Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals-Day 2
Thursday, May 8, 2008

Introduction and Overview

Approximately 25 people attended. The agenda included 5 items.

John Warren of CMM presented an educational overview (attached) of Medicare payment for part B drugs, biologicals and radiopharmaceuticals. 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 as it relates to the overall HCPCS coding process.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes 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 website at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes and considers all input provided at the Public Meetings regarding preliminary coding recommendations. CMS also reconsiders its Medicare payment 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.

All requestors will be notified in writing, in November, of the final decision regarding the HCPCS code request(s) they submitted. At around the same time, the HCPCS Annual Update is published at:
www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

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/downloads/2008guidelines.pdf . 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 at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals
Thursday, May 8, 2008, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment #08.15
Request to establish a code for ixabepilone, trade name: Ixempra™.

No Primary Speaker

AGENDA ITEM #2
Attachment #08.18
Request to establish a code for Lanreotide, trade name: Somatuline® Depot Injection.

No Primary Speaker

AGENDA ITEM #3
Attachment #08.93
Request to establish revise the dose descriptor of existing code J3100.

No Primary Speaker

AGENDA ITEM #4
Attachment #08.125
Request to establish a code for levoleucovorin calcium for injection, trade name: ISO-Vorin™.

No Primary Speaker

AGENDA ITEM #5
Attachment #08.14
Request to establish a code for Bendamustine HCl, trade name: Treanda®.

No Primary Speaker

HCPCS Public Meeting Agenda #1
May 8, 2008

Attachment #08.15

Topic/Issue:
Request to establish a code for ixabepilone, trade name: Ixempra™.

Background/Discussion:
According to the requester, Ixempra™ is the first FDA approved epothilone agent. Iabepilone is a microtubule dynamics inhibitor belonging to a class of antineoplastic agents the epothilones and their analogs. Ixabepilone is a semi-synthetic analog of epothilone beta. It binds directly to the beta-tubulin subunits on microtubules, leading to suppression of microtubule dynamics. It suppresses the dynamic instability of alpha-beta-II and alpha-beta-III microtubules. Ixabepilone possesses low in vitro susceptibility to multiple tumor resistance mechanisms including efflux transporters. Ixabepilone blocks cells in the mitotic phase of the cell division cycle, leading to cell death. Ixempra is indicated in combination with capecitabine for the treatment of patients with metastic or locally advanced breast cancer resistant to treatment of with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated. It is also indicated as monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine. Ixempra is administered at 40mg/m2 IV over 3 hours every 21 days. Doses for patients with body surface area (BSA) greater than 2.2 m2 should be calculated based on 2.2 m2. Ixempra is supplied as a 2-vial system (a vial of ixabepilone powder and a vial of diluent for ixabepilone). Only the supplied diluent can be used for constituting Ixempra for injection. The diluent for Ixempra is a sterile, non-pyrogenic solution of 52.8% (w/v) purified polyoxyethylated castor oil and 39.8% (w/v) dehydrated alcohol, USP. Ixempra is supplied in two dosage forms and strengths:
NDC 0015-1910-12 Ixempra, for injection 15 mg supplied with diluent for ixempra, 8 ml
NDC 0015-1911-13 Ixempra, for injection 45 mg supplied with diluent for ixempra, 23.5 ml.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, IXABEPILONE, 1 MG"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda #2
May 8, 2008

Attachment #08.18

Topic/Issue:
Request to establish a code for Lanreotide, trade name: Somatuline® Depot Injection. Applicant's suggested language: "Injection, Lanreotide, 1 mg"

Background/Discussion:
According to the requester, the Somatuline is indicated for the long-term treatment of the acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/radiotherapy is not an option. The active component of Somatuline Depot is Lanreotide. Lanreotide is an octapeptide analog of natural somatostatin which is believed to be similar to that of natural somatostatin. Somatuline is injected subcutaneously into the superior quadrant of the buttock. Patients should begin treatment with 90mg via the deep subcutaneous route at 4 week intervals for 3 months. After 3 months, the dosage may be adjusted if necessary. The injection site should alternate between the right and left side. Somatuline Depot (lanreotide) Injection is supplied as:
60 mg (60 mg/0.2 ml) – single-use pre-filled syringe (NDC 15054-0060-01)
90 mg (90 mg/0.3 ml) - single-use pre-filled syringe (NDC 15054-0090-01)
120 mg (120 mg/0.5 ml) - single-use pre-filled syringe (NDC 15054-0120-02).
According to the applicant, while a C code (C9237) was established 1/1/2008 for OPPS, there is no specific HCPCS code for use when administered in a physician's office.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, LANREOTIDE, 1 MG"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda #3
May 8, 2008

Attachment #08.93

Topic/Issue:
Request to establish revise the dose descriptor of existing code J3100 "INJECTION, TENECTEPLASE, 50MG" from 50mg to 1mg. Trade name: TNKase

Background/Discussion:
According to the requester, TNKase is indicated for use in the reduction of mortality associated with acute myocardial infarction (AMI). This change is requested in order to more accurately recognize the billing and coding weight-based dosing for tenecteplase. TNKase is supplied in a 50mg single dose vial with typical patient dosing ranging from 30mg to 50mg, depending on weight. The current descriptor of "50mg" represents the entire contents of the vial, because the amount administered is based on patient weight and can be less than 50mg the current dose descriptor does not allow for accurate reporting of the amount administered to patients.

CMS HCPCS Preliminary Decision:
1) Discontinue J3100 "INJECTION, TENECTEPLASE, 50 MG" eff. 12/31/08
2) Establish Jxxxx "INJECTION, TENECTEPLASE, 1 MG"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item, however the applicant submitted written comments in support of CMS' published preliminary decision.

HCPCS Public Meeting Agenda #4
May 8, 2008

Attachment #08.125

Topic/Issue:
Request to establish a code for levoleucovorin calcium for injection, trade name: ISO-Vorin™. Applicant's suggested language: "Levoleucovorin calcium for injection, 1 mg"

Background/Discussion:
According to the requester, ISO-Vorin™ contains the pure, natural levo-(or 6S-) isomer of 5-formyl-tetrahydofolic acid that is pharmacologically active and is devoid of the unnatural dextro (or 6R-) isomer that is pharmacologically inactive. ISO-Vorin™ is to be administered by intravenous injection or infusion. ISO-Vorin™ is an orphan drug intended to rescue patients from the toxicity of high-dose methotrexate therapy in osteogenic sarcoma (osteosarcoma). ISO-Vorin™ is also intended to diminish the toxicity and counteract the effects of the impaired elimination or inadvertent overdose of methotrexate. For normal methotrexate elimination, 7.5 mg ISO-Vorin™ is administered every six hours for 60 hours as an intravenous injection or infusion. For delayed late methotrexate elimination, patients continue with 7.5mg intravenously every six hours until the methotrexate level is less than 0.05 micromalar. Upon market launch, ISO-Vorin™ is to be supplied in 50mg vials of freeze-dried powder. Each 50 mg vial of ISO-Vorin™ for injection, when reconstituted with 5ml of sterile diluent, yields a concentration of 10mg/ml of levoleucovorin. According to the requester, this product is not identified by existing HCPCS codes. A new code will facilitate patient access to this product, while it will also allow payer systems to capture important product-specific data, and eliminate billing and coding errors.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, LEVOLEUCOVORIN CALCIUM, 0.5 MG"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda #5
May 8, 2008

Attachment #08.14

Topic/Issue:
Request to establish a code for Bendamustine HCl, trade name: Treanda®. Applicant's suggested language: "Injection, Bendamustine HCl, 5 mg"

Background/Discussion:
According to the requester, Treanda is an antineoplastic purine analog alkylating hybrid, synthesized to combine the activities of the purine antimetabolite benzimidazole with the alkylating properties of the bifunctional mechlorethamine nitrogen mustard. As such, Treanda is used as a chemotherapy agent to induce apoptosis and non-apoptotic cell death. Treanda is awaiting approval for use as an antineoplastic in the treatment of patients with chronic lymphocytic leukemia (CLL). Use of Treanda results in interstrand DNA crosslinks, DNA double-strand breaks and other actions that result in cell cycle arrest and cell death. It is active against both quiescent and dividing cells and exhibits a low level of cross-resistance with other cytotoxic agents. The precise mechanism of action of Treanda in humans has not been fully characterized. Treanda is given intravenously at a dose of 100 mg/m2 over 30 minutes on two consecutive days. Treatment may be repeated every 28 days through six treatment cycles. Treanda must be reconstituted with 20ml of sterile water for injection to a concentration of 5mg/ml. Treanda is supplied in individual, sterile, single-use vials containing 100 mg of Treanda as a lyophilized solid. A 25 mg vial is under development and should be available in January 2009. Cephalon therefore requests a 5mg HCPCS code descriptor to minimize fractional billing units.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, BENDAMUSTINE HCL, 1 MG"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

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 (AWP), 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.

After carefully examining Section 1847A of the Social Security Act, as established in the MMA, CMS has been reviewing its coding and pricing determinations to ensure that separate and appropriate payment is made for single source drugs and biologics as required by this section of the Act. In order to facilitate separate and appropriate payment, it may be necessary to create unique HCPCS level II codes for certain products. As part of this effort, we are also closely reviewing how we operationalize the terms ‘single source drug,’ ‘multiple source drug,’ and ‘biological product’ in the context of payment under section 1847A to identify the potential need to make any changes to our assignment of National Drug Codes to billing codes for payment purposes.

So that we can implement coding and pricing changes swiftly, CMS has used and will continue to use its internal process, when appropriate, for modifying the code set. Please be aware that internally generated code requests are not part of the HCPCs public meeting process.

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 dispensed 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 2008, the furnishing fee is $0.158 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