Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Welcome to the Drug and Biological Pass-Through Application

Application Guidance

Background:

Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the Balanced Budget Refinement Act of 1999 (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs,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 sources used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also provided for certain "new" drugs, devices and biological agents that were not 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:

Hospital Outpatient Regulations and Notices

MLN Matters Articles

Application Process and Timeline

What is the application timeframe?

We will accept transitional pass-through applications for drugs, biologicals, and radiopharmaceuticals 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.

Applications submitted by	Earliest effective date for pass-through status
March 1st	July 1st
June 1st	October 1st
September 1st	January 1st
December 1st	April 1st

How the Online Application Works

Fields and Inputs
All fields are required unless marked as optional.

Saving
The application saves automatically so you can continue where you left off.

Submission
CMS may request additional information and/or documentation to support this application.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0802 (Expires: 01/31/2025). This is a required information collection. The time required to complete this information collection is estimated to average 16 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

CMS Disclosure

Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact the CMS point of contact for this module using the form available at the bottom of the MEARIS™ Drug and Biological Pass-through resources page.

A. Contact Information

1. Who is the primary contact?
    - First Name
    - Middle Name (optional)
    - Last Name
    - US Phone Number
    - Extension (optional)
    - Email Address
    - Country: United States
    - Mailing Address Line 1
    - Mailing Address Line 2 (optional)
    - City
    - State
    - Zip Code
    - Organization (optional)
    - Relationship:
        - Consultant
        - Manufacturer
        - Other (Describe “other”)
2. Who is the secondary contact?
    - First Name
    - Middle Name (optional)
    - Last Name
    - US Phone Number
    - Extension (optional)
    - Email Address
    - Country
    - Mailing Address Line 1
    - Mailing Address Line 2 (optional)
    - City
    - State
    - Zip Code
    - Organization (optional)
    - Relationship:
        - Consultant
        - Manufacturer
        - Other (Describe “other”)

B. Drug Information

1. Have you completed other MEARIS™ applications for this drug? (Yes/No)
   a) If Yes: Please provide information about your previous applications. If No: Continue to b.
      - Applications Type:
        - New Technology Add-on Payments (NTAP)
        - Device Pass-through
        - Drug and Biological Pass-through
        - New Technology Ambulatory Payment Classification (APC)
        - Healthcare Common Procedure Coding System (HCPCS) Level II
        - International Classification of Diseases Request (ICD-10-PCS)
      - Applications Status (optional):
        - Approved
        - Denied
        - Withdrawn
        - Pending
      - Description
      - Submission Date (optional)
   b) Provide information about the drug.
      - Drug Trade Name
      - Generic Name
      - Drug Type
        - Drug
        - Biological
        - Radiopharmaceutical
        - Viscosupplements
        - Other (Describe "other")
      - What is the drug's form?
        - Solution
        - Tablet
        - Other (Describe "other")
      - What is the date of commercial market availability or date of sale of first unit?
      - What is the composition and clinical indication(s) of the drug?
      - What is the manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.)?

Note for applicant: Packaging, that is, the quantity of the drug, biological or radiopharmaceutical that is represented by an NDC or similar product identifier, must be able to be verified through a publicly available source, e.g., the DailyMed website.

2. Provide administration and dosage information about the drug.
   - Administration
     - Intramuscularly
     - Intravenously
     - Orally
     - Subcutaneously
     - Sublingually
     - Other (Describe "other")
   - Minimum dosage per patient (include unit)
   - Maximum dosage per patient (include unit)
   - 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?
   - How are dosages measured? (See below for dosage guidelines.)

Dosage Guidelines

Guidance 1
For drugs and biologicals other than contrast agents or radiopharmaceuticals, specify how dosages are measured, e.g., in milligrams, micrograms.

Guidance 2
For diagnostic and therapeutic radiopharmaceuticals 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 Average Wholesale Price (AWP) (or other price) is stated “per vial” or "per ampule," indicate how many doses can be administered from one vial or one ampule.
C. If the AWP (or other price) 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.

3. Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code?
   a) If Yes: What are the details of your HCPCS application? If No: Continue to b.
      - Submission Date
      - What is the status?
        - Approved
        - Pending
   b) Using Healthcare Common Procedure Coding System (HCPCS) Level I (CPT) and/or Level II code(s), list all of the specific procedure(s) and/or services with which the drug is used.
      - Enter HCPCS level I (CPT) and/or Level II code(s)

HCPCS General Information

Notes for applicant:

- *HCPCS Level 1 codes (also known as CPT codes) associated with the specific procedure(s) and/or services with which the drug is used are required to be submitted or the application will be considered incomplete.*
- *HCPCS Level II code that currently identifies the product/item, including an unlisted HCPCS Level II code (e.g., A, C, J, or Q code). Note: Approval of a drug, biological or radiopharmaceutical for a transitional pass-through payment under the hospital OPPS is not contingent on prior assignment of a national HCPCS Level II code. If no HCPCS Level II code is currently available, please specify the requested code descriptor, including dosage units.*

C. FDA Information

1. Upload your FDA approval letter.
    - Page Number(s)
    - Summarize the supporting information contained in this file.
2. What date was the FDA approval?

D. Cost Information

1. What is the current cost of the drug to hospitals?
    - Current total cost
    - Minimum dosage cost
    - Maximum dosage cost
    - Typical dosage cost

Notes for applicant:

- *For products where the amount of drug product represented by an NDC varies (ie. Radiopharmaceuticals, clotting products), please report the cost per each unit (cost can be reported as WAC and/or AWP).*
- *Current cost of the drug to hospitals should be the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind.*

2. Please upload a copy of the most recently published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC).
    - What date was publication?
    - What is the compendium where published? (For example, RED BOOK™ or Medi- Span® Price Rx®)
    - Upload AWP and WAC
        - Page Number(s)
        - Summarize the supporting information contained in this file.

Note for applicant: The price submitted by the application deadline (which is subject to verification by CMS) will be used for initial determination of pass-through payment. No price updates after the application deadline will be accepted. If the applicant has not determined the price by the application deadline or if the applicant wants to update the price after the application deadline, then the applicant must withdraw the application and reapply for pass-through in a subsequent quarter.

3. If available, what is the average sales price (ASP) for each unit of the drug? (optional)

E. Volume and Utilization

1. Identify all projected units/volume by site of service that reflects one full year of utilization based on the drug's package size.
    - Indicate the specific projected timeframe for the utilization.
    - Packaging Size
        - Volume
        - Units
        - Site of Service in Volume and Percentage
            - Medicare Hospital Outpatient
            - Medicare Ambulatory Surgical Center (ASC)
            - Medicare Hospital Inpatient
            - Medicare Physician Office
            - Medicare Other Identify (optional)
            - Total (Percentage should equal 100%)

F. Attachments

1. List all referencing files and documents (see below for a list of items to include).
    - Page Number(s)
    - Summarize the supporting information contained in this file.

Items to Include

Marketing Materials

- Booklets, pamphlets, and brochures
- Product catalogs
- Price lists and package inserts
- Case Studies

FDA Documentation

- FDA decision letter
- FDA New Drug application
- Biologics License application approval letter
- Premarket Approval (PMA) letter
- FDA label
- Package insert
- Carton label

Cost Documentation

- Itemized cost lists
- Manufacturing invoices
- Pricing guides