

an integral part of a procedure or treatment under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs. (See section XXIV.D of Transmittal A-02-129, issued on January 3, 2003.)

In general, supplies that are an integral component of a procedure or treatment are not reported with a HCPCS code. The charges for such supplies are typically reflected either in the charges on the line for the HCPCS for the procedure or on another line with a revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.

Correct Coding Initiative Edits

5. Generic Drugs, and Radiopharmaceuticals

In general, hospital acquisition costs for drugs, biologicals, and radiopharmaceutical agents with generic competitors are lower than the acquisition costs for sole source or multi-source drugs. In order to ensure that Medicare recognizes these lower costs in a timely manner, we proposed a new method of calculating payment amounts for drugs, biologicals, and radiopharmaceuticals that are separately paid under the OPPS and for which the Food and Drug Administration (FDA) has recently approved generic alternatives.

Because many hospitals have long term purchasing arrangements for drugs and radiopharmaceuticals, we believe that there is generally a 12-month lag between the time that generic items are made available and when our claims data will accurately reflect the costs associated with the availability of the generic alternative. Therefore, during the interval between FDA approval of a generic item and the time when we would reasonably expect claims data to reflect the cost of generic alternatives, we proposed to adopt the following methodology to price the affected drugs, biologicals, and radiopharmaceuticals under the OPPS.

We proposed to identify items approved for generic availability by the FDA during the 6 months before the first day of the claims period we use as the basis for an annual OPPS update. Where we determine that our claims data do not reflect the costs of generic alternatives for a separately payable drug, biological, or radiopharmaceutical, we proposed to base our payment rate on 43 percent of the AWP for the drug, biological, or radiopharmaceutical.

To apply this payment methodology to the 2004 OPPS update, we reviewed FDA approvals for generic drugs, biologicals, and radiopharmaceuticals issued between October 2001 and December 2002. We found six drugs, which we proposed to be separately paid under the 2004 OPPS that had generic alternatives approved during that time. These drugs are: Daunorubicin, Bleomycin, Pamidronate, Paclitaxel, Ifosfomide, and Idarubicin. Table 21 shows the dates when the FDA approved generic alternatives for these drugs.

We solicited comments on this proposed method of calculating payment for drugs, biologicals, and radiopharmaceuticals for which generic alternatives have recently been approved. Specifically, we were interested in comments concerning our proposed methodology for identifying these items, whether we properly identified all the items, and whether our proposed payment policy for these generic alternatives is appropriate.

We received many comments on our proposal regarding generic drugs and radiopharmaceuticals, which are summarized below along with our responses.

Comment: One commenter applauded CMS's efforts to lower payment for generic products to an amount more closely aligned with hospital acquisition cost. However, the commenter indicated that payment for generic cancer products would continue to be excessive and contribute to an environment where hospitals may offer treatments using less effective chemotherapy products. Alternatively, comments from a national hospital association and numerous manufacturers stated that the presence of generic alternatives in the market does not necessarily result in cost savings for hospitals. They indicated that established multi-year contracts may prevent providers from switching immediately to generic alternatives. As a result, providers would not realize any cost savings from buying the generic products until the conclusion of their existing contract, which in some cases may be a few years after the generics are available in the market. Commenters also indicated that it is quite common for shortages of generic equivalents to occur when they first appear in the market. Thus, there is no guarantee that sufficient quantities of generic alternatives will be available in the marketplace for all providers to purchase them. Furthermore, adoption of generic drugs by hospitals is also affected by whether the providers determine they are safe to use in

comparison to the brand name products. One commenter recommended that CMS continue to use its 2002 claims data to set the payment rated for these drugs.

Response: We appreciate these insightful comments and agree with the commenters that the time it takes for hospitals to realize cost savings (or price decreases) from purchasing generic products is longer than we initially expected because of the various reasons described by the commenters. Further research on this issue also shows that cost savings due to competition between generic and name brand drugs can vary. One reason is that in some cases regulations allow the first generic marketed to compete with a name brand drug to have a period of exclusivity during which time no other generics may come on the market. This period of exclusivity may mean that cost savings during this period of exclusivity are less than cost savings that occur once more than one generic is put on the market. For 2004, we believe that calculating payment rates for generics according to the methodology discussed above would not sufficiently take into consideration the true costs incurred by hospitals for purchasing generic products. Therefore, we believe that it is appropriate to calculate the payment rates for generics according to the same methodology used for other separately payable drugs and radiopharmaceuticals.

6. Orphan Drugs

In the proposed rule we stated that we no longer believe that paying for orphan drugs at reasonable cost, outside of OPPS is appropriate, and we proposed the following payment policy:

- We proposed to continue using the same criteria to identify single indication orphan drugs (67 FR 66772).
- We proposed to discontinue retrospective cost payments and to make prospective payments under the OPPS for those identified single indication orphan drugs.
- We proposed to base payments on the same methodology we use to pay for other drugs including any limitation on payment reductions (as described above).
- We proposed to make separate payment for the single indication orphan drugs and place them in APCs.

The 11 single indication orphan drugs that would be affected by our proposal are: (J0205 Injection, alglucerase, per 10 units; J0256 Injection, alpha 1-proteinase inhibitor, 10 mg; J9300 Gemtuzumab ozogamicin, 5 mg; and J1785 Injection, imiglucerase, per unit); J2355 Injection, oprelvekin, 5 mg; J3240 Injection, thyrotropin alpha, 0.9 mg;