563 and J1564, effective 12/31/2005.

4) Discontinue 4 "Q" codes effective 12/31/2005.

5) Establish 4 new "J" codes to replace "Q" codes, using identical language, effective 1/1/2006.

Primary Speaker – Paul Pinciaro of Grifols Biologicals, Inc.

- With IGIV being used to treat patients with a variety of disorders, it is important to recognize that all IGIV products are not alike, and therefore, should not be considered commodities.
- Differences in product composition, efficacy, tolerability, safety, packaging, convenience and economics translate directly into both positive and negative effects on both patients and health care providers.
- The safety, efficacy & tolerability profile of Flebogamma® 5% suggests that patients could be easily prescribed the product without undue adverse events.
- The ready to use nature of the product and its low AE rate has positive pharmacoeconomic implications.

Considerations:

- Due to their unique manufacturing steps, IGIV products from the various manufacturers have differences that may be important for some patients:
    - Viral Removal and Inactivation – enveloped & non-enveloped
    - Biological properties
        - IgG Content
        - IgA Content
        - Specific Antibody Titers
    - Chemical Properties
        - Osmolality
        - Ph (Acidity)
        - Stabilizers – sugar vs. non-sugars
    - Tolerability
    - Formulation – liquid vs. lyophilized
    - Shelf Life

Meeting Agenda Item #2
June 14, 2005
HCPCS Request #05.56

Background/Discussion:
Terry Tenbrunsel of Bayer Healthcare LLC has submitted a request to establish a J code for Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified, Trade Name: Gamunex®. According to the requester, Gamunex is indicated as a replacement therapy for primary immunodeficiency states in which severe impairment of antibody forming capacity has been shown. It is indicated in idiopathic thrombocytopenic purpura to rapidly raise platelet counts to prevent bleeding or allow a patient with ITP to undergo surgery. It is administered by intravenous infusion only. It is recommended that it initially be infused at a rate of 0.01 mL/kg per minute for the first 30 minutes. If well-tolerated, the rate may be gradually increased to a maximum of 0.08 mL/kg per minute. It is supplied as a solution for intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish 4 new "Q" codes effective 4/1/2005:

Q9941 Injection, immune globulin, intravenous, lyophilized, 1 G.
Q9942 Injection, immune globulin, intravenous, lyophilized, 10 mg.
Q9943 Injection, immune globulin, intravenous, non-lyophilized, 1 G.
Q9944 Injection, immune globulin, intravenous, non-lyophilized, 10 mg.

2) Change coverage indicator to "not valid for Medicare" for J1563 and J1564, effective 4/1/2005.

3) Discontinue codes J1563 and J1564, effective 12/31/2005.

4) Discontinue 4 "Q" codes effective 12/31/2005.

5) Establish 4 new "J" codes to replace "Q" codes, using identical language, effective 1/1/2006.

Primary Speaker – Dr. Erwin W. Gelfand, M.D., disagreed with the preliminary decision. We suggest that the codes be expanded to also recognize other IGIV components that result in significant therapeutic distinctions among IGIV products. HCPCS Level II coding should differentiate among products based upon these significant and clinically relevant components:

- Formulation – lyophilized or non-lyophilized
- Concentration – regular or high (10%+)
- Sugar content – with or without
- Sodium content – regular or low
- Osmolality – physiologic or non-physiologic
- Viral inactivation – methodology

Where these products significantly differentiate they are indeed different biologicals and should be coded as such.

Meeting Agenda Item #3
June 14, 2005
HCPCS Request #05.35

Background/Discussion:
Mark Reese of Ortho Biotech Products has submitted a request to establish a code for high molecular weight hyaluronan, Trade Name: ORTHOVISC. According to the requester, ORTHOVISC is a high molecular weight, ultra-pure natural hyaluronan dissolved in physiological saline drug that is supplied in a single use syringe and is intended for one time use only. ORTHOVISC is used in the treatment of pain due to osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g. acetaminophen). The treatment course consists of three or four intra-anticular injections administered weekly. The requester claims that combined analysis of two large clinical studies demonstrate significantly larger proportion of ORTHOVISC-treated patients achieving a 40% or 50% improvement in WOMAC pain score (Western Ontario McMaster) compared to controls. Clinical safety and efficacy studies have demonstrated symptomatic relief for 27 weeks.

CMS HCPCS Workgroup Preliminary Decision: Revise code J7317 to read: "sodium hyaluronate, per 20 to 30 mg dose for intra-articular injection", effective 1/1/2006, in order to include Orthovisc in the code category with similar products. Until the code is revised, use C9220 for HOPPS and J3490 for physicians' offices.

There is currently insufficient evidence of a difference in clinical outcome based on molecular weight and no payer identified a national program operating need to differentiate similar products based on molecular weight.

Primary Speaker – Mark Reese of Ortho Biotech Inc., disagreed with the preliminary decision. We feel that Orthovisc should have a separate "J" code. These are the following key points for why a new code should be issued.

- ORTHOVISC is a distinct product with physical differences, administrative differences over a course of therapy and clinical differences compared to other viscosupplements.
- CMS recognizes Orthovisc as a distinct product for drug payment and OPPS payment purposes.
- The impact of combining Orthovisc with other products in an existing code may dramatically skew the market and reduce access to the product and favor a competitor that already has a separate code.
- The absence of a distinct code will eliminate the ability to track the utilization and outcomes of separate products.
- A recent meta-analysis suggests there are outcome differences among viscosupplement products.

We feel that a separate "J" code is needed for ORTHOVISC.

Meeting Agenda Item #4
June 14, 2005
HCPCS Request #04.137

Background/Discussion:

Marsha Kantor, of Sanofi-Synthelabo, Inc., has submitted a request to establish a code for sodium hyaluronate, Trade Name: Hyalgan®. Hyalgan is a prescription injectable material that has both pharmacologic and bio-mechanical properties. It is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy, and to simple analgesics, e.g., acetominophen. Intra-articular administration of Hyalgan into arthritic knees lead to an increase in the viscoelasticity of the synovial fluid. Activation of endogenous hyaluronate production, decreased hyaluronate degradation, increased extracellular matrix production in cartilage, extended maintenance of chondrocyte viability, modulation of inflammatory responses, and coating of pain receptor thereby dampening their activation have also been reported. The standard dose is 20 mg. It is administered by intra-articular injection. A treatment cycle consists of five injections given at weekly intervals. It is supplied as a sterile, non-pyrogenic solution in 2mL vials or 2mL pre-filled syringes, both of which contain 20mg. of Hyalgan.

CMS HCPCS Workgroup Preliminary Decision: Continue to code Hyalgan at existing J7317. The dose descriptor of J7317 will be revised, effective 1/1/06 to read "SODIUM HYALURONATE, PER 20 TO 30 MG DOSE FOR INTRA-ARTICULAR INJECTION" in order to include similar products in this category.

There is currently insufficient evidence to differentiate among products in this code category based on molecular weight or a therapeutic distinction.

Primary Speaker – Paul Radensky, M.D., J.D., disagreed with the preliminary decision. Suggests coding be distinct for each product on the market based on molecular weight. Dr. Radensky claims that scientifically and financially, there is no reason to group some products into one code and leave other products under single codes. Discrete coding and nomenclature for each hyaluronan product will:

- Provide coding and payment equity across the class
- Eliminate coding/payment policies that have resulted in payment and market distortions
- Be scientifically rational

Meeting Agenda Item #5
June 14, 2005
HCPCS Request #04.138

Background/Discussion:

Bill Gittinger, of Smith & Nephew, Inc., has submitted a request to establish a code for 1% sodium hyaluronate (hyaluronan), Trade Name: Supartz®. Supartz is a solution made up of highly purified, sodium hyaluronate, which is a natural chemical found in the body and is in particularly high concentrations in joint tissues and in the fluid that fills the joints. It acts like a lubricant and shock absorber in synovial fluid of a healthy joint. Osteoarthritis reduces a person's synovial fluids ability to protect and lubricate the joint. Supartz joint fluid therapy (2.5ml) is administered by intra-articular injection once a week for a total of five injections. It is supplied as a sterile, non-pyrogenic solution in a 2.5 ml pre-filled syringe. Each 2.5ml pre-filled syringe of Supartz contains sodium hyaluronate 25.0mg, sodium chloride 21.25 mg, dibasic sodium phosphate dodecahydrate 1.343mg., sodium dihydrogen phosphate dihydrate 0.04mg, and water for injection q.s..

CMS HCPCS Workgroup Preliminary Decision: Continue to code Supartz at existing J7317. The dose descriptor of J7317 will be revised, effective 1/1/06 to read "SODIUM HYALURONATE, PER 20 TO 30 MG DOSE FOR INTRA-ARTICULAR INJECTION" in order to include similar products in this category.

There is currently insufficient evidence to differentiate among products in this code category based on molecular weight or a therapeutic distinction.

Primary Speaker – Dr. Edward Miller, Smith & Nephew respectfully disagreed with the HCPCS Workgroup's initial decision to deny its application for a separate HCPCS code for Supartz. Dr. Miller claimed that differences in molecular weight are not relevant, but differences in purity is relevant, and h reiterated Smith & Nephew's request for a unique code to identify Supartz. "Supartz is different enough from other intra-articular injections of hyaluronic acid (IA-HA) to justify it being described by its own unique HCPCS code. While the active ingredient in IA-Has may be chemically identical to one another, the true differences in the Supartz preparation are ingredients Supartz DOES NOT HAVE in the amounts present in the other IA-HA products. These include contaminants such as protein, endotoxins and nucleic acids that can contribute to an increased rate of adverse events. The global clinical experience represented by more than 143 million injections of Supartz over 18 years means that its safety and effectiveness is well-documented, and that unexpected adverse events should not become an issue with Supartz. An exclusive HCPCS code for Supartz joint fluid therapy is justified by the product's unique material differences and extensive clinical experience".

Meeting Agenda Item #6
June 14, 2005
HCPCS Request #05.51

Background/Discussion:
Tom Mitro of ISTA Pharmaceuticals has submitted a request to establish a code for Ovine Hyaluronidase, Trade Name: Vitrase®. According to the requester, Vitrase is derived from ovine testes from New Zealand, a non-bovine spongiform encephalopathy (BSE) source. As a spreading agent, it has found medical applications in ophthalmic anesthesia, subcutaneous urography, hypodermoclysis, and the treatment of certain malignancies. It is a spreading or diffusing substance, which modifies the permeability of connective tissue through the hydrolysis of hyaluronic acid. Hyaluronidase hydrolyzes hyaluronic acid by splitting the glucosaminidic bond between C1of the glucosamine moiety and C4 of glucuronic acid. This temporarily decreases the viscosity of the cellular cement and promotes diffusion of injected fluids or of localized transudates or exudates, thus facilitating their absorption. Dosages range from 55 IU in 50 µL to 200,000 IU. It is commonly injected, including subcutaneous, peribulbar, Sub Tenons, retrobulbar and intravitreal. For certain malignancies, intravenous use may be utilized. Vitrase is supplied in sterile 6200 units of lyophilized ovine hyaluronidase non-preserved in a single use 5ml vial, one 1 mL sterile polycarbonate syringe and one 5 µm sterile needle. It is also supplied as 200 USP units/mL of ovine hyaluronidase non-preserved in a single use 2mL glass vial.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "J" code.

J???? Injection, hyaluronidase, preservative free, up to 100 usp units.

Primary Speaker – Timothy R. McNamara, Pharm.D., agreed with preliminary decision to establish a new code, but are requesting that the new code reflect the origin of preservative-free hyaluronidase as "hyaluronidase (ovine)". Justifications for this request are as follows:

- Vitrase is the only highly purified, preservative free, ovine hyaluronidase product on the market.
- Hyaluronidase (ovine) has been distinguished with its own USAN.
- Vitrase is the only hyaluronidase to be studied in vitreous hemorrhage in humans for safety and efficacy, and is currently the only available non-surgical treatment (off-label).
- The J code for billing Vitrase should be specific for hyaluronidase (ovine).
- Billing units should be based upon 240u for both the 240u and 6200u single dose vials.

Meeting Agenda Item #7
June 14, 2005
HCPCS Request #05.52

Background/Discussion:
Nick Poulios, PhD of Elan Pharmaceuticals, Inc. has submitted a request to establish a code for Natalizumab, Trade Name: Tysabri®. Applicant requests the following code language: Jxxxx INJECTION, NATALIZUMAB FOR INTRAVENOUS INFUSION, 300MG, to differentiate Tysabri from other products. According to the requester, Tysabri, the only humanized monoclonal antibody approved for the treatment of multiple sclerosis (MS), inhibits adhesion molecules on the surface of immune cells. Adhesion molecules allow cells to bind to each other, and in the case of MS, allow activated lymphocytes to bind to endothelial cells, which is a key step in these cells' entering the central nervous system to cause immune damage to the brain. Research suggests that Tysabri works by preventing these immune cells from migrating from the blood stream into the brain where they otherwise might cause inflammation and potentially damage nerve fibers and their insulation. Tysabri is a biologic administered by intravenous infusion over a period of approximately one hour and is indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations. The recommended dose is 300 mg IV infusion every four weeks. It is supplied as a sterile, colorless, and clear to slightly opalescent concentrate for IV infusion. Each package contains 300mg of Tysabri in a single-use vial.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "J" code.

J???? Injection, natalizumab, 1 mg.

Primary Speaker – Mitchell Cohen, Regional Medical Scientist, agreed with the preliminary decision to establish a new code, however, Elan Pharmaceuticals would like the unit descriptor changed to 300mg.

Meeting Agenda Item #8
June 14, 2005
HCPCS Request #05.153

Background/Discussion:
Lisa Colleran of LifeCell Corporation submitted a request to establish a series of 6 codes to distinguish varying thicknesses of Decellularized human tissue; human allogeneic skin; acellular tissue; allograft, Trade Name: AlloDerm® Regenerative Tissue Matrix. The applicant suggests the following language for the requested 6 codes: "Dermal tissue of human origin with or without other bioengineered or processed elements, without metabolically active elements, *by thickness*, per square centimeter". The requester claims that a series of codes is needed to account for different procedures, (implant and/or graft); thickness, and price). According to the requester, AlloDerm® is a regenerative tissue matrix. AlloDerm® acellular dermal graft is a human donor-derived single layer decellularized dermal sheet product for the repair or replacement of human tissue that is freeze dried before packaging. AlloDerm® is used in various procedures for the replacement or repair of damaged or inadequate integumental tissue including closing complicated ventral/incisional hernias, breast reconstruction, and open wound repairs. The tissue derived component is comprised of native human dermal architecture, consisting of about 70-85% collagen (mainly type 1 w/additional collagen type III and IV components), less than 2% each of the chondroitin sulfate and hyaluronic acid glycosaminoglycans, and up to 10% elastin.

CMS HCPCS Workgroup Preliminary Decision: No new code.

This implantable product is not separately payable in any setting. In the inpatient setting, this item is included in the DRG. In an outpatient setting the product is included in the APC or in the practice expense. For Medicare, it is inappropriate to bill using C9221, J7344, or any miscellaneous code to identify this product.

Primary Speaker – Edward Dougherty, consultant to LifeCell Corporation.
LifeCell Corporation appreciates the HCPCS Workgroup's careful review of its coding request. It agrees with the Workgroup's comments in three areas:

- Decellularized human tissue products like AlloDerm are not separately payable when used in the inpatient treatment setting as part of a complex surgical procedure.
- C9221 is not appropriate to describe AlloDerm.
- A miscellaneous HCPCS code is not appropriate to describe AlloDerm.

However, Lifecell respectfully disagreed with the Workgroup's comments in three important areas:

- Decellularized human tissue products are fundamentally different from lower cost supplies, such as mesh. While mesh may be appropriately included in the practice expense for payment purposed, decellularized human tissue products are not appropriately included in the PC or practice expense.

- Decellularized human tissue products are separately payable in the outpatient treatment setting.
- Although J7344 is not adequate, it is appropriate to describe decellularized human tissue products including AlloDerm.

Conclusion and Recommendation to the HCPCS Workgroup:

- Decellularized human tissue products such as AlloDerm provide a regenerative human tissue matrix critical to the success of a variety of complex surgical procedures. These products help restore structure, function and physiology in complex surgical procedures.
- In the absence of new codes to describe decellularized human tissue products, including AlloDerm, providers should use J7344 to bill Medicare for product use in the outpatient treatment setting.

Meeting Agenda Item #9
June 14, 2005
HCPCS Request #05.152

Background/Discussion:
Sajini Thomas of Wright Medical Technology, Inc. submitted as request to establish a code for Micronized Acellular Soft-Tissue Scaffold, Trade Name: GRAFTJACKET® XPRESS Flowable Soft-Tissue Scaffold. According to the requester, this product is a micronized (finely ground) decellularized soft tissue scaffold indicated for the repair or replacement of damaged or inadequate integumental tissue, specifically deep, dermal wounds that exhibit tunneling, and extension from the wound base that may extend deep into the tendon and bone. It is processed and regulated in accordance with the FDA's requirements for the procurement and processing of banked human tissues (CFR Title 21, Part 1270 and 1271) and standards and guidelines of the AATB. The GRAFTJACKET® XPRESS is a soft tissue graft (reconstituted as a "gel"), which is comprised solely of human dermal tissue, including its native protein and collagen structure and essential biochemical composition. The re-hydrated skin substitute scaffold is placed into the tunnels or tracts and produces the same or superior clinical outcomes with a minimally invasive procedure. The applicant claims that C9222 DECELLULARIZED SOFT TISSUE SCAFFOLD, PER 1 CC was established by CMS in 2005 for use in HOPPS, and that the sheet form of the product was assigned to J7344 DERMAL TISSUE, OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER in 2005. The applicant requests a J code for use in the physician office and ASC settings to identify the syringe-delivered form of this product. The applicant suggests the following language for the requested code: "Acellular soft-tissue scaffold gel, per 1 cc". The product is supplied in powder form as part of a kit that includes: 2cc volume of GRAFTJACKET® EXPRESS powder packaged 5cc syringe; 3cc syringe for rehydration; 21 G needle, 19G OPTIVA® catheter; and syringe connector.

CMS HCPCS Workgroup Preliminary Decision: No new code.

Your reported sales volume was insufficient to support your request for a revision to the national codes. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. In addition, more clinical evidence is needed to demonstrate that this product provides a better clinical outcome compared to similar products. Only one study with 15 patients was completed at the time of application.

Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, use A4649 (surgical supply; miscellaneous), for a physician's office. In an ASC, the cost of this product is bundled into the facility fee. For coding guidance for private sector health insurance systems, please contact the individual private

insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe this item.

Primary Speaker – Stephen Brigido, D.P.M., disagreed with the preliminary decision and recommends that CMS re-considers its determination and issue category-specific code for the micronized, flowable form of GRAFTJACKET XPRESS as:
J734X *Acellular dermal soft-tissue scaffold gel, per 1cc*
Rational for new code:

- To provide mechanism to report use of GRAFTJACKET® XPRESS Scaffold micronized, flowable, injectable form of acellular, dermal soft-tissue, in the hospital inpatient, physician office and ASC settings of care, Wright Medical submitted a HCPCS coding request by the January 2005 deadline
- J7344 is not appropriate to describe the GRAFTJACKET® XPRESS Scaffold biologic because the GRAFTJACKET® XPRESS Scaffold is not marketed in sheets with sq cm area
- J7350 "Dermal tissue of human origin, injectable, with or without other bioengineered or processed elements, but without metabolized active elements, per 10 mg"--code descriptor is a near fit, but cannot be used because GRAFTJACKET® XPRESS Scaffold is distributed in "cc" units--not "10 mg" units
- Established coding using J3490 or J3590 cumbersome for providers and payers since requires manual review to confirm product
- The C9222 code is not appropriate as it is applicable only in the HOPD setting of care
- Recommendation included in application was code to parallel J7344 but to reflect flowable, injectable form marketed in "cc" units--not "sq cm" units.

Meeting Agenda Item #10
June 14, 2005
HCPCS Request #05.154

Background/Discussion:

Kathleen Schaum of Kathleen Schaum & Associates, Inc. submitted a request to establish a code for acellular porcine-derived, small intestine submucosa products, trade names: OASIS® Wound Matrix and OASIS® Burn Matrix. The applicant requests a new J-code, to differentiate acellular, procine-derived, small intestine submucosa products from already existing J-codes assigned to dermal and epidermal tissues of human and non-human origin. Oasis is biologically derived, extracellular matrix-based wound care products, translucent and off-white in color. They are obtained from the small intestinal submucosa (SIS) layer of the domestic pig. The isolated submucosa is chemically cleaned, decellularized, freeze-dried, and terminally sterilized. According to the applicant, existing codes (J7340-J7344) do not accurately describe this product for the following reasons: 1) this product is acellular and is not dermal or epidermal; 2) this product is of non-human origin; 3) this product contains bioactive components, however, according to the applicant, "it is not with/without metabolically active elements". The applicant suggests the following language for the requested code: "Acellular submucosal tissue of non-human origin (e.g. porcine), with bioactive components, per square centimeter".

CMS HCPCS Workgroup Preliminary Decision: To establish a new "J" code.

J???? Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter.

Primary Speaker – Robert Demling, MD, supports the preliminary decision to establish a new "J" code and category description that will be appropriate for OASIS Wound Matrix and OASIS Burn Matrix products.

Meeting Agenda Item #11
June 14, 2005
HCPCS Request #05.42
(Duplicate of Request #04.152)

Background/Discussion:
Barbara Ossias, of GE Healthcare, has submitted request establish separate codes for Technetium-99m Exametazime, (Ceretec™) for use in cerebral scintography and infection imaging. According to the requester, Ceretec can be used as an adjunct in the detection of altered regional cerebral perfusion in stroke. Without methylene blue stabilization, it is indicated for leukocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease. Currently, A9521 (Supply of radiopharmaceutical diagnostic imaging agent, technetium Tc 99m exametazine, per dose) is used to denote Ceretec for both infection imaging and brain imaging, despite the variants in how the product is administered for each utilization. The Ceretec kit is supplied as a kit containing five vials with different clinical utilizations. Each vial of Ceretec contains a predispensed sterile, non-pyrogenic, lyophilized mixture of 0.5mg Exametazime. In addition, each package contains five 1ml vials of Methylene Blue Injection USP and five 4.5ml vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP.

CMS HCPCS Workgroup Preliminary Decision:
1) Revise code A9521 to read: (technetium TC-99M exametazine, per study dose, up to 25 millicuries).

2) Use revised code A9521 for leukocyte labeled scintography.

3) Establish a new "A" code.
A???? Injection, methylene blue, 1ML

There was no primary speaker for this item.

Meeting Agenda Item #12
June 14, 2005
HCPCS Request #05.31

Background/Discussion:
Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9523 (Supply of radiopharmaceutical therapeutic imaging agent, Yttrium 90 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkins lymphoma. It is prepared by a radiopharmacist in a patient-specific single use dose, who then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

CMS HCPCS Workgroup Preliminary Decision:
1)Discontinue code A9523 "supply of radiopharmaceutical therapeutic imaging agent, yttrium 90 ibritumomab tiuxetan, per mCi.

2) Establish a new "A" code.
A???? Yttrium Y-90 ibritumomab tiuxetan, therapeutic agent, per study dose, up to 40 millicuries.

There was no primary speaker for this item.

Meeting Agenda Item #13
June 14, 2005
HCPCS Request #05.32
(Duplicate of Request #04.151)

Background/Discussion:

Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9522 (Supply of radiopharmaceutical diagnostic imaging agent, Indium-111 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkin's lymphoma. ^{111}Indium Zevalin is prepared using the ^{111}Indium Zevalin kit, which contains all of the non-radioactive ingredients necessary to produce a single dose of ^{111}Indium Zevalin. The radiopharmacist prepares a single patient-specific dose, and then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code A9522 supply of radiopharmaceutical diagnostic imaging agent, indium-111 ibritumomab tiuxetan, per MCI.

2) Establish a new "A" code.
A???? Indium-111 ibritumomab tiuxetan, diagnostic agent, per study dose, up to 5 millicuries.

There was no primary speaker for this item.

Meeting Agenda Item #14
June 14, 2005
HCPCS Request #05.37

Background/Discussion:
Marie DiFiore of Bracco Diagnostics has submitted a request to change existing code Q3000 " SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, RUBIDIUM RB-82, PER DOSE" to an "A" code for Rubidium Chloride Rb-82, Trade Name: CardioGen-82®. Proposed code A95XX with exact same language as Q3000. According to the requester, CardioGen-82 is a generator containing accelerator produced strontium Sr-82 absorbed on stannic oxide in a lead-shielded column and provides a means for obtaining sterile nonpyrogenic solutions of rubidium chloride Rb-82 injection. The injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction. CardioGen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (60 mCi) and a cumulative dose of 4440 MBq (120 mCi).

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3000 effective 12/31/2005.

2) Establish a new "A" code, effective 1/1/2006.
A???? Rubidium RB-82, per study dose, up to 60 millicuries.

There was no primary speaker for this item.

Meeting Agenda Item #15
June 14, 2005
HCPCS Request #05.185

Background/Discussion:
Skip E. Purich of ChiPhoClin, Inc. submitted a request to establish a code for human secretin, trade name: ChiRhoStim. According to the requestor, ChiRhoStim (synthetic human secretin) is an exact copy of a naturally occurring human hormone produced by cells in the intestinal tract. Secretin is used as a diagnostic agent. It naturally stimulates the exocrine pancreas gland and tests to see whether the pancreas is functioning normally or not in terms of measuring the amount and content of pancreatic juice produced after administration of secretin. Secretin stimulates gastrin secretion to aid in the diagnosis of gastrinoma. It also stimulates pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

CMS HCPCS Workgroup Preliminary Decision: No new code.

In a hospital in-patient environment, this product is included in the DRG. In a physician's office, it is included in the CPT (in the practice expense for the ERCP procedure). In an ASC, it is included in the payment. No insurer identified a national program operating need to separately identify this product because it is bundled, and not separately payable.

Primary Speaker – Skip Edward Purich, Marketing Director, fervently disagreed with the preliminary decision about not issuing a new code. GI physicians may require Secretin for the following procedures:

- CPT 43271 Endoscopic Retrograde Cholangiopancreatography (DX)
- CPT 89105 Duodenal Intubations/Aspiration Multiple specimen W/stimulation of pancreas or gallbladder (Pancreatic Function Testing)
- CPT 82938 Gastrin after Secretin stimulation

However, during ERCP and Pancreatic function testing physicians may or may not use Secretin. Secretin should have a separate J-code for reimbursement. In conclusion, Human Secretin is an injectable drug product. It helps diagnose pancreatic cancer, aids physicians in performing ERCP, AND Pancreatic Function Tests. Some of these tests are performed with or without Secretin and should not be grouped together; instead they should have a separate reimbursement code. I thank the panel for this time and urge you to assign Human Secretin a J-code.

Meeting Agenda Item #16
June 14, 2005
HCPCS Request #05.33

Background/Discussion:
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to convert C1093 SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, TECHNETIUM TC 99M FANOLESOMAB, PER DOSE (10 - 20 mCi) to an A or J code. The language suggested by the requester is AXXXX Supply of Radiopharmaceutical diagnostic imaging agent, Technetium Tc99m fanolesomab per dose (10-20 mCi). The product that is the subject of this request, NeutroSpec™, according to the requester, is a Technetium labeled antibody that is injected directly into a patient. It is an intravenously administered diagnostic imaging agent that binds in vivo, with high affinity and specificity to white blood cells and myeloid precursors. It is administered in a single intravenous dose of 10-20 mCi for diagnostic nuclear imaging procedures.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code C1093 .

2) Establish a new "A"code.
A???? Technetium TC-99M fanolesomab, per study dose, up to 25 millicuries.

Primary Speaker - See agenda item #26.

Meeting Agenda Item #17
June 14, 2005
HCPCS Request #05.28A-E

Background/Discussion:
Request #05.28A-E
Lisa Saake, of Tyco Healthcare/Mallinckrodt, has submitted a request modify the coding for low osmolar contrast drugs for 2006. She has presented two options, which are as follows:
Option 1: Revise A4644 to include a quantity of contrast administered. For example, A4644 Low osmolar contrast 100-199 concentration, per mL. Delete A4645 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 240 concentration, per mL. Delete A4646 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 300 concentration, per mL.
Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine, as below:

Optiray 160– Indicated for intra-arterial digital subtraction angiography. Ioversol injection 34% (Optiray 160) is available in 50 ml and 100 ml glass bottles. It opacifies vessels in the path of the flow of the contrast medium permitting radiographic visualization of the internal structures for diagnostic or therapeutic purposes.

Optiray 240 – Indicated for angiography and venography as well as contrast enhanced computed tomographic imaging of the head and body. It is also indicated for intravenous excretory urography. Ioversol 51% (Optiray 240) is available in 50 mL, 100 mL, 150 mL, and 250 mL glass bottles, 50 mL hand-held syringes, and 125 mL power injector syringes.

Optiray 300 - Indicated for cerebral angiography and peripheral arteriography, as well as contrast enhanced computer tomographic imaging of the head and the body, venography and intravenous excretory urography. Ioversal Injection 64% (Optiray 300) is supplied in 50 mL, 100 mL, 150 mL, and 200 mL glass bottles, 50 mL hand held syringes, 100 mL power injector syringe, and 500 mL Pharmacy bulk pack.

Optiray 320 - Indicated in adults for angiography throughout the cardiovascular system. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management. Ioversal Injection 68% is supplied in 20 mL, 30 mL, 50 mL, 75 mL, 100 mL, 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL and 125 mL power injector syringes, and 250 mL pharmacy bulk packs.

Optiray 350– Indicated in adults for peripheral and coronary arteriography and left ventriculography. It is also indicated for contrast enhanced computer tomographic imaging of the head and the body, intravenous excretory urography, intravenous digital

subtraction angiography and venography. It is indicated in children for angiocardiography. Ioversol Injection 74% (Optiray 350) is available in 50 mL, 75 mL, 100 mL, 150 mL, and 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL, and 125 mL power injector syringes, and 250 mL and 500 mL pharmacy bulk packs.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish seven new "Q" codes effective 4/1/2005.

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646 effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Primary Speaker – Gail Daubert
Ultrasound (Echo) Imaging Drugs
MICAA strongly supports the three new codes for these three distinct chemical entities
Q9955 Injection, perflaxane lipid microspheres, per ml.
Q9956 Injection octafluoropropane, per ml.
Q9957 Injection, perflutren lipid microspheres, per ml.
Recommend "J" codes rather than "A" codes as proposed

Medical Imaging Agents
MICAA supports changes which clarify that low osmolar contrast material and medical imaging agents are drugs
Support deleting terms, such as
"material"
"supply of"
"agent"

MICAA strongly supports CMS's decision to delete the old "A"codes
A9525
A9644-A4646
A4643-4647
MICAA also recommends deleting A9700 supply of echocontrast
Maintaining supply code is confusing to payers and providers
Keeping dual code is inconsistent with HIPAA which requires a uniform code set

Appropriate Classification
MICAA recommends assigning medical imaging drugs "J" codes
These drugs are not "self-administered
"Reasonable and necessary for the diagnosis of an illness injury
Appropriate classification would facilitate use and recognition of these codes by all payers and providers

Additional Recommendations HCPCS codes

- Clarify billing instructions for medical imaging drugs
- Notify carriers of coding changes
- Notify private payers any mid-year coding changes

Final Considerations

- Need time to gain experience with new codes that have been established
- MICAA is working with providers and medical specialty societies to educate providers and payers on the new codes
- We urge CMS to remain open to further refinements that may be required as experience with these codes unfold
- Consider additional changes as needed, especially as new Medicare programs are implemented, e.g., Competitive Acquisition Program, effective 2006, may trigger need for further refinement

Meeting Agenda Item #18
June 14, 2005
HCPCS Request #05.30

Background/Discussion:
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to discontinue A4643 and A4647 and establish new codes that more accurately describe magnetic resonance contrast agents based on the chemical ingredient. In addition, the requestor would like to add a quantity description, per mL, to the code. Specifically, the requester suggests the establishment of a new code and recommended the following language: "GADOVERSETAMIDE INJECTION, PER ML", Trade Name: OptiMARK®. According to the requester, OptiMARK® is a paramagnetic agent that develops in a magnetic moment when placed in a magnetic field. The relatively large magnetic moment can enhance the relaxation rates of water protons in its vicinity leading to an increase in signal intensity, (brightness) of tissue. OptiMARK® is available in 5, 10, 15 and 20mL glass vials and 10, 15, 20, and 30mL plastic syringes.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 3 "Q" codes, effective 4/1/2005.

Q9952 Injection, gadolinium-based magnetic resonance contrast agent, per ml.
Q9953 Injection, iron-based magnetic resonance contrast agent, per ml.
Q9954 Oral magnetic resonance contrast agent, per 100 ml.

2) Discontinue codes Q9952-Q9954 effective 12/31/2005 and crosswalk to new "A" codes.

3) Change coverage indicator to "not valid for Medicare" for codes A4643 & A4647, effective 3/31/2005.

4) Establish 3 new "A" codes identical to the discontinued "Q" codes, effective 1/1/2006.

5) Discontinue codes A4643 and A4647 effective 12/31/2005, no crosswalk.

Primary Speaker - SAME AS AGENDA ITEM #17

Meeting Agenda Item #19
June 14, 2005
HCPCS Request #05.29

Background/Discussion:

Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to:
Option 1: Revise code A4644 to include a quantity of contrast administered, delete A4645 and A4646 and replace them with a series of codes that more accurately describe the products on the market today, or
Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine.
This request would also include the establishment of a code for Ioxaglate Meglumine 39.3% and Ioxaglate Sodium 19.6% Injection USP, Trade Name: Hexabrix.

According to the requester, Hexabrix opacifies vessels in the path of the flow of contrast medium permitting readiographic visualization of the internal structures for diagnostic or therapeutic purposes. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes, effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/05, no crosswalk.

Primary Speaker - SAME AS AGENDA ITEM #17 & 18

Meeting Agenda Item #20
June 14, 2005
HCPCS Request #05.43

Background/Discussion:
Tamar Thompson, of Amersham Health Inc., d.b.a. GE Healthcare, has submitted a request to establish a unique code for iso-osmolar contrast materials, including Visipaque, and other future IOCM products. According to the requester, Visipaque is a dimeric, nonionic, water soluble, iodinated, radiographic contrast medium that is isosmolar to blood at all clinically relevant concentrations. It is administered via intravascular administration and delivers twice the iodine of other contrast agents per molecule with less than half of the osmality of conventional low osmolar agents, and significantly less than high osmolar agents providing advantages, according to recent literature, for high risk patients. It is used to visualize organs. Contrast mediums work by blocking x-rays, thus increasing the visual contrast of soft tissues in the body.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes, effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/05, no crosswalk.

There is currently insufficient evidence to differentiate between iso-osmolar and low osmolar contrast agents based on clinical outcome.

Primary Speaker – Dr. Elliott Fishman, GE Healthcare disagreed with the preliminary decision to deny a separate code category for iso-osmolar contrast materials.
Summary:

- Osmolality is an important factor associated with increased risk of adverse events following contrast administration
- LOCM agents have been demonstrated to be clinically differentiated versus HOCM and is reflected in coding.
- IOCM agents have demonstrated a clinically differentiated adverse event profile from certain LOCM agents and a separate code would assist in management both from a clinical and cost management perspective.

Meeting Agenda Item #21
June 14, 2005
HCPCS Request #05.49

Background/Discussion:
Jay Schafer of Berlex Laboratories submitted a request to establish a code for gadopentetate dimeglumine, trade name: Magnevist®. According to the requester, Gadopentetate dimeglumine is a paramagnetic extracellular contrast drug for Magnetic Resonance Imaging (MRI). Gadopentetate dimeglumine is used to detect and characterize lesions with abnormal vascularity. Gadopentetate dimeglumine gives radiologists the ability to distinguish normal and abnormal tissues in MR exams. This impacts the confidence and accuracy of the diagnosis as well as the speed of the MRI exam. Gadopentetate dimeglumine is injected either directly into a vein or through a catheter into an artery prior to magnetic imaging procedure. The recommended dosage of gadopentetate dimeglumine is 0.2 ml/kg (0.1 mmol/kg) administered intravenously at a rate not to exceed 10mL per 15 seconds.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 3 "Q" codes, effective 4/1/2005:

Q9952 Injection, gadolinium-based magnetic resonance contrast agent, per ml.
Q9953 Injection, iron-based magnetic resonance contrast agent, per ml.
Q9954 Oral magnetic resonance contrast agent, per 100 ml.

2) Discontinue codes Q9952-Q9954 effective 12/31/2005 and crosswalk to new "A" codes.

3) Change coverage indicator to "not valid for Medicare" for codes A4643 & A4647 effective 3/31/2005.

4) Establish 3 new "A" codes identical to the discontinued "Q" codes effective 1/1/2006.

5) Discontinue codes A4643 and A4647 effective 12/31/05, no crosswalk.

Primary Speaker – Jay Schafer, Berlex Labs, agreed with the establishment of new codes, however:

- Magnevist and Ultravist are drugs and should thus be classified with “J” codes.
- New HCPCS codes should be specific to the molecular entities of the individual drugs.
- FDA approved as durgs, under New Drug Applications (NDA).
- Contrast drugs are recognized by Congress as within the Medicare definition of drugs (Social Security Act section 1861(t)(1)).
- Treated as drugs in standard guidelines, including JCAHO guidelines for hospitals and outpatient clinics.

Meeting Agenda Item #22
June 14, 2005
HCPCS Request #05.45

Background/Discussion:
Jay Schafer of Berlex Laboratories submitted a request to establish a unique code for Iopromide, Trade Name: Ultravist®. According to the requester, Ultravist® (Iopromide) is a nonionic, water soluble, tri-iodinated x-ray contrast agent for intravascular administration. Intravascular injection of iopromide opacifies those vessels in the path of flow of the contrast agent, permitting radiographic visualization of the internal structures until hemodilution occurs. Ultravist® (Iopromide) is injected either directly into a vein or through a catheter into an artery prior to x-ray imaging procedure. Injection for any patient scheduled to undergo an imaging procedure that requires the use of a contrast agent (CAT scan, IVP, arteriogram, angiogram, cardiac cath procedure, etc). According to the applicant, existing codes A4644, A4645 and A4646 describing low osmolar contrast agents "do not effectively distinguish drugs which are separate chemical entities".

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Primary Speaker - SAME AS AGENDA ITEM #21

Meeting Agenda Item #23
June 14, 2005
HCPCS Request #05.50

Background/Discussion:
John Warner of Guerbet LLC has submitted a request to establish 2 codes for Oxilan (Ioxilan) Injection: one for 300mgI/ml; and one for 350 mgI/ml. According to the requester, Oxilan Injection is a non-toxic, iodinated, low osmolality contrast medium used for contrast enhancement during x-ray and CT examination procedures. It provides contrast needed to adequately image vasculature, internal organs, etc. due to atoms of iodine carried by the molecule, which are optically dense, thereby giving an image with different visual gradations. It is supplied as Oxilan 300mg/mL and Oxilan 350 mg/mL.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Primary Speaker – John Warner, supports the expansion of the previous 3 applicable A codes to new Q codes which allow more precise coding based upon the amount of iodine administered. However, Guerbet does feel that the assignment of *future* HCPCS codes for imaging agents should also be made on a fair application of what is, presumably, the basis upon which the decision was made to treat non-ionic iodinated agents as a like category. That is, it appears this decision was based upon a finding of similar clinical application, mechanism of actions, etc.

New imaging agents under development will be very different from this current group of agents. These new agents will have various distinct chemical structures, widely varying

mechanisms of action, and for various different indications. Guerbet would hope that as future applications comes before CMS for new agents, the assignment of HCPCS codes will be based upon the unique clinical properties of the agents and that truly unique agents will be assigned unique descriptors in order to allow for specific coding and reimbursement as warranted.

Meeting Agenda Item #24
June 14, 2005
HCPCS Request #05.54

Background/Discussion:
Kathy Francisco of The Pinnacle Health Group, Inc. has submitted a request to establish a code Perflexane Lipid Microspheres, Trade Name: Imagent®. According to the requester, Imagent is a kit for the preparation of perflexane lipid microspheres for injectable suspension. It is a sterile, non-pyrogenic white powder with a diluted perflexane headspace that, after reconstitution into a suspension of microspheres is used for contrast enhancement during the indicated ultrasound imaging procedures. It is indicated for use in subjects with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Imagent must be reconstituted and withdrawn from the vial via the supplied vented 5µm filter dispensing pen. The recommended dose is 0.00625 mL/kg (0.125 mg/kg) administered as a single intravenous bolus over a period of not less then 10 seconds and immediately followed by a saline flush. Imagent must be used within 60 minutes of reconstitution. Imagent kit for the preparation of Perflexane-Lipid Microspheres Injectable Suspension is supplied for single-use and each kit contains a 10-mL glass vial containing 200mg of Imagent powder, a 20-mL plastic vial of Sterile Water for Injection, and 10-mL disposable plastic sterile syringe, a sterile, vented 5µm filter dispensing pen, and a package insert.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish three "Q" codes as follows, effective 4/1/2005.

Q9955 Injection, perflaxane lipid microspheres, per ml.
Q9956 Injection octafluoropropane, per ml.
Q9957 Injection, perflutren lipid microspheres, per ml.

2) Discontinue Q9955-57 effective 12/31/2005 and crosswalk to three new “A” codes.

3) Establish three new “A” codes identical to discontinued Q9955-57, effective 1/1/2006.

There was no primary speaker for this item.

Meeting Agenda Item #25
June 14, 2005
HCPCS Request #05.115

Background/Discussion:
Tuana Pryor of Bristol-Myers Squibb Medical Imaging has submitted a request to establish a code for perflutren lipid microsphere injectable suspension, Trade Name: Definity® and recommends the following language: INJECTION, ACTIVATED PERFLUTREN LIPID MICROSPHERE, PER 2ML. According to the requestor, Definity is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. The visualization of cardiac structures is necessary for a complete assessment of the echocardiographic image. It is administered intravenously, with a typical dose being 1.3 mL. It is supplied sterile as a single use 2-mL clear glass vial.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish a new "Q" code, effective 4/1/2005.
Q9957 Injection, perflutren lipid microspheres, per ml.

2) Discontinue code C9112, effective 12/31/2005.

3) Discontinue code Q9957, effective 12/31/2005.

4) Establish a new "A" code to replace Q9957, effective 1/1/2006.

Primary Speaker – Gordon Schatz, supports the preliminary recommendation to replace the temporary Q9957 code with a permanent code that can be used across multiple settings. However, we do not support the recommendation to replace the Q9957 code with an "A" code. Establishing a permanent "A" code would exacerbate coding problems for providers who use DEFINITY when medically necessary. We respectfully request that CMS:

- Convert the temporary codes Q9957 to the drug "J" series, instead of the supply "A" series of codes. This will more accurately describe the products for what they are – medical imaging drugs. The Medicare statute expressly recognizes contrast agents as drugs (Soc. Sec Act §1861(t)). Using "J" codes will contribute to a more uniform and appropriate reimbursement recognition of echocardiography contrast agents as drugs by all payers.
- Delete the non-specific code A9700, (*Supply of injectable contrast material for use in echocardiography, per study*). We feel that maintaining the A9700 "supply" code that describes echocardiography contrast agents non-specifically is confusing to providers and payers. They may not be directed to the more specific codes and may continue to use the non-specific code despite the issuance of permanent specific codes. Keeping a dual code is inconsistent with the intent of HIPAA to promote the adoption and use of a uniform code set.

Meeting Agenda Item #26
June 14, 2005
HCPCS Request #04.153

Background/Discussion:
Lisa Saake of Healthcare Economics submitted a request to discontinue code Q3010 and establish a "J" code for technetium Tc99m labeled red blood cells, trade name: UltraTag® RBC. UltraTag is a radiopharmaceutical used for blood pool imaging, including cardiac first pass and gated equilibrium imaging; and for detection of sites of gastrointestinal bleeding. Ultra tag causes technetium Tc99m tracer to stick to red blood cells allowing the nuclear imaging camera to follow the flow of blood. The recommended dosage of ultra tag is 10–20 mCi. It is supplied in two components; a non-radioactive component containing the reaction vials and a 20-30mCi of Technetium Tc99m.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3010, effective 12/31/05

2) Establish new code A????, "TECHNETIUM TC-99M LABELED RED BLOOD CELLS, PER STUDY DOSE, UP TO 45 MILLICURIE", effective 1/1/06

AGENDA ITEMS #16, #26 - #31

Primary Speaker – Gordon Schatz, supports preliminary decision "with some fine tuning":

- Eliminate unnecessary repetition of word "diagnostic" with a few exceptions
- Assign radiopharmaceuticals "J" codes instead of "A" codes to ensure that all payors understand and treat these products as drugs and not supplies.
- Eliminate "supply of"; "imaging"; "agent" from the descriptors.
- All radiopharmaceuticals are and should be considered "brand" products, we request to delete the "C" codes C9400-C9403.
- Omit "diagnostic" from all descriptors except: I-131 iodide solution and capsules
- Change "per study dose" to "per dose".
- If using dose range; don't exceed FDA package insert

Meeting Agenda Item #27
June 14, 2005
HCPCS Request #04.154

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3009 and establish a "J" code for Technetium Tc99m oxidronate, trade name: TechneScan HDP®. TechneScan is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis in adult and pediatric patients. It is injected intravenously and is distributed via blood flow throughout the body. TechneScan passively diffuses into the extravascular and extracellular spaces and binds to the hydration shell around the bone crystal. Delayed images will demonstrate the radionuclide bound to the bone crystal, depicting the skeletal system. Recommended dosage of TechneScan is 10-20mCi. It is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3009, effective 12/31/05

2) Establish new code A???? "TECHNETIUM TC-99M OXIDRONATE, PER STUDY DOSE, UP TO 45 MILLICURIES", effective 1/1/06

Primary Speaker - Same as Item #26

Meeting Agenda Item #28
June 14, 2005
HCPCS Request #04.155

Background/Discussion:
Lisa Saake, Director of Health Care Economics, submitted a request to discontinue code Q3005 and establish a "J" code for technetium Tc99m mertiatide, trade name: TechneScan Mag3®. TechneScan is a renal imaging agent used to treat congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatrics patients. Following intravenous injection of technetium Tc99m Mertiatide, the appearance, concentration, and excretion of the tracer in the kidney can be monitored to assess renal function. The suggested dosage for renal function and imaging studies is 5-10 mCi. Technescan is supplied as a sterilized, nonpyrogenic lyophilized powder. Each vial contains betiatide. The vial is reconstituted in a nuclear pharmacy with sterile Sodium Pertechnetate Tc99m forming Technetium mertiatide.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3005, effective 12/31/05

2) Establish new A???? "TECHNETIUM TC-99M MERTIATIDE, PER STUDY DOSE, UP TO 25 MILLICURIES", effective 1/1/06

Primary Speaker - Same as Item #26

Meeting Agenda Item #29
June 14, 2005
HCPCS Request #04.156

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3007 and establish a "J" code for sodium phosphate solution, trade name: Sodium Phosphate P-32 Solution. Sodium Phoshate is a radiopharmaceutical used to treat polycythemia vera. It is also effective for the treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. Polycythemia vera is a disorder that stimulates overproduction of red blood cells, white blood cells, and platelets. Sodium phosphate travels to the bone marrow and impacts the overactive marrow cells. Recommended dosage is 1-8 millicurie depending on the stage of disease and the size of patient. Sodium Phosphate is supplied as a sterile, nonpyrogenic solution in single dose vials containing 5 mCi of phosphorus P-32.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3007, effective 12/1/05

2) Establish new code A???? "SODIUM PHOSPHATE P-32, PER MILLICURIE", effective 1/1/06

Primary Speaker - Same as Item #26

Meeting Agenda Item #30
June 14, 2005
HCPCS Request #04.157

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3011 and establish a "J" code for chromic phosphate P 32 suspension, trade name: Phosphocol® P-32. Phosphocol is a radiopharmaceutical employed by intracavitary instillation for the treatment of peritoneal or pleural effusions caused by metastatic disease and may be injected interstitially for the treatment of cancer. Phosphocol treatment results in cessation or significant decrease in ascites and pleural effusion caused by ovarian, renal, breast and lung cancers or GI tract tumors. Recommended dosage is 10-20mCi. Phosphocol is supplied as a sterile, nonpyrogenic aqueous suspension in a 15 mCi single dose vial.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3011, effective 12/31/2005

2) Establish new code A????, CHROMIC PHOSPHATE P-32 SUSPENSION, PER MILLICURIE, effective 1/1/06

Primary Speaker - Same as Item #26

Meeting Agenda Item #31
June 14, 2005
HCPCS Request #04.158

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3008 and establish a "J" code for Indium-In-111 Pentetreotide, trade name: OctreoScan. OctreoScan is a radiopharmaceutical agent used for the scintigraphic localization of primary and metastic neuroendocrine tumors bearing somatostatin receptors. Indium III works by binding to somatostatin receptors. Recommended dosage of OctreoScan is 6.0 mCi given through intravenous administration. It is supplied as a kit containing an OctreoScan reaction vial, and a vial containing Indium In-111 chloride sterile solution.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue Q3008, effective 12/31/2005

2) Establish new code A????, "INDIUM IN-111 PENTETREOTIDE, PER MILLICURIE", effective 1/1/06

Primary Speaker - Same as Item #26

Meeting Agenda Item #32
June 14, 2005
HCPCS Request #04.159

Background/Discussion:
Denise Merlino of the Society of Nuclear Medicine submitted a request to modify the descriptions of 57 codes for radiopharmaceuticals. These changes are being requested so that the radiopharmaceuticals codes can be consistent in abbreviations and terms used in both short and long descriptors; and to accurately reflect the quantity or unit that is typically purchased, supplied, and administered to the patient. The first recommendation is that the words "supply of" and "imaging" can be removed primarily because these words do not provide any additional clarification to product being described. Secondly, some of the units of measurement should read "per dose". Thirdly, it is requested that all "C" and "Q" codes for radiopharmaceuticals be converted to "A" codes. It is also recommended that radiopharmaceuticals be assigned a consistent designation in column listed by CMS as PI1 for all radiopharmaceuticals under the drug section.

CMS HCPCS Preliminary Decision:
1) Revise code A4641 to read: "RADIOPHARMACEUTICAL DIAGNOSTIC AGENT, NOT OTHERWISE CLASSIFIED"

2) Revise code A4642 to read: "INDIUM IN-111 SATUMOMAB PENDETIDE, PER STUDY DOSE, UP TO 6 MILLICURIES"

3) Revise code A9500 to read: "TECHNETIUM TC-99M SETAMIBI, PER STUDY DOSE, UP TO 45 MILLICURIES"

4) Revise code A9502 to read: "TECHNETIUM TC-99M TETROFOSMIN, PER STUDY DOSE, UP TO 45 MILLICURIES"

5) Revise code A9503 to read: "TECHNETIUM TC-99M MEDRONATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

6) Revise code A9504 to read: "TECHNETIUM TC-99M APCITIDE, PER STUDY DOSE, UP TO 25 MILLICURIES"

7) Revise code A9505 to read: "THALLIUM TI-201 THALLOUS CHLORIDE, PER MILLICURIE"

8) Revise code A9507 to read: "INDIUM IN-111 CAPROMAB PENDETIDE, PER STUDY DOSE, UP TO 25 MILLICURIES"

9) Revise code A9508 to read: "IODINE I-131 IOBENGUANE SULFATE, DIAGNOSTIC AGENT, PER 0.5 MILLICURIE"

10) Revise code A9510 to read: "TECHNETIUM TC-99M DISOFENIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

11) Discontinue codes A9511, A9513, A9514, A9515, A9519, A9520, A9522, A9523, A9533, A9534, eff. 12/31/2005

12) Establish new code A????, "TECHNETIUM TC-99M DEPREOTIDE, PER STUDY DOSE, UP TO 45 MILLICURIES"

13) Revise code A9512 to read: "TECHNETIUM TC-99M PERTECHNETATE, PER MILLICURIE"

14) Establish new code A????, "TECHNETIUM TC-99M MEBROFENIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

15) Establish new code A????, "TECHNETIUM TC-99M PYROPHOSPHATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

16) Establish new code A????, "TECHNETIUM TC-99M PENETATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

17) Revise code A9516 to read "IODINE I-123 SODIUM IODIDE CAPSULE, DIAGNOSTIC AGENT, PER 100 MICROCURIES"

18) Revise code A9517 to read "IODINE I-131 SODIUM IODIDE CAPSULE, THERAPEUTIC AGENT, PER MILLICURE"

19) Establish new code A???? "TECHNETIUM TC-99M MACROAGGREGATED ALBUMIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

20) Establish new code A???? "TECHNETIUM TC-99M SULFUR COLLOID, PER STUDY DOSE, UP TO 25 MILLICURIES"

21) Revise code A9521 "TECHNETIUM TC-99M EXAMETAZIME, PER STUDY DOSE, UP TO 25 MILLICURIES"

22) Establish new code A???? "INDIUM IN-111 IBRITUMOMAB TIUXETAN, DIAGNOSTIC AGENT, PER STUDY DOSE, UP TO 5 MILLICURIES"

23) Estabish new code A???? "YTTRIUM Y-90 IBRITUMOMAB TIUXETAN, THERAPUETIC AGENT, PER STUDY DOSE, UP TO 40 MILLICURIES"

24) Revise code A9524 to read: "I-131 IODINATED SERUM ALBUMIN, DIAGNOSTIC AGENT, PER 5 MICROCURIES"

25) Revise code A9526 to read "NITROGEN N-13 AMMONIA, PER STUDY DOSE, UP TO 40 MILLICURIES"

26) Revise code A9528 to read "IODINE I-131 SODIUM IODIDE CAPSULE, DIAGNOSTIC AGENT, PER MILLICURIE"

27) Revise code A9529 to read "IODINE I-131 SOUDIM IODIDE SOLUTION, DIAGNOSTIC AGENT, PER MILLICURIE"

28) Revise code A9530 to read "IODINE I-131SODIUM IODIDE SOLUTION, THERAPEUTIC AGENT, PER MILLICURIE"

29) Revise code A9531 to read "IODINE I-131 SODIUM IODIDE, DIAGNOSTIC AGENT, PER MICROCURIE (UP TO 100 MICROCURIES)

30) Revise code A9532 to read "SERUM ALBUMIN, DIAGNOSTIC AGENT, PER 5 MICROCURIES"

31) Establish new code Axxxx "IODINE I-131 TOSITUMOMAB, DIAGNOSTIC AGENT, PER STUDY DOSE, UP TO 40 MILLICURIES"

32) Establish new code Axxxx "IODINE I-131 TOSITUMOMAB, THERAPEUTIC AGENT, PER STUDY DOSE, UP TO 100 MILLICURIE"

33) Revise code A9600 to read: "STRONTIUM SR-89 CHLORIDE, PER MILLICURIE"

34) Revise code A9605 to read: "SAMARIUM SM-153 LEXIDRONAMM, 50 MILLICURIES

35) Revise code A9699 to read: "RADIOPHARMACEUTICAL THERAPEUTIC AGENT, NOT OTHERWISE CLASSIFIED"

36) Discontinue codes C1079, C1091, C1092, C1093, C1122, C1200, C1201, C1775, C9000, C9013, C9102 and C9103, eff. 12/31/2005

37) Establish new code A???? "COBALT CO-57/58, CYANOCOBALMIN, PER STUDY DOSE, UP TO 1 MICROCURIE"

38) Establish new code A???? "INDIUM IN-111 OXYQUINOLINE, PER 0.5 MILLICURIE"
39) Establish new code A???? "INDIUM IN-111 PENTETATE, PER 0.5 MILLICURIE"

40) Establish new code A???? "TECHNETIUM TC-99M ARCITUMOMAB, PER STUDY DOSE, UP TO 25 MILLICURIES"

41) Establish new code A???? "TECHNETIUM TC-99M SODIUM GLUCEPTATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

42) Establish new code A???? "TECHNETIUM TC-99M SUCCIMER, PER STUDY DOSE, UP TO 25 MILLICURIES"

43) Establish new code A???? "FLUORODEOXYGLUCOSE F-18 FDG, PER STUDY DOSE, UP TO 45 MILLICURIES"

44) Establish new code A???? "CHROMIUM CR-51 SODIUM CHROMATE, PER STUDY DOSE, UP TO 0.25 MILLICURIES"

45) Establish new code A???? "IODINE I-125 SODIUM IOTHALAMATE, DIAGNOSTIC AGENT, PER 10 MICROCURIES"

46) Discontinue codes Q3000, Q3002, Q3003, Q3004, Q3005, Q3006, Q3007, Q3008, Q3009, Q3010, Q3011 and Q3012, eff. 12/31/2005

47) Establish new code A???? "RUBIDIUM RB-82, PER STUDY DOSE, UP TO 60 MILLICURIES"

48) Establish new code A???? "GALLIUM GA-67 CITRATE, PER MILLICURIE"

49) Establish new code A???? "TECHNETIUM TC-99M BICISATE, PER STUDY DOSE, UP TO 25 MILLICURES"

50) Establish new code A???? "XENON XE-133 GAS, PER 10 MILLICURIES"

51) Establish new code A???? "COBALT CO-57 CYANOCOBALAMIN, PER STUDY DOSE, UP TO 1 MICROCURIE", effective 1/1/06

Primary Speaker – Denise Merlino, SNM concurs with:

- Remove “Supply of”, “imaging” and “agent”
- Change Some RP description to “per study dose”
    - The SNM accepts “per study dose” and understands and does not object to other organizations request for a “per dose” designation which is consistent with current practitioner terminology
- All “C” & “Q” RP codes be converted to “A” codes
    - All Radiopharmaceuticals should be located in a single HCPCS grouping such as “A” or “J” HCPCS designation
        - The SNM accepts “A” and understands and does not object to other organizations request for “J” designation if CMS believes this is more appropriate
    - Needed to eliminate current barriers for use of these codes by all payers across payer settings

<u>SNM recommends:</u>

1. ALL RP must contain dx or rx in the HCPCS description
   - CMS has dropped some RP descriptions which identify the RP as diagnostic (dx) or therapeutic (rx)
     - To keep consistent with the Diagnostic and Therapeutic Hospital Revenue Codes 0343 & 0344
     - To avoid future issues with coding as new RP labeling emerges for both Diagnostic and Therapeutic uses
       - Diagnostic 35 codes require this change (see attachment)
       - Therapeutic 4 codes require this change (see attachment)

2. Add an (S) to any radiopharmaceutical listed as a capsule.
     - Some radiopharmaceutical doses can be administered as a single capsule while the same dose could be administered with 2 or more capsules. The code description should clearly allow for the administered dose irrespective of the number of capsules used to attain that dose.
     - Applies to HCPCS Codes A9516, A9517 & A9528

3. Some Radiopharmaceuticals are supplied in more than one form, for those radiopharmaceuticals, with clearly accepted alternate medical practice applications (public guidelines, text books), we recommend clarification of current codes and creation of additional separate codes, for the following:
   - A9516 IODINE I-123 SODIUM IODIDE CAPSULE(S), DIAGNOSTIC, PER 100 MICROCURIES, UP TO 600 MICROCURIES
   - CMS should create a new code for I-123 doses ranging one millicurie or above:
     A95XX IODINE I-123 SODIUM IODIDE CAPSULE(S), DIAGNOSTIC, PER MILLICURIE (DO NOT USE THIS CODE FOR DOSES LESS THAN 1 MILLICURIE USE CODE A9516)
   - CMS should create additional separate codes for radiopharmaceuticals:
     - **A95XX** TECHNETIUM TC-99M EXAMETAZINE WHITE BLOOD CELLS, DIAGNOSTIC, PER STUDY DOSE, UP TO 2 MILLICURIES
     - **A95XX** TECHNETIUM TC-99M PENETATE AEROSOL, DIAGNOSTIC, PER STUDY DOSE, UP TO 75 MILLICURIES
     - **A95XX** TECHNETIUM TC-99M FILTERED SULFUR COLLOID, DIAGNOSTIC, PER STUDY DOSE, UP TO 5 MILLICURIES

4. Misc. Corrections:
   - Correct Spelling of Sestamibi
   - Dose up to level changes: (examples below; see attachment for all)
     - Q3009 (HDP) A95XX & A9503 (MDP) change to; "up to 30 millicuries"
     - A9626 (Bexxar®) Therapy change to; "up to 325 millicuries"
       - The SNM accepts the up to dose concept for most RP described per dose however we also understand and we do not object to other organizations requests to delete this up to dose, if CMS believes this is more appropriate
     - Q3008 (OctreoScan®) change to; INDIUM IN-111 PENTETREOTIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 6 MILLICURIE
   - A9532 SNM recommends adding the radiochemical Iodine 125 to the description, see SNM proposed code description: IODINE I-125 SERUM ALBUMIN, DIAGNOSTIC, PER 5 MICROCURIES

- C1080, C1081, C1082 & C1083 will CMS delete these effective December 31, 2005?
  - CMS did not mention these specific codes being deleted in the open door preliminary decision documents, what will CMS do with these codes?
  - We believe CMS has accounted for these RP in items 22, 23 & 31, 32

5. Create HCPCS JXXXX Injection Sincalide, per 5 mcg for use with nuclear medicine procedures

- We support the manufacturer application for a separate and distinct J code for Kinevac® sincalide which is commonly used in conjunction with nuclear medicine hepatobiliary procedures:
  - AHA HCPCS Coding Clinic, SNM & ACR recommend coding & billing for Sincalide using J3490
  - See attached letter from the AMA supporting coding separately for Nuclear Medicine related drugs
  - See attached copy of two Medicare carriers Palmetto and WPS, supply coding and pricing information for Sincalide

Meeting Agenda Item #33
June 14, 2005
HCPCS Request # 05.98

Background/Discussion:
Sharon Levy, MD of Dermik Laboratories submitted a request to establish a code for injectable poly-L-lactic acid, Trade Name: Sculptra™. According to the requestor, Sculptra™ is an injectable implant containing microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy family. It is intended for restoration and/or correction of the signs of facial fat loss in people with HIV. It is only FDA approved for HIV patients with lipodystophy. Sculptra™ is injected into the deep dermis resulting in a gradual filling of the facial defect. It is supplied as a sterile freeze-dried preparation for injection in a clear glass vial, which is sealed by a penetrable stopper and covered by an aluminum seal with a flip-off cap. Each carton (unit) of Sculptra™ contains two vials.

CMS HCPCS Workgroup preliminary decision: Not to establish a new code.

Appropriate code assignment is made by the insurer in whose jurisdiction a claim is filed. For Medicare, A9270 NON-COVERED ITEM OR SERVICE is the appropriate code. This item does not fit a Medicare benefit category. For private insurers, code S0196 INJECTABLE POLY-L-LACTIC ACID, RESTORATIVE IMPLANT, 1 ML, FACE (DEEP DERMIS, SUBCUTANEOUS LAYERS) is available for assignment by insurers, if they so choose. Medicaid did not identify a national program operating need to identify the product or treatment, which is considered cosmetic and generally not covered by Medicaid. For coding guidance and policy for private insurance systems, contact the individual insurance contractor. For coding guidance and policy for Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

There was no primary speaker for this item.

Closing Remarks

In light of new information provided at CMS' HCPCS Public Meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation. By mid November 2005, the HCPCS workgroup will mail letters to every requestor of its final decision. The 2006 HCPCS Level II Annual Update, including any coding changes, will be effective January 1, 2006, and will be published at: www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp by mid November, 2005.

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting, and for all the time and effort that was spent on the presentations.

Michael Barron also thanked the audience for their participation, and officially adjourned the meeting.