

Application Process for Submitting Transitional Pass-Through Applications for Drugs, Non-Implantable Biologicals and Radiopharmaceuticals Under the Hospital Outpatient Prospective Payment System (OPPS)

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Background

Section 1833(t)(6) of the Social Security Act established temporary additional payments or “transitional pass-through payments” for certain drugs, biologicals, and radiopharmaceutical agents. This provision requires the Secretary to make additional payments that is at least 2 but no more than 3 years.

Drugs Eligible for Pass-Through Payments

(1) Orphan drugs

- Designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(2) Cancer therapy drugs and biologicals

- chemotherapeutic agent
- antiemetic
- hematopoietic growth factor
- colony stimulating factor
- biological response modifier
- bisphosphonate

Drugs Eligible for Pass-Through Payments

(3) Radiopharmaceuticals

- Under the hospital OPPS, diagnostic and therapeutic radiopharmaceuticals are considered drugs for pass-through purposes

(4) Other Drugs and Biologicals

- Drugs not paid as a hospital outpatient drug as of December 31, 1996
- Biologicals are not surgically implanted or inserted into the body

Criteria For Consideration for Pass-Through Payment

- Complete application
 - Approved by the Food and Drug Administration (FDA)
 - Non-implantable biological products
 - ❖ listed in the United States Pharmacopeia, or
 - ❖ received FDA approval as a biological
- Must fall into one of the types of products eligible for pass-through status
- Potentially payable under the hospital OPPS

Criteria For Consideration for Pass-Through Payment

- ✓ Cost of the drug is “not insignificant” relative to APC payment of the procedure associated with the drug
- ✓ Pass cost-significance test
 - (1) Average cost of the new drug exceeds 10 percent of applicable APC payment
 - (2) Average cost of the new drug exceeds the cost of the drug portion of the APC payment amount by at least 25 percent.
 - (3) Difference between the average cost of new drug and cost of drug-related portion of APC payment exceeds total APC payment by 10 percent

Cost Significance Test

- Three pronged test that compares reasonable cost of the product to
 - ✓ APC payment for services most appropriately billed with the drug or biological; and
 - ✓ Portion of the APC payment for services most appropriately billed with the drug or biological that is attributable to packaged drugs and biologicals.
 - ✓ Uses a different APC payment portion depending on the product
 - “Policy Packaged” - diagnostic radiopharmaceuticals and contrast agents
 - “Threshold Packaged” - drugs and non-implantable biologicals subject to OPPS packaging threshold
 - 2011 Offset Amounts by APC available on our website http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage

Application Timeframe

We accept transitional pass-through applications on an ongoing basis.

To Be Considered for Pass-Through Status Effective . . .	Complete Application Received by First Business Date:
January 1	September
April 1	December
July 1	March
October 1	June

Application Information Sheet

- Information sheet on submission can be found on our website at <http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf>
- No official form

Required Information To Process Application

- An application is not considered complete until:
 - All required information has been submitted, AND
 - All questions related to the application have been answered

Required Information To Process Application (continued)

- Once the review is complete and a decision has been made, a letter will be sent to the designated contact individual:
 - denial letter indicating reason for the denial; or
 - approval letter indicating the effective date of the pass-through status for the product
- approval for pass-through does not guarantee payment, subject to contractor local medical review policy

When Approved for Pass-Through Status

- A Healthcare Common Procedure Coding System (HCPCS) code will be assigned to the drug (temporary or permanent)
- The HCPCS code will be effective with the start date of the pass-through drug, which is the beginning of a quarter (i.e., Jan 1, Apr 1, Jul 1, or Oct 1)

Payment Methodology for Pass-Through Drugs

- Payment for OPPS pass-through drugs is set at the rate established by the Average Sales Price (ASP) methodology (ASP + 6%) for Part B drugs, or at the rate under the Competitive Acquisition Program (CAP) for Part B drugs, if the CAP program is active
- Since the CAP program has been suspended since January 2009, for CY 2011, payments for pass-through drugs is based on the ASP methodology
- For contrast agents and diagnostic radiopharmaceuticals, payment reduced by (offset by) the amount of packaged drug cost in associated APCs

Payment Updates for Pass-Through Drugs

- ASP amounts are updated on a quarterly basis as part of the ASP methodology process, and the OPPS payment rates are adjusted accordingly
- Additional information on the ASP methodology is available at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>

Current List of Pass-Through Drugs

- OPPTS: Most recent quarterly update of Addendum B
 - HCPCS code
 - Payment status indicator (SI) “G” (pass-through drugs and biologicals)
 - Payment rate
 - <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp#TopOfpage>

- ASC : Most recent quarterly update of Addendum BB
 - Medicare makes the same payment for drugs in the ASC as under the OPPTS, when drugs are ancillary to a covered surgical procedure
 - Payment indicator (PI) “K2”
 - Payments are updated quarterly
 - http://www.cms.gov/ASCPayment/11_Addenda_Updates.asp#TopOfPage

Questions on the Application Process for OPPS Pass-through Drugs

For further assistance with the application process:

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