Process and Information Required to Determine Eligibility of Drugs, Non-Implantable Biologicals, and Radiopharmaceutical Agents for Transitional Pass-Through Status Under the Hospital Outpatient Prospective Payment System (OPPS)

Please note: Effective January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) will be evaluated for device pass-through payment under the instructions using the device pass-through process. For the processes and information required to apply for designation of **New Technology services or new pass-through device categories** go to the main OPPS web page, currently at http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf to see the latest instructions. (NOTE: Due to the continuing development of the new cms.hhs.gov web site, this link may change.)

This announcement describes in detail the process and information required for applications requesting transitional pass-through payment for drugs, non-implantable biologicals, and radiopharmaceutical agents under the Medicare hospital outpatient prospective payment system (OPPS). These instructions apply solely to requests submitted **on or after January 1, 2010** for transitional pass-through status for drugs, non-implantable biologicals, and radiopharmaceuticals.

Because CMS intends to make information used in the ratesetting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

We will accept transitional pass-through applications for drugs, non-implantable biologicals, and radiopharmaceutical agents on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which transitional pass-through status is sought to allow time for analysis, decision-making, and computer programming. The table below indicates the earliest date that pass-through status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the first business date in	**Earliest Date To Be Considered For Pass-Through Status Effective. . .**
March	July 1
June	October 1
September	January 1
December	April 1

A longer evaluation period may be required if an application is incomplete or if further information is required upon which to base a determination of pass-through eligibility.

An application is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

BACKGROUND:

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as "current," the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of BIPA (Pub. L. 106-554), on December 21, 2000).

Transitional pass-through payments are also provided for certain "new" drugs, devices and biological agents that were not being paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. Transitional pass-through payments for drugs and biologicals under the OPPS are discussed in the final rule published in the April 7, 2000 Federal Register (65 FR 18478), and in subsequent OPPS rules and issuances, which can be found at, http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage, http://www.cms.hhs.gov/MLNMattersArticles/, and http://www.cms.hhs.gov/Manuals/.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Payment for OPPS pass-through drugs and biologicals is set at the rate under the Competitive Acquisition Program (CAP) for Part B drugs or, if the drug is not included in the CAP, at the rate established by the ASP methodology. For CY 2011, payment rates will be established under ASP methodology. Under the hospital OPPS, radiopharmaceuticals are considered drugs for pass-through purposes. For CY 2011, payment for diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status will be based on the ASP methodology.

The most current list of the drugs and biologicals that are separately paid under the OPPS, along with their payment rates, can be found in the most recent quarterly update of Addendum B, located at http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage. Information on Average Sales Price is found at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/.

REQUIRED INFORMATION:
The information in **items 1-12**, below, is required in **every application** for pass-through payment for a drug, biological or radiopharmaceutical. An application that does not include the following information is considered incomplete and cannot be acted upon:

1. The trade name and generic name of the product.

2. A detailed description of the clinical application of the product:
    a. What it is and what it does.
    b. The form in which it is supplied (i.e., solution, tablet, etc.).
    c. Method of administration (intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.).
    d. Manner of packaging (indicate dosages/concentrations per ml, per tablet, per mCi, etc.).
    e. The usual minimum dosage per administration for one patient.
    f. The usual maximum dosage per administration for one patient.

g. The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day?
h. How dosages are measured.

3. A copy of the most recently published average wholesale price (AWP) and/or wholesale acquisition cost (WAC), including the date of publication and compendium where published (examples include Red Book® and Medi-Span®). NOTE: Applicants may be responsible for updating their compendia submission prospectively.

4. Average Sales Price (ASP) or Wholesale Acquisition Cost (WAC) for specified units of the drug.

5. The current cost of the drug or biological to hospitals, that is, the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the actual cost to hospitals for a specific drug or biological specified in terms of dosage and concentration.

6. The actual market date or date of sale of first unit. NOTE: If a drug is pending imminent FDA approval, indicate estimated FDA approval date and anticipated date of sale of first unit.

7. List the Healthcare Common Procedure Coding System (HCPCS) code(s) associated with the product.
   a. CPT or Level II alphanumeric HCPCS code that reflects the procedure code(s) associated with the product's use (e.g.,CPT codes for drug administration, etc.).
   b. Level II alphanumeric HCPCS code that specifically identifies the product/item (if available). Specifically, list the C-code, J-code, Q-code, or any other Level II alphanumeric HCPCS code that appropriately describes the item,
   (NOTE: APPROVAL OF A DRUG OR BIOLOGICAL FOR A TRANSITIONAL PASS-THROUGH PAYMENT UNDER THE OPPS IS NOT CONTINGENT ON PRIOR ASSIGNMENT OF A NATIONAL HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODE.). If no HCPCS code is currently available, please specify the requested code descriptor, including dosage units.

8. Usage: Projected (units) volume by site of service that reflects **one full year of utilization** based on the drug's package size. Indicate the projected timeframe for the utilization (e.g., Jan 1 – Dec 31, 2008, Apr 1 – Mar 30, 2008, etc.). If a drug is packaged in multiple sizes, list projections for every single package size. List projected volume separately by the following categories:
   a. Medicare Inpatient Hospital
   b. Medicare Outpatient Hospital
   c. Medicare Physician's Office
   d. Medicare Ambulatory Surgical Center
   e. Other sites of services (e.g., Medicaid, Veterans Administration, etc.).

9. A copy of the Food and Drug Administration (FDA) approval/clearance letter (including FDA summary sheets) for the product. NOTE: If a drug is pending imminent FDA approval, indicate estimated FDA approval date.

10. A copy of the package insert.

11. For non-implantable biological application(s), a copy of the United States Pharmacopeia (USP) Monograph for the product is required if it has not received FDA approval as a biological.

12. Applicant name(s), company name, address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different

from the requester, give the applicant name, company name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.

13. Other information as CMS may require to evaluate a specific request or that the applicant believes CMS may need to evaluate the application.

IN ADDITION, answer 13A. or 13B., whichever is applicable.

13A. For drugs and non-implantable biologicals OTHER THAN contrast agents or radiopharmaceutical products, specify how dosages are measured, i.e., in milligrams, micrograms, etc.

13B. For diagnostic and therapeutic radiopharmaceutical drugs and for contrast agents, specify the following information:

a. Indicate whether the product is available in milligrams (mg), millicuries (mCi), or microcuries (uCi), including concentration before and after reconstitution.
b. If the AWP is stated "per vial" or "per ampule," indicate how many doses can be administered from one vial or one ampule.
c. If the AWP is stated "per dose," "per vial," or "per ampule," but the item is administered in milligrams (mg), millicuries (mCi), or microcuries (uCi), indicate how many mg, mCi, or uCi are in one dose, one vial and/or one ampule.

NOTE: A separate application is required for each distinct drug, non-implantable biological or radiopharmaceutical agent included in a request. For example, if an applicant requests transitional pass-through status for five new drugs, the required information listed above must be completed for each of the five drugs.

WHERE TO SEND APPLICATIONS

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail. Mail **six** (6) copies of each completed application to the following address:

OPPS Pass-Through Applications
Division of Outpatient Care
Mailstop C4-05-17
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Questions pertaining to the pass-through payment application process for drugs, non-implantable biologicals or radiopharmaceutical agents may be sent via e-mail to the Division of Outpatient Care mailbox, OutpatientPPS@cms.hhs.gov, or by phone to 410-786-0378.

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