

separately paid drug were administered via the same route of administration (and therefore only one code was billed), we would pay the APC only for the administration of the packaged drug and would pay separately for the separately paid drug and would not pay the APC for administration of the separately paid drug. In no case would we pay for more than one unit of an administration code.

Under options 2, 3, and 4, we would return a claim to the provider when a chemotherapy administration code was reported without a HCPCS code for a chemotherapy drug. Therefore, it is very important that commenters advise us as to whether there are any cancer chemotherapy drugs that are not included in Addenda L, M, N, O, P, or Q. Specifically, we solicit comments as to whether there are any cancer chemotherapy drugs that do not have HCPCS codes.

We do not propose payment amounts for this option because the budget neutrality scalar would be different under this proposal than under option 2 (which was used in the scalar and impact analysis). We solicit comment on each option described above.

General Billing Instructions

Any previous regulatory or sub-regulatory guidance notwithstanding, we propose to implement the following billing rules under any of the above payment options:

(1) Q0081 may not be used to bill separately for the hanging of a bag of solution for which the sole purpose is to administer chemotherapy drugs; that charge should be billed as part of the charge for Q0084 or Q0085.

(2) Q0081 may not be billed when it is an integral part of another procedure. In those cases, the charge for the procedure should reflect the costs of the infusion therapy, either as part of the charge for the HCPCS code or as a revenue code charge (for example, hydration or drug administration during a surgical procedure performed under general anesthesia).

(3) Q0081, Q0083, and Q0084 should not be used to bill for the administration of radiopharmaceuticals that are administered as part of diagnostic or therapeutic nuclear medicine procedures. In those cases, the radionuclide should be billed with the appropriate nuclear medicine HCPCS code.

(4) Q0081, Q0083, and Q0084 may not be used to report the transfusion of blood, platelets, or any other blood

products. Those transfusions should be reported by use of the appropriate HCPCS code(s) in APC 0110.

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 are proposing 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 when we determine our claims data do not reflect the costs of the 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 propose to adopt the following methodology to price the affected drugs, biologicals, and radiopharmaceuticals under the OPPS.

We would first identify items approved for generic availability by the FDA during the 6 months before the first day of the claims period we would 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 propose to base our payment rate on 43 percent of the AWP for the drug, biological, or radiopharmaceutical. As described in the 2003 OPPS rule (67 FR 66768), the ratio of hospital acquisition cost, on average, to AWP for multisource drugs with generic competitors equals 0.43. We believe that using this ratio would allow us to appropriately calculate the costs that hospitals incur when purchasing generic drugs or radiopharmaceuticals. When we determine that our claims data accurately reflect the cost of the generic alternative(s), we would use the claims data to set payment rates in preference

to 43 percent of AWP for the drug or radiopharmaceutical.

We considered another payment option where we would base our payment rate on the lower of: (1) The median cost (with dampening if applicable) based on claims data; or (2) the Federal Supply Schedule price. We are not proposing this policy because we believe we would not be able to calculate payment rates that are close to the actual hospital acquisition costs of generic alternatives since the Federal Supply Schedule represents prices that are lower than the prices paid by most hospitals. Also, median costs from the claims data would not reflect the actual cost of generics because of the time lag described above.

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 propose 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 understand that there is a wide range of utilization for these drugs in the OPPS and that price reductions for generic drugs will depend on their utilization and the types of illnesses for which they are used. However, we would not expect claims data from April 1, 2002 through December 31, 2002 to reflect fully the availability of the generic alternatives.

Table 21 shows the median cost for these six drugs as determined by claims data (with any adjustments for APCs that decreased in median cost by more than 15 percent from 2003 to 2004) and their costs at 43 percent of AWP as determined under the July 2003 update of the Medicare Single Drug Pricer.

We solicit comments on this proposed method of calculating payment for drugs, biologicals, and radiopharmaceuticals for which generic alternatives have recently been approved. Specifically, we are 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.