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

Change Crosswalk

Original Drug Application	Changes to Drug Application	Explanation	Burden Effect
Process and Information Required to Determine Drugs, Biologicals, and Radiopharmaceutical Agents, Eligible for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) Page: 1 of 4		The subtitle was removed because it duplicated the main title. Two titles were not necessary.	N/A
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)	**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)**	Removed the word non-implantable and agents for clarification on the past thru-drug application.	N/A
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		This note was removed because it contained outdated language.	N/A

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.	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).	Removed the word non-implantable and agents to clarify the pass thru-drug application. This note was removed because it contained outdated language.	N/A
Because CMS intends to make information used in the rate setting 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.	.	This note was removed because it contained outdated language.	N/A
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.	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. 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.*	Removed the word non-implantable and agents to clarify the pass thru-drug application. This footnote was added to clarify the pass thru-drug application.	N/A

Process and Information Required to Determine Drugs, Non-Implantable Biologicals, and Radiopharmaceutical Agents, Eligible for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) Page: 2 of 4	.	This subtitle was removed on the updated application.	N/A
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).	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.	We defined the acronym. We deleted outdated language contained on the application.	N/A

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/*.	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/.	We deleted the old hyperlink and updated the hyperlink to the correct website.	N/A

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/.	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. Skin substitutes and similar products that aid wound healing (regardless of FDA approval or clearance type) 3. Any product approved or cleared by the FDA as a medical device except for viscosupplements for osteoarthritis.	We deleted outdated language and replaced it with clarifying language.	N/A

Required Information			
h. How dosages are measured.	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.	We added clarifying language to the pass thru-drug application.	N/A
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.	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.*	We deleted the word or and we added clarifying language to the drug application.	N/A

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.	6. The date of commercial market availability or date of sale of first unit.	We deleted the old language and replaced it with clarifying language to make the drug application more effective.	N/A
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.**	7. List the Healthcare Common Procedure Coding System (HCPCS) code(s) associated with the product. a. CPT or Level II 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.**	Under subsection A. we deleted the example of CPT codes for drug administration and we added the word drug administration. We then added or other procedure code to help clarify the drug application. Under subsection B. we deleted the word specifically and replaced it with currently. We also deleted the (if available). Specifically, list the C-code, J-code, Q-code, or any other Level II alphanumeric HCPCS code that appropriately describes the item, and replace it with including an unlisted HCPCS code (e.g., A, C, J, or Q code). We also added or radiopharmaceutical .	N/A

10. A copy of the package insert.	10. A copy of the FDA label (package insert).	Added the word FDA label to the drug application.	N/A
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.		This language was removed because it doesn't apply to the drug applications any longer. As a result of deleting number 11, numbers 12 and 13 moves from the old form up to numbers 11 and 12 on the revised form.	N/A
Process and Information Required to Determine Drugs, Non-Implantable Biologicals, and Radiopharmaceutical Agents, Eligible for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) Page: 4 of 4		This subtitle was removed.	N/A
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.		This section was removed and added to section 2 h. ii C. The removal and placement in that section added more clarity to the drug application.	N/A
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:	Send three hard copies and one electronic copy of each completed application with all supporting information to the following address and e-mail address:	We deleted the old language and replace it with more clarifying language	N/A
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.	drugptapplications@cms.hhs.gov 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 or by phone to 410-786-7267.	The hyper link was added to the revised drug application and the word non-implantable was deleted. We also revised the application the updated drug application email address and revised phone number.	N/A

