Medlearn Matters
Information for Medicare Providers

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Implementation Date: January 5, 2004

2004 Update to the Hospital Outpatient Prospective Payment System

Background

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act), authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L.106–554), enacted on December 21, 2000, made further changes in the OPPS. The OPPS was first implemented for services furnished on or after August 1, 2000.

Since the inception of OPPS in 2000, the Centers for Medicare and Medicaid Services has continued to make updates and improvements to this payment methodology. 2004 is no exception. The November 7, 2003, *Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, Final Rule*; the *Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)*; the December 31, 2003, *Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, Final Rule, Correction*; and the January 6, 2004, *Medicare Program: Hospital Outpatient Prospective Payment System: Payment Reform for Calendar Year 2004, Interim Final Rule* have made changes to the OPPS effective January 1, 2004.

Drugs, Biologicals and Radiopharmaceutical Agents

Payment for "Specified Covered Outpatient Drugs"

A "specified covered outpatient drug" is terminology used in the MMA to refer to a covered outpatient drug for which a separate ambulatory payment classification group (APC) exists and that is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

MMA requires classification of separately paid radiopharmaceutical agents and drugs or biologicals that had transitional pass-through status on or before December 31, 2002, into three categories: sole source drugs; innovator multiple source drugs; and noninnovator multiple source drugs. Payment levels based on the reference average wholesale price are specified for each category.

Definitions and Payment Rates for MMA-specified Categories for Drugs, Biologicals, and Radiopharmaceutical Agents

Sole (or single) source drugs are brand name drugs for which there is no FDA generic approval. In 2004, a sole source drug shall be paid no less than 88 percent and no more than 95 percent of the reference AWP.

Innovator multiple source drugs are multiple source drugs that were originally marketed under a new drug application (NDA) approved by the FDA. These drugs were originally sole source drugs for which FDA subsequently approved a generic alternative(s). In 2004, an innovator multiple source drug shall be paid no more than 68 percent of the reference AWP.

Noninnovator multiple source drugs are drugs that are not innovator multiple source drugs. In effect, they are generic drugs approved by the FDA. Noninnovator multiple source drugs in 2004 shall be paid no more than 46 percent of the reference AWP.

In order to implement the provisions timely on January 1, 2004, CMS is instructing hospitals to use the existing HCPCS code that describes the drug for services furnished on or after January 1, 2004. For sole source drugs, the existing HCPCS code is priced in accordance with the provisions of the Act and is displayed in Table 1 of the January 6, 2004, OPPS interim final rule (69 FR 820). However, existing HCPCS codes do not allow for a differentiation between payment amounts for innovator multiple source and noninnovator multiple source forms of the drug.

Therefore, for the January 1, 2004 implementation, CMS has set payment rates for all multiple source innovator and noninnovator drugs, biologicals and radiopharmaceutical agents at the lower of the payment rate in the November 7, 2003 final rule or 46 percent of the reference AWP. These rates are shown in Table 2 of the January 6, 2004, OPPS interim final.

On April 1, 2004, CMS will implement new HCPCS codes that will differentiate noninnovator and innovator multiple source drugs. Use of the new codes will enable providers to bill more accurately and receive appropriate payment. The new HCPCS codes will be effective January 1, 2004, so that providers may submit adjustment bills after April 1, 2004 to receive appropriate payment for the multiple source drugs.

Exceptions: Drugs that are not included in the definition of “specified covered outpatient drugs” include the following:

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision.
- A drug or biological for which a temporary HCPCS code has not been assigned. MMA requires that payment be made at 95 percent of the average wholesale price (AWP) for new drugs and biologicals until a HCPCS code is assigned.
- An orphan drug during 2004 and 2005.

Orphan Drugs

Orphan drugs will no longer be paid at reasonable cost as they were in 2003. Separate payment will be made for single indication orphan drugs by placing them in APCs. Twelve single indication orphan drugs were identified in the November 7, 2003 final rule and December 31, 2003 correction. Of these single indication orphan drugs, two of them (imiglucerase and alglucerase) will be paid at 94 percent of the average wholesale price (AWP). The others will be paid at 88 percent of the AWP.

The 12 single indication orphan drugs are:

J0205 Injection, alglucerase, per 10 units

J0256 Injection, alpha 1-proteinase inhibitor, 10 mg

J9300 Gemtuzumab ozogamicin, 5 mg

J1785 Injection, imiglucerase, per unit)

J2355 Injection, oprelvekin, 5 mg

J3240 Injection, thyrotropin alpha, 0.9 mg

J7513 Daclizumab parenteral, 25 mg

J9015 Aldesleukin, per vial

J9017 Arsenic trioxide, 1mg

J9160 Denileukin diftitox, 300 mcg

J9216 Interferon, gamma 1–b, 3 million units

Q2019 Injection, basiliximab, 20 mg

Pass-through Drugs and Biologicals

MMA established different rates for drugs with pass-through status in 2004, depending on the date of Food and Drug Administration approval. Drugs or biologicals that were first paid on a pass-through basis under the OPPS on or after January 1, 2003, and that were approved by the FDA for marketing as of April 1, 2003, are paid at 85 percent of AWP. Pass-through drugs and biologicals furnished during 2004 that were not approved by the FDA as of April 1, 2003, will be paid at 95 percent of AWP.

There are nine drugs and biologicals with pass-through status in 2004 that also meet the criteria for "specified covered outpatient drugs." Payment for these will be at 88 percent of AWP.

Pass-through Drugs Reimbursed at 85 Percent of AWP:

J9395 Injection, Fulvestrant, per 25 mg

C9121 Injection, Argotroban, per 5 mg

C9123 TransCyte, per 247 sq cm

C9205 Injection, Oxaliplatin, per 5 mg

C9203 Injection, Perflexane lipid microspheres, per single use vial

J3315 Injection, Triptorelin pamoate, per 3.75 mg

J3486 Injection, Ziprasidone mesylate, per 10 mg

C9211 Injection, IV, Alefacept, per 7.5 mg

C9212 Injection, IM, Alefacept, per 7.5 mg

Pass-through Drugs Paid at 95 Percent of AWP:

C9207 Injection, IV, Bortezomib, per 3.5 mg

C9208 Injection, IV, Agalsidase beta, per 1 mg

C9209 Injection, IV, Laronidase, per 2.9 mg

C9210 Injection, IV, Palonosetron HCI, per 0.25 mg (250 micrograms)

Pass-through Drugs Paid at 88 Percent of AWP:

J0583 Injection, Bivalirudin, per 1 mg

C9112 Injection, Perflutren lipid microsphere, per 2 ml

C9113 Injection, Pantoprazole sodium, per vial

J1335 Injection, Ertapenem sodium, per 500 mg

J2505 Injection, Pegfilgrastim, per 6 mg single dose vial

C9200 Orcel, per 36 square centimeters

C9201 Dermagraft, per 37.5 square centimeters

J2324 Injection, Nesiritide, per 0.5 mg

J3487 Injection, Zoledronic acid, per 1 mg

Outliers

CMS has established two separate outlier thresholds for CY 2004, one for Community Mental Health Clinics (CMHCs) and one for hospitals. The outlier threshold for CMHCs is 3.65 times the APC payment. The outlier threshold for hospitals is 2.60 times the APC payment. The outlier payment percentage is 50 percent of the amount of costs in excess of the threshold for both CMHCs and hospitals.

MMA excludes separately payable drugs and biologicals as well as brachytherapy sources from outlier payments.

Transitional Outpatient Payments (TOPS)

TOPS are being eliminated for most providers effective January 1, 2004, except for cancer hospitals and children's hospitals, which are held harmless permanently under the transitional corridor provisions of the Act, and small rural hospitals with fewer than 100 beds and sole community hospitals (SCHs) located in rural areas.

MMA extends hold-harmless protection to small rural hospitals with 100 beds or less for a two year period. Eligible providers will continue to receive TOPS payments from January 1, 2004, through December 31,

2005. Additionally, MMA authorizes such protection for Sole Community Hospitals (SCHs) located in rural areas for the period which begins with their cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. There may be a short period after January 1, 2004, during which SCHs will not be eligible to receive TOPS until their cost reporting period begins after January 1, 2004. However, if the SCHs also meet the criteria of being rural with 100 beds or less, they can continue TOPS payments from January 1, 2004 through December 31, 2005, if applicable, without any interruption in the payments.

Brachytherapy Sources Are To Be Paid Separately

Section 621(b)(1) of the MMA of 2003 amends the Act by adding section 1833(t)(16)(C) and section 1833(t)(2)(H) which establish separate payment for devices of brachytherapy consisting of a radioactive source (e.g. seeds, threads) based on a hospital's charges for the service, adjusted to cost. Further, charges for the brachytherapy devices shall not be used in determining any outlier payments and consistent with our practice under OPPS to exclude items paid at cost from budget neutrality consideration, these items will be excluded from budget neutrality as well. The period of payment under this provision is for brachytherapy sources furnished from January 1, 2004 through December 31, 2006.

The status indicator for brachytherapy sources is changed to ''H'' and the definition of status indicator ''H'' is changed for 2004 to include non-pass-through brachytherapy sources paid for on a cost basis. This use of status indicator ''H'' is a pragmatic decision that allows CMS to pay for brachytherapy sources in accordance with new section 1833(t)(16)(C) effective January 1, 2004, without having to modify our claims processing systems. CMS will revisit the use and definition of status indicator ''H'' for this purpose for the OPPS update for 2005.

Brachytherapy Sources to be Paid Separately, Using Charges Reduced to Cost:

C1716 Brachytx source, Gold 198

C1717 Brachytx source, HDR Ir-192

C1718 Brachytx source, Iodine 125

C1719 Brachytx source, Non-HDR Ir-192

C1720 Brachytx source, Paladium 103

C2616 Brachytx source, Yttrium-90

C2632 Brachytx solution, I–125, per mCi

C2633 Brachytx source, Cesium-131

C2632 Brachytx sol, I–125, per mCi

Flu and Pneumonia Vaccines

Flu and pneumonia vaccines furnished on or after January 1, 2004, are paid on a reasonable cost basis.

Hospital Outpatient Prospective Payment System Information Resources

Publications

- Federal Register, Vol. 69, No. 3 / Tuesday, January 6, 2004, Medicare Program: Hospital Outpatient Prospective Payment System, Payment Reform for Calendar Year 2004, Interim Final Rule
- Federal Register, Vol. 68, No. 250 / Wednesday, December 31, 2003, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, Final Rule, Correction
- Medicare Prescription Drug, Improvement, and Modernization Act of 2003
- Federal Register, Vol. 68, No. 216 / Friday, November 7, 2003, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, Final Rule.

Hospital Outpatient PPS Website (www.cms.hhs.gov/medlearn/refopps.asp)

- Quick reference guide
- Resources
- Instructions
- Educational materials
- Join outpatient PPS listserv (electronic mailing list)