Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Friday, May 12, 2006

Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 70 people attended. The agenda included 18 items.

CMM staff Amy Bassano presented an educational overview of Medicare payment for part B drugs, biologicals and radiopharmaceuticals. The overview was also provided as a written attachment to the agenda. For additional information, please see the following web links regarding Part B versus Part D coverage**:**
http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf

http://www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf

Cindy Hake provided an overview of the HCPCS public meeting process and the overall HCPCS process.

Prior to Public Meetings, the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare 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 posted on the HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will use the input provided at the Public Meeting to reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendations. The CMS HCPCS workgroup is the entity that 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.

Public Meetings are not CMS HCPCS workgroup meetings. Final decisions are not made at the public meetings. All requestors will be notified in writing, in November, of the 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 are posted on the official HCPCS

world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo in a document entitled: "Alpha-Numeric HCPCS Coding Recommendation Format. The standard application format 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.

Meeting Agenda Item #1
May 12, 2006
HCPCS Request #06.06

Topic/Issue:
Request to establish a code for nitric oxide pharmaceutical gas, trade name: INOmax®.

Background/Discussion:
According to the requester, INOmax (nitric oxide gas) is a drug administered by inhalation. Nitric oxide, the active substance in INOmax, is a pulmonary vasodilator. INOmax is a gaseous blend of nitric oxide and nitrogen (0.08% and 99.92%, respectively for 800 ppm; 0.01% and 99.99% respectively for 100 ppm). INOmax is supplied in aluminum cylinders as a compressed gas under high pressure (2000 pounds per square inch gauge [psig]). It is the first and only FDA approved pulmonary vasodilator for the treatment of neonatal hypoxic respiratory failure (HRF). INOmax, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation (ECMO). In clinical trials, INOmax improved oxygenation (indicated by significant increases in PaO_2) and significantly reduced the need for ECMO.

According to the applicant, existing codes are inadequate to describe this product because: 1) existing code S1025 INHALED NITRIC OXIDE FOR THE TREATMENT OF HYPOXIC RESPIRATORY FAILURE IN THE NEONATE; PER DIEM is not paid by Medicare; 2) The text of S1025 describes the product's indication and therefore would not include new indications when available; 3) Billing for S1025 is "per diem", which is not how this product is used or charged in medical practice; and 4) J3490 UNCLASSIFIED DRUGS slows processing of claims. Requester suggested language: JXXXX – "inhaled nitric oxide; up to one hour"

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish an additional code to identify this product. It is used exclusively in an inpatient setting and it is included in the DRG. For Medicare, it is not separately payable, and use of J3490, J7699 or other miscellaneous codes is inappropriate. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be submitted. For Medicaid, contact the Medicaid agency in the state in which a claim would be filed. For coding guidance for private insurers, contact the individual private insurance contractor.

Primary Speaker:
On behalf of INO Therapeutics LLC, the primary speaker disagreed with the workgroup's preliminary decision and requested reconsideration for establishment of a new code or revision to existing code S1025 to indicate "up to one hour" or "up to 20ppm". The speaker stated that existing S1025 is used for commercial or managed MA payer drug carve-outs when applicable. The speaker claimed that S1025 is too limiting and not reflective of their current business model, which is based on hourly charges;

INOmax is the first FDA approved gas and both the current S code or other J codes off no baseline comparator; and INOmax is administered by a neonatologist during an inpatient hospital stay and should be covered under Medicare Part B under “Drugs paid on a cost or prospective payment basis” with an appropriate, representative code.

Meeting Agenda Item #2
May 12, 2006
HCPCS Request #06.13

Topic/Issue:
Request to establish a "J" code for fluocinolone acetonide intravitreal long-acting implant, trade name: RETISERT™.

Background/Discussion:
According to the requester, RETISERT is a long-acting ophthalmic drug implant designed to release medication to the posterior segment of the eye for 30 months. It is indicated for the treatment of chronic, non-infectious uveitis, affecting the posterior segment of the eye, which is a cause of serious and permanent visual impairment. Each RETISERT implant contains one 0.59 mg tablet of the active ingredient fluocinolone acetonide. The tablet is encased in a silicone elastomer cup containing a release orifice and a polyvinyl, alcohol membrane positioned between the tablet and the orifice. The silicone elastomer cup assembly is attached to a polyvinyl alcohol suture tab with silicone adhesive. The drug implant is surgically implanted into the posterior segment of the eye through a pars plana incision. Fluocinolone acetonide is then released slowly into the posterior segment of the eye over the approximately 30 month period. CMS' division for outpatient care approved a pass-through C code for RETISERT, but a permanent HCPCS J code is needed for non-Medicare patients and in settings other than the hospital outpatient. Proposed Language: Fluocinolone acetonide intravitreal long-acting implant, per 0.59mg.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish an additional code to identify RETISERT. When used with an inpatient procedure, it is included in the DRG. For Medicare, when used in HOPPS, existing code C9225 INJECTION, FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT, PER 0.59 MG may be used. When used with a procedure performed in an ASC, it is included in the ASC payment. When used with a procedure performed in a physician's office, code J3490 UNCLASSIFIED DRUGS may be billed with the appropriate CPT code. For coding guidance for Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For coding guidance for private insurance, contact the individual private insurance contractor.

Primary Speaker:
On behalf of Bausch & Lomb, the primary speaker disagreed with the workgroup's preliminary decision and reiterated the original code request and proposed language. The speaker stated that Retisert is an orphan drug used by a small population of patients. The speaker also indicated that there is a C code specific to Retisert, but a J code is also needed for use by non-Medicare insurers.

Meeting Agenda Item #3
May 12, 2006
HCPCS Request #06.14

Topic/Issue:
Request to establish a "J" code for ibandronate sodium injection, trade name: BONIVA Injection.

Background/Discussion:
According to the requester, BONIVA is an intravenous nitrogen-containing bisphosphonate formulation that will be used for the treatment of osteoporosis in postmenopausal (PMO) women. BONIVA inhibits osteoclast-mediated bone resorption. The action of ibandronate on bone tissue is based on its affinity for hydroxyapatite crystals. Ibandronate inhibits osteoclast activity at the cellular level by preventing the formulation of the ruffled border, and thereby preventing the osteoclasts to form a tight seal at the resorption site, and hindering the resorption process. In PMO women, ibandronate reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, IBANDRONATE SODIUM, 1MG"

Primary Speaker:
On behalf of Roche Laboratories, Inc., the primary speaker agreed with the workgroup's preliminary decision to establish a code, but asked that the workgroup consider a "3 mg" dose descriptor. According to the speaker, Boniva is packaged in a 3mg pre-filled syringe and there is no provision to bill or administer any dose other than 3mg. In addition, a 3mg dosage would reduce billing errors.

Meeting Agenda Item #4
May 12, 2006
HCPCS Request #06.32

Topic/Issue:
Request to establish a code for tigecycline for injection, trade name: TYGACIL®.

Background/Discussion:
According to the requester, TYGACIL is a glycylcycline for intravenous infusion. TYGACIL is indicated for the treatment of complicated skin and skin structure infections (cSSSI) and complicated intra-abdominal infections (cIAI) caused by susceptible strains of the designated microorganisms in the conditions listed in the Prescribing Information. Examples of these infections are complicated appendicitis, intra-abdominal abscesses, deep soft tissue infections and infected ulcers. TYGACIL is indicated for use in adults. TYGACIL is a broad spectrum antibiotic with a recommended dose of 100 mg IV initially, followed by 50 mg IV infusions every 12 hours. TYGACIL is supplied in a single-dose 5 mL glass vial containing 50 mg lyophilized powder for reconstitution. Requester suggested language: "Injection, tigecycline, per 50 mg"

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, TIGECYCLINE, 1MG".

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #5
May 12, 2006
HCPCS Request #06.21

Topic/Issue:
Request to establish a "J" code for galsulfase solution for intravenous infusion only, trade name: Naglazyme

Background/Discussion:
According to the requester, Naglazyme is indicated for patients with mucopolysaccharidosis VI (MPS VI) and has been shown to improve walking and stair-climbing capacity. Patients with MPS VI are deficient in the enzyme N-acetylgalactosamine 4-sulfatase required for the catabolism of glycosaminoglycans (CAGs). This results in GAG accumulation throughout the body, and leads to widespread cellular, tissue, and organ dysfunction. Naglazyme is intended to provide an exogenous enzyme that will be taken up by lysosomes and increase the catabolism of GAGs. The product is used in the outpatient hospital treatment setting and in physician office/infusion center settings that are equipped to infuse on a weekly basis. The recommended dosage regimen for Naglazyme is 1mg/kg of body weight administered once weekly as an intravenous infusion. The total volume of the infusion should be delivered over no less than 4 hours by controlled IV infusion using an infusion pump.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX – "INJECTION, GALSULFASE, 1MG"

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #6
May 12, 2006
HCPCS Request #06.135

Topic/Issue:
Request to establish a code for Abatacept, trade name: ORENCIA®.

Background/Discussion:
According to the requester, ORENCIA® is the first selective T cell costimulation modulator approved for use in rheumatoid arthritis (RA). It is indicated for reducing signs and symptoms, inducing major clinical response, impeding the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs, such as methotrexate or TNF antagonists. ORENCIA should be administered as a 30-minute intravenous infusion at the dose determined by the patient's body weight. Following the initial infusion, ORENCIA should be given at 2 and 4 weeks, then every 4 week thereafter. ORENCIA will be supplied as a lyophilized powder for intravenous infusion in an individually packaged, single-use vial. Each ORENCIA vial provides 250mg of abatacept for intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, ABATACEPT, 10MG"

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #7
May 12, 2006
HCPCS Request #06.62

Topic/Issue:
Request to establish a code for Busulfan, trade name: IV BUSULFEX® Injection.

Background/Discussion:
According to the requester, IV BUSULFEX® is a drug administered by intravenous (IV) Infusion for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia (CML). A hematopoietic stem cell transplant (HSCT) is the only curative treatment for patients with CML. Prior to blood or marrow transplantation, a conditioning or preparative regimen is administered to eradicate malignant cells, make space in the marrow for the donor stem cells, and limit the patient's immune response. Delivery of the intended regimen is a key contributing factor in determining the overall success of the transplant. Busulfan is a bi-functional alkylating agent in which two labile methanesulfonate groups are attached to opposite ends of a four-carbon alkyl chain. In aqueous media, busulfan hydrolyzes to release the methanesulfonate groups. This produces reactive carbonium ions that can alkylate DNA. The approved adult dose is 0.8mg/kg of ideal body weight or actual body weight; whichever is lower, administered every six hours for four days (a total of 16 doses). Requester suggested language: J9XXX – "Injection, busulfan, per 6mg"

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, BUSULFAN, 1 MG"

Primary Speaker:
On behalf of PDL BioPharma, the primary speaker supported the workgroup's preliminary decision to establish a new code, however requested a dose descriptor of 6mg instead of 1mg so that the language will be consistent with the C code that has been in effect for the past 6 years, and billing errors can be avoided.

Meeting Agenda Item #8
May 12, 2006
HCPCS Request #06.22

Topic/Issue:
Request to establish a "J" code for mecasermin [rDNA origin] injection, trade name: Increlex™.

Background/Discussion:
According to the requester, Increlex is indicated for the long-term treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to growth hormone. Increlex replaces IGF-1 in children who do not produce adequate amounts of recombinant human insulin-like growth factor-1). IGF-1 is the principal hormonal mediator of statural growth. Under normal circumstances, growth hormone binds to its receptor in the liver, and other tissues, and stimulates the synthesis/secretion of IGF-1. In target tissues, the Type 1 IGF-1 receptor, which is homologous to the insulin receptor, is activated by IGF-1, leading to intracellular signaling which stimulates multiple processes leading to statural growth. The metabolic actions of IGF-1 are in part directed at stimulating the uptake of glucose, fatty acids, and amino acids so that metabolism supports growing tissues. IGF-1 is the Severe Primary IGFD patients cannot be expected to respond adequately to exogenous GH treatment. The dosage of Increlex™ should be individualized for each patient. Recommended starting dosage is 0.04 to 0.08 mg/kg (40 to 80µg/kg), twice daily by subcutaneous injection. If well-tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to the maximum dose of 0.12mg/kg given twice daily. Increlex is supplied as a 10mg/mL sterile solution in multiple dose glass vials (40mg/vial).

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, MECASERMIN, 1MG"

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #9
May 12, 2006
HCPCS Request #06.29

Topic/Issue:
Request to establish a code for nelarabine, trade name: ARRANON®.

Background/Discussion:
According to the requester, ARRANON® is indicated for the treatment of T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) in pediatric and adult patients whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. No existing code describes nelarabine. The recommended adult dose of ARRANON is 1,500 mg/m² administered intravenously over 2 hours on days 1, 3, and 5 repeated every 21 days. The recommended pediatric dose of ARRANON is 650 mg/m² administered intravenously over 1 hour daily for 5 consecutive days repeated every 21 days. ARRANON Injection is supplied as a clear, colorless, sterile solution in Type I, clear glass vials with a gray butyl rubber (latex-free) stopper and a red snap-off aluminum seal. Each vial contains 250 mg of nelarabine (5 mg nelarabine per mL) and the inactive ingredient sodium chloride (4.5 mg per mL) in 50 mL Water for Injection, USP. Vials are available in packages of 1 and 6.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, NELARABINE, 50MG

Primary Speaker:
On behalf of Glaxo Smith Kline, the primary speaker agreed with the workgroup's preliminary decision to establish a code, but requested that the workgroup consider dose descriptor of 250 mg, to reflect the vial size of Arranon. According to the speaker, no patient should ever receive a 50mg dose; and usage of 50mg as the unit of measure for the code "requires math" and could lead to errors in claims and reimbursement. According to the speaker, a dose descriptor of 250mg as the unit of measure is more appropriate for CMS and other payers because the product is delivered in single use 250 mg vials.

Meeting Agenda Item #10
May 12, 2006
HCPCS Request #06.27

Topic/Issue:
Request to establish a code to uniquely describe Recombinant (hyaluronidase human injection), trade name: Hylenex.

Background/Discussion:
According to the requester, Hylenex is a purified preparation of the enzyme recombinant human hyaluronidase indicated as an adjuvant to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents. Hylenex is the first and only human recombinant alternative to the animal-derived hyaluronidase enzymes currently in use for drug dispersion enhancement. The derivation source of hyaluronidase products is clearly distinct from manufacturing, structural, and patient-safety perspectives. The process by which animal-derived hyaluronidase is manufactured results in multiple impurities and potential contaminants in the preparations, while human recombinant hyaluronidase manufacturing greatly reduces this risk. The FDA designated recombinant hyaluronidase human as a "new chemical entity" and approved the Hylenex NDA under Priority Review status based on the elimination or a substantial reduction of a treatment-limiting drug reaction, transmissible spongiform encephalopathies, compared to the animal-derived hyaluronidase products. Requester suggested language for requested new code – JXXXX "recombinant hyaluronidase human injection, per 50 U"

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code J3470 "INJECTION, HYALURONIDASE, UP TO 150 UNITS"
2) Establish new code JXXXX "INJECTION, HYALURONIDASE, RECOMBINANT, 1 USP UNIT"
3) Revise code J3471 to replace the word "ovine" with "non-recombinant" to read as follows: "INJECTION, HYALURONIDASE, NON-RECOMBINANT, PRESERVATIVE FREE, 1 USP UNIT (UP TO 999 USP UNITS)"
4) Revise code J3472 to replace the word "ovine" with "non-recombinant" to read as follows: "INJECTION, HYALURONIDASE, NON-RECOMBINANT, PRESERVATIVE FREE, PER 1000 USP UNITS"

Primary Speaker:
On behalf of Baxter Healthcare Corporation, the primary speaker supported the workgroup's preliminary decision to revise codes J3471 and J3472, and add a new code to differentiate between recombinant and non-recombinant sources. The speaker claimed that "this differentiation is important because hyaluronidase products from recombinant to non-recombinant derivation sources are clearly distinct from manufacturing, structural, and patient-safety perspectives as determined by the FDA".

Meeting Agenda Item #11
May 12, 2006
HCPCS Request #06.31

Topic/Issue:
Request to establish a "J" code for apomorphine hydrochloride injection, trade name: APOKYN™.

Background/Discussion:
According to the requester, APOKYN is a dopamine agonist used for the acute, intermittent treatment of hypomobility "off" episodes in patients with advanced Parkinson's disease (PD). When injected during an "off" episode, APOKYN may improve the patient's ability to control body movements. APOKYN is an adjunct to PD medications. Prior to APOKYN entering the market, there was no effective acute pharmacological treatment for these episodes. APOKYN is administered via a subcutaneous injection. APOKYN functions like dopamine in the brain to improve the signals between nerve cells and to improve control of muscle activity. When injected during an "off" episode, APOKYN may improve the patient's ability to walk, talk and move around. APOKYN must only be used after proper titration of the initial dose by a physician, in a setting where blood pressure can be closely monitored. APOKYN is supplied in 3 mL cartridges designed to be used with the APOKYN Pen, a manual, reusable multiple-dose injector pen. APOKYN is recommended for injection in the stomach area, upper arm, or upper leg.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, APOMORPHINE HYDROCHLORIDE, 1MG

Primary Speaker:
On behalf of Vernalis Pharmaceuticals, Inc., the primary speaker agreed with the workgroup's preliminary decision to establish a new code, and agreed with the code language.

Meeting Agenda Item #12
May 12, 2006
HCPCS Request #06.33

Topic/Issue:
Request to establish a code for enfuvirtide injection, trade name: FUZEON®.

Background/Discussion:
According to the requester, FUZEON is the first in a new class of antiretrovirals (ARVs) known as fusion inhibitors for the treatment of the human immunodeficiency virus (HIV). Fusion inhibitors use a novel mechanism of action that differs substantially for that of the three oral ARV drug classes currently available: Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) and Protease Inhibitors (PIs). FUZEON is the first injectable ARV to be used as part of a combination therapy. Fusion inhibitors are a new class of anti-HIV medicines that block the virus's ability to fuse to the host's vulnerable CD4 cells. The drug targets the virus outside the CD4 cell, blocking HIV's ability to infect healthy CD4 cells. FUZEON is the only approved anti-HIV medicine that works outside the CD4 cell by blocking viral replication before it starts. It interferes with the entry of HIV-1 into cells by inhibiting fusion of viral and cellular membranes. FUZEON is administered via subcutaneous injection and is always used in combination with other anti-HIV medicines to treat adults and children ages 6 hears and older with HIV infection. When used with other anti-HIV medicines, FUZEON can reduce the amount of HIV in the blood and increase the number of CD4 cells in the blood. The recommended dose is 90mg (1ml) twice daily.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, ENFUVIRTIDE, 1MG".

Primary Speaker:
On behalf of Roche Laboratories, Inc., the primary speaker supported the workgroup's preliminary decision to establish a code, but suggested a 90mg dosage "to reflect the dosing and packaging designation of the approved Food and Drug Administration (FDA) label". The speaker claimed that changing the dose description to match the approved labeled dosing would save physician and facility time and reduce billing errors.

Meeting Agenda Item #13
May 12, 2006
HCPCS Request #06.117

Topic/Issue:
Request to establish a code for Conivaptan hydrochloride injection, trade name: Vaprisol®.

Background/Discussion:
According to the requester, Vaprisol® is the first drug specifically indicated for the treatment of euvolemic hyponatremia, a potentially life-threatening condition that occurs when the body's blood sodium level falls significantly below normal. Euvolemic hyponatremia is frequently encountered in hospitalized patients with hypothyroidism, cancer and syndrome of inappropriate antidiuretic hormone (SIADH). Vaprisol® is for intravenous use only. The recommended loading dose of Vaprisol® is 20mg IV administered as a 30 minute infusion followed by 20 mg administered as a continuous infusion over 24 hours. Following the initial day of treatment, Vaprisol® is to be administered for an additional 1 to 3 days as a continuous infusion of 20 mg/24 hours. Vaprisol® may be titrated upward to 40 mg daily if serum sodium is not rising at the desired rate. Requester suggested language: "injection, conivaptan hydrochloride, 20 mg".

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this product. Given the nature of the continuous IV infusion (one to four day) regimen, it is used primarily in an inpatient setting, and as such, it is included in the DRG, and is not separately payable.

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #14
May 12, 2006
HCPCS Request #06.124

Topic/Issue:
Request to establish a "J" code for methyl aminolevulinate (MAL), trade name: Metvixia©.

Background/Discussion:
According to the requester, Metvixia© is methyl aminolevulinate (MAL), used in the photodynamic therapy (PDT) of actinic keratosis (AK). Metvixia© is indicated for the treatment of thin or non-hyperkeratotic and non-pigmented AK on the face and scalp. Metvixia© cream in combination with 570 to 670 nm wavelength red light illumination using the CureLight Broadband Model CureLight 01 lamp is indicated for treatment of non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation (debridement using a sharp dermal curette) in the physician's office when other therapies are unacceptable or considered medically less appropriate. Metvixia© targets the haem biosynthetic pathway, leading to the accumulation of photoactive porphyrins (PAPs). When exposed to light of appropriate wavelength and energy, the accumulated photoactive porphyrins produce a photodynamic reaction, resulting in a cytotoxic process dependent upon the simultaneous presence of oxygen. The standard treatment is two treatments separated by one week. Requester suggested language: "METHYL AMINOLEVULINATE (MAL) FOR TOPICAL ADMINISTRATION, 2 GM TUBE"

CMS HCPCS Workgroup Preliminary Decision:
This product is not on the market in the United States. No insurer identified a national program operating need to establish a code to identify it. CMS' HCPCS Workgroup will be happy to consider a subsequent application in a later coding cycle, once this product has been marketed in the United States.

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #15
May 12, 2006
HCPCS Request #06.36

Topic/Issue:
Request to establish an "L" code for recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) and Absorbable Collagen Sponge (ACS), trade name: INFUSE® Bone Graft.

Background/Discussion:
According to the requester, the INFUSE® Bone Graft is a bone graft substitute based on Bone Morphogenetic Protein (BMP), a naturally occurring protein that is engineered through recombinant techniques. The product consists of recombinant human bone morphogenetic protein-2 (rhBMP-2), which induces bone formation in fracture sites, and an absorbable collagen sponge (ACS) matrix, which serves as the carrier for the rhBMP-2 at the fracture site. INFUSE® Bone Graft is used to treat acute, open tibial shaft fractures. It is implanted at the fracture site, following internal fixation of the fracture with an intramedullary nail and management of the open wound (cleaning the wound, treating any infection and preparing the wound for closure). INFUSE® Bone Graft reduces the frequency and severity of secondary procedures to promote bone healing; reduces the rate of non-union; increases the chance of fracture healing; and it reduces the incidence of infection in severe open fractures. Requester suggested language: LXXXX "Bone graft substitute, recombinant human Bone Morphogenetic Protein (rhBMP)

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify this product. When used during an in-patient procedure, it is included in the DRG. This product is not a prosthetic, and therefore use of "L" codes is inappropriate. For Medicare, use of "C" and "J" codes is also inappropriate. When used during a procedure performed in HOPPS, it is included in the facility fee; when used in an ASC, it is not separately payable. For coding guidance for Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For coding guidance for private insurance, contact the individual private insurance contractor. Inquiries regarding the inclusion of this product in the procedure code should be submitted to the American Medical Association (AMA) CPT Coding Committee.

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #16
May 12, 2006
HCPCS Request #06.37

Topic/Issue:
Request to establish a code for topical Nonsteroidal Cream, trade name: Atopiclair™.

Background/Discussion:
According to the requester, Atopiclair nonsteroidal cream is indicated to manage and relieve the itching, burning and pain experienced with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis. Atopiclair provides three unique benefits to patients suffering from atopic dermatitis. First, Atopiclair contains key physiologic lipids that help restore the skin-barrier to a healthy state. Second, due to Glycyrrhetinic acid's anti-inflammatory and anti-itch properties, Atopiclair calms the itch, burning and pain associated with atopic dermatitis. Third, Atopiclair contains Sodium hyaluronate, which provides hydration and moisturization. Biafine®, the predicate device for Atopiclair, is a wound dressing emulsion and a radiodermatitis emulsion for radiation/chemotherapy induced skin redness, erythema, and dry/moist desquamation. Requester suggested language: "anti-inflammatory topical cream with sodium hyaluronate, 0.1%, and glycyrrhetinic acid, 2.0%, 100 gram tube"

CMS HCPCS Workgroup Preliminary Decision:
Existing code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE" adequately describes this product. Moisturizer and anti-inflammatory is a common combination. No insurer identified a national program operating need to establish a new code to distinguish this product. Applicant did not present evidence-based clinical studies demonstrating a superior clinical outcome when this product is used, when compared with other products coded in theA6250 category.

Primary Speaker:
On behalf of Chester Valley Pharmaceuticals, the primary speaker disagreed with the workgroup's preliminary decision. According to the speaker, Atopiclair is indicated for treatment of atopic dermatitis, which "offers more therapeutic benefit" and differentiates it from other products coded at A6250. The speaker stated that Atopiclair is not a topical moisturizer nor is it an over-the-counter item. A prescription is required to purchase Atopiclair. The speaker reiterated the original request for a new code for a prescription, anti-inflammatory, non-steroidal cream for the treatment of atopic dermatitis.

Meeting Agenda Item #17
May 12, 2006
HCPCS Request #06.55

Topic/Issue:
Request to establish a "J" code for Naltrexone for extended-release injectable suspension, trade name: VIVITROL™.

Background/Discussion:
According to the requester, VIVITROL™ (naltrexone for extended-release injectable suspension) is an opiate antagonist intramuscular (IM) injection for the treatment of alcohol dependence. VIVITROL is supplied as a microsphere formulation of naltrexone for suspension. Naltrexone blocks the effects of opioids by competitive binding at opioid receptors. It has been proposed that, in patients with alcohol dependence, blocking of the endogenous opioid peptides leads to decreased craving for alcohol, decreased urge to drink, and reduction in the consumption of alcohol. The recommended dose is 380 mg every 4 weeks or once a month. The injection should be administered by a health care professional as an IM gluteal injection, alternating buttocks. Requester suggested language**:** JXXXX – "naltrexone for extended-release injectable suspension, 380mg".

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, NALTREXONE, DEPOT FORM, 1MG".

Primary Speaker:
On behalf of Cephalon, Inc., the primary speaker agreed with the workgroup's preliminary decision.

Meeting Agenda Item #18
May 12, 2006
HCPCS Request #06.101

Topic/Issue:
Request to establish a new code for decitabine for injection, trade name: Dacogen™ for injection.

Background/Discussion:
According to the requester, Dacogen™ (decitabine) for injection, a cytosine nucleoside analog, is an epigenetically active antineoplastic agent. It is a potent DNA hypomethylating agent. Dacogen will be supplied as a lyophilized preparation. Each 20-mL glass vial contains 50 mg of decitabine. The proposed indication for Dacogen is for treatment of patients with Myelodysplastic Syndrome (MDS) including previously treated and untreated, de novo and secondary MDS of the following subtypes: FAB: refractory anemia, refractory anemia and ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia. Dacogen is administered intravenously to patients with MDS from all causes and across the spectrum of MDS severity. The National Comprehensive Cancer Center Network (NCCN) guidelines provide guidance on the use of DNA hypomethylating agents, such as Dacogen and azacitidine across the spectrum of MDS severity. Dacogen is administered at a dose of 15 mg/m^2 as an intravenous infusion over 3 hours, every 8 hours on 3 consecutive days, every 6 weeks. Treatment may be continued as long as the patient continues to benefit. Requester suggested language**:**
JXXXX - "decitabine injection, IV, 1 mg".

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, DECITABINE, 1MG"

Primary Speaker:
On behalf of MGI Pharma, Inc., the primary speaker agreed with the workgroup's preliminary decision to establish a code.

PAYMENT FOR PART B DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Background

Medicare Part B currently covers a limited number of prescription drugs. For the purpose of this discussion, the term "drugs" will hereafter refer to both drugs and biologicals. Currently, covered Medicare Part B drugs generally fall into three categories:

- Drugs furnished incident-to a physician's service - Injectable or intravenous drugs as well as non-injectable or non-intravenous drugs are administered incident-to a physician's service. Under the "incident-to" provision, the physician must incur a cost for the drug, and must bill for it. "Incident-to" coverage is limited to drugs that are not usually self-administered;
- Drugs administered via a covered item of durable medical equipment - DME drugs are administered through a covered item of DME, such as a nebulizer or pump; and
- Drugs covered by statute - Drugs specifically covered by statute include immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained

home dialysis patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities; and osteoporosis drugs.

Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are outside of the scope of the current drug payment methodology include--drugs furnished during an inpatient hospital stay (except clotting factor); drugs paid under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

Part B Drug Payment Methodology

Historical Payment Methodology

Prior to January 1, 2004, payment for the majority of Medicare Part B drugs was set at 95 percent of the average wholesale price. The statutory term, average wholesale price, was not defined in law or regulation. In creating payment limits for Medicare covered drugs, Medicare relied on the list AWP which referred to the AWP published in commercial drug compendia such as Red Book, Price Alert, and Medispan.

In 2004, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the drug payment methodology, reducing the payment rate for most covered Part B drugs from 95 percent of the AWP to 85 percent of the AWP.

Current Methodology

In 2005, the MMA again revised the drug payment methodology by creating a new pricing system based on a drug's Average Sales Price (ASP). Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act, manufacturers submit to us the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance. The WAC is defined, with respect to a drug or biological, as

the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Exceptions to ASP pricing methodology

The MMA exempted certain drugs from the ASP pricing methodology and payment for these drugs remained at 95 percent of the AWP. These drugs include:

- Vaccines – Influenza, Pneumococcal, Hepatitis B;
- Infusion drugs furnished through DME; and
- Blood and blood products (other than blood clotting factor)

Payment for Radiopharmaceuticals

The payment methodology for radiopharmaceuticals did not change under the MMA. Specifically, Section 303(h) states that "[n]othing in the amendments . . . shall be construed as changing the payment methodology . . . for radiopharmaceuticals . . ."

Dispensing/Supplying/Furnishing Fees

Dispensing Fees

Currently, Medicare pays an initial dispensing fee of $57.00 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as Medicare beneficiaries.

Medicare also pays a dispensing fee of $33.00 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispenses during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee will be paid for a 30-day period of inhalation drugs, except in those circumstances where an initial 30-day dispensing fee is applicable instead.

The pharmacy will also receive a dispensing fee of $66.00 for each dispensed 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time.

Supplying Fees

For 2005, Medicare provided a supplying fee of $24 to a pharmacy for each supplied prescription of immunosuppressive drugs, oral anti-cancer drugs and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. The pharmacy also received a supplying fee of $50 for the initial supplied prescription of the above-mentioned drugs during the 1st month following the beneficiary's transplant.

Currently, Medicare pays a supplying fee of $24.00 for the first prescription of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Each pharmacy that supplies the above-mentioned drugs to a beneficiary during a 30-day period will be eligible for one $24 fee in that 30-day period. The pharmacy will be limited to one $24 fee per 30-day period even if the pharmacy supplies more than one category of the above-mentioned drugs (for example, an oral anti-cancer drug and an oral anti-emetic drug) to a beneficiary.

Additionally, Medicare pays a supplying fee of $16.00 to a pharmacy for each subsequent prescription, after the first one, of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Medicare pays the supplying fee for each prescription, including prescriptions for different strengths of the same drug supplied on

the same day (for example, prescriptions for 100mg tablets and 5 mg tablets).

Furnishing Fees

For 2005, Medicare provided a furnishing fee of $0.14 per unit of clotting factor to entities that furnish blood clotting factor unless the costs of furnishing the blood clotting factor are paid through another payment system.

For 2006, the furnishing fee is $0.146 per unit of clotting factor. For subsequent years, the furnishing fee for blood clotting factor will be increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year.

Part B versus Part D

The implementation of Medicare Part D does not change Medicare Part B drug coverage in any way. Drugs that were covered by Medicare Part B prior to the implementation of Part D continue to be covered by Medicare Part B.

Please see the following Web links for additional information regarding Part versus Part D coverage:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf

http://www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf