October 30, 2010

Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status

In light of the imminent deadline for submitting ASP data for OPPS payment beginning on January 1, 2010, we encourage manufacturers wishing to submit ASP data for the January 2010 OPPS update to contact us immediately through the OPPS mailbox at OutpatientPPS@cms.hhs.gov so we can facilitate the submission process.

Overview

Beginning in CY 2010, CMS provides payment for separately payable therapeutic radiopharmaceuticals and pass-through radiopharmaceuticals using OPPS ASP data, if data are submitted by all manufacturers of the radiopharmaceutical for a given calendar quarter. For radiopharmaceuticals paid based on ASP data under the OPPS, we expect that OPPS ASP data reported in a "patient-specific dose" or "patient ready form" would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor. Manufacturers should report OPPS ASP data in units that are compatible with the long code descriptor of the applicable HCPCS code, such as "treatment dose" or "millicurie," representing the manufacturer's sales price for all component materials. Component materials may include a "cold kit" (nonradioactive compound or complex that is combined with a radioisotope and results in a radiopharmaceutical) and the associated radioisotope. Manufacturers of radiopharmaceuticals may include in their calculation of ASP for OPPS payment purposes, in addition to the prices for the component materials, the portion of the sales price attributable to the production of the manufactured product as it is sold by the manufacturer reporting OPPS ASP data, taking into account "bona fide service fees" for radiolabeling or other services, as discussed in more detail in the examples.

Data Collection

ASP data submission procedures for therapeutic radiopharmaceuticals for payment purposes under the OPPS are parallel to existing ASP data submission procedures for drugs and biologicals for payment in the physician's office setting under section 1847A of the Act and its implementing regulations at §414.804. Information regarding timeframes and the instructions and format for ASP reporting are available on the CMS ASP web site at: http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/.

For therapeutic radiopharmaceutical payment under the OPPS, manufacturers may submit ASP data for OPPS payment in any given calendar quarter on a quarter-by-quarter basis. For those quarters where OPPS ASP data are not available for a therapeutic radiopharmaceutical (if a manufacturer does not submit ASP data), CMS will pay for a therapeutic radiopharmaceutical under the OPPS at the therapeutic radiopharmaceutical's most recent mean unit cost derived from hospital claims data.

Considerations Specific to OPPS ASP Reporting for Radiopharmaceutical Payment

1. As noted above, we expect manufacturers of therapeutic radiopharmaceuticals to report the sales price of all of the component materials for the radiopharmaceutical as a "patient-specific dose" or "patient ready form" in units that are compatible with the applicable HCPCS code descriptor for OPPS ASP payment purposes. The submission should be reported on the ASP Data Form (Addendum A) that may be downloaded from the CMS ASP web site provided above.

2. Fees paid by the manufacturer under contract for the radioisotope and/or for the radiolabeling process may be considered "bona fide service fees." Under the ASP regulations, "bona fide service fees" are fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity whether or not the entity takes title to the drug. "Bona fide service fees" are not deducted from ASP (that is, they are not netted against the radiopharmaceutical price for purposes of calculating ASP used for OPPS payment). Therefore, for purposes of the OPPS, if the manufacturer pays a "bona fide service fee" for the services of a freestanding radiopharmacy, hospital pharmacy, or other entity, and reflects that fee in its sales price for the radiopharmaceutical, the amount of the "bona fide service fee" would be taken into account in the reported OPPS ASP data. However, manufacturers are not required to pay for the preparation of a radiopharmaceutical in a freestanding radiopharmacy, hospital pharmacy, or other entity, and in that case, the cost of those services would not be taken into account in the OPPS ASP data submitted to CMS.

3. When submitting OPPS ASP data for radiopharmaceuticals, manufacturers should provide their submissions under the most appropriate NDC number(s) for the radiopharmaceutical, even if the NDC number(s) only represents the unique product-defining component material for the final radiopharmaceutical product (such as the cold kit). As is standard with any ASP submission, manufacturers should note any assumptions in their OPPS ASP submission to CMS.

Examples

Scenario 1 *A manufacturer sells a radiopharmaceutical with all component materials <u>except</u> the radioisotope. The radioisotope is not provided by the manufacturer, but instead is furnished by a freestanding radiopharmacy, hospital pharmacy, or other entity that goes on to prepare the final product by radiolabeling the component materials provided by the manufacturer.*

Result 1A If the manufacturer sells only a portion of the component materials to a freestanding radiopharmacy, hospital pharmacy, or other entity that then proceeds to prepare the radiopharmaceutical itself (as described by the HCPCS code) through the addition of a radioisotope purchased from another source, the manufacturer would be unable to report OPPS ASP data that reflect the sales of all component materials necessary for the radiopharmaceutical. Therefore, the

OPPS would not pay for this radiopharmaceutical based on ASP and would base payment on mean unit cost.

Result 1B If the manufacturer pays "bona fide service fees" to a freestanding radiopharmacy, hospital pharmacy, or other entity to obtain the radioisotope and combine all of the component materials, the manufacturer would be able to report OPPS ASP data for the radiopharmaceutical. OPPS ASP data submitted to CMS would reflect the sales of all component materials necessary for the product described by the HCPCS code, taking into account the "bona fide service fees" incurred by the manufacturer to purchase the radioisotope and radiolabeling services.

Scenario 2 *A separately payable radiopharmaceutical is sold by the manufacturer with all component materials included but not combined together in preparation for patient administration. Therefore, the sale of all of the component materials (including the radioisotope) could be included in the reported OPPS ASP data. However, further processing at a freestanding radiopharmacy, hospital pharmacy, or other entity must occur to prepare the radiopharmaceutical for ultimate patient administration in the hospital outpatient department.*

Result 2 Manufacturers are not required to pay for the preparation of a radiopharmaceutical at a freestanding radiopharmacy, hospital pharmacy, or other entity after sale of the component materials and, in that case, the cost of those services would not be reflected in the OPPS ASP data submitted to CMS. We consider radiopharmaceutical processing services performed at a freestanding radiopharmacy, hospital pharmacy, or other entity to be similar to pharmacy overhead and handling services for other drugs and nonimplantable biologicals paid under the OPPS. Payment for these costs would be made through the single OPPS ASP-based payment for both the acquisition cost and associated pharmacy overhead cost of the radiopharmaceutical.

Scenario 3 *The manufacturer sells a radiopharmaceutical with all component materials combined together to constitute the final radiopharmaceutical product (as described by the HCPCS code) and this product is packaged into a single use vial that is shipped by the manufacturer to a hospital. Upon receipt of the single use vial, the hospital draws up the radiopharmaceutical into a syringe for administration and calibrates the radiopharmaceutical immediately prior to patient administration.*

Result 3 The OPPS ASP data submitted by the manufacturer would be reflective of the sales of the component materials in the form provided (i.e., the single use vial), but not the drawing up of the product into a syringe for administration and the calibration performed by the hospital. In this case, the OPPS ASP data would take into account the processing activities performed by the manufacturer but would not take into account the hospital's costs for the final preparation of the dose for administration to the patient. Payment for the hospital preparation costs would be made through the single OPPS ASP-based payment for both the acquisition cost and associated pharmacy overhead cost of the radiopharmaceutical.