Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radiopharmaceuticals for Transitional Pass-Through Status under the Hospital Outpatient Prospective Payment System (OPPS)

This announcement describes in detail the process and information required for applications requesting transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals under the Medicare hospital outpatient prospective payment system (OPPS).

We will accept transitional pass-through applications for drugs, biologicals, and radiopharmaceuticals on an ongoing basis. [1] 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 a complete application and all necessary information by the first business date in:	**Earliest possible date for pass-through status to be 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 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 As originally enacted by the Balanced Budget Refinement Act of 1999 (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs,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 http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html?redirect=/MLNMattersArticles/; and http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/Manuals/.

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

The following products are not eligible to apply for transitional pass-through payments through this drug, biological and radiopharmaceutical pass-through application process and instead must apply through the device transitional pass-through application process:

1. Implantable biologicals (regardless of Food and Drug Administration [FDA] approval or clearance type)
2. Any product approved or cleared by the FDA as a medical device except for viscosupplements for osteoarthritis.

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 will not be acted upon:

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

2. A detailed description of the product including the following:
   a. Composition and clinical indication(s).
   b. The form in which it is supplied (e.g., solution, tablet, etc.).
   c. Method of administration (e.g., intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.).
   d. Manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.).
   Note – 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 web site.
   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.
      i. For drugs and biologicals other than contrast agents or radiopharmaceuticals, specify how dosages are measured, e.g., in milligrams, micrograms, etc.
      ii. 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. A copy of the most recently published AWP and Wholesale Acquisition Cost (WAC), including the date of publication and compendium where published (please include either *RED BOOK*™ or *Medi-Span Price Rx* among the compendium in which the price is published). *Note – 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.*

4. Average Sales Price (ASP) for specified units of the drug.

5. The current cost of the drug, biological or radiopharmaceutical 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 product specified in terms of dosage and concentration.

6. The date of commercial market availability or 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 I HCPCS code that reflects the drug administration procedure code(s) or other procedure code associated with the product.
    b. Level II HCPCS code that currently identifies the product/item, including an unlisted HCPCS 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 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 specific projected timeframe for the utilization (e.g., Jan 1–Dec 31, 2015, or April 1, 2015–March 30, 2016, etc.). If a drug is packaged in multiple sizes, list projections for every single package size. List projected units separately by the following categories for every single package size:
    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., Federally Qualified Health Centers, Rural Health Clinics, Veterans Administration Hospitals, etc.).

9. A copy of the FDA New Drug Application or Biologics License Application approval letter. Only for viscosupplements for osteoarthritis may a Premarket Approval (PMA) letter be submitted.

10. A copy of the FDA label (package insert).

11. Applicant name(s), company name, address(es), e-mail address(es) 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.

12. Other information as CMS may require or that the applicant believes CMS may need to evaluate the application.

Note: A separate application is required for each distinct drug, biological or radiopharmaceutical 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.

HOW TO SUBMIT APPLICATIONS AND ASK QUESTIONS:

The electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), is available for Drugs, Biologicals, and Radiopharmaceuticals Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System application submissions beginning March 2, 2021. The application form designed for MEARIS™ is similar to the current OMB-approved paper application, containing the required elements above, used to apply for transitional pass-through payment for drugs, biologicals and radiopharmaceuticals. Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to the paper submission process. The CMS Drug, Biologicals, and Radiopharmaceuticals Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System (i.e. "Drug and Biological Pass-through") application can be accessed at: https://mearis.cms.gov/public/home.

Beginning June 1, 2022, CMS will only accept applications for transitional pass-through payment for drugs and biologicals submitted via MEARIS™ and any application submitted through the Drug Pass-through application mailbox will not be considered.

Please note that the time required for application submission, including the time needed to gather relevant information as well as to complete the form, is estimated to be around 16 hours per submission. Applicants are encouraged to start in advance of the due date to ensure adequate time for submission including registering for access to the system.

Please refer to the following resources in MEARIS™ for support:

Guidance regarding the application submission process can be found in the "Resources" section at: https://mearis.cms.gov/public/resources

Technical support is available under "Useful Links" on MEARIS™ at: https://mearis.cms.gov/secure/applications

Submit application related questions to CMS using the form available under "Contact" at: https://mearis.cms.gov/public/resources?app=Drug-PTP

Questions pertaining to the pass-through payment application process for drugs, biologicals or radiopharmaceuticals may be sent via e-mail to drugptapplications@cms.hhs.gov .