

TABLE 21.—PROPOSED LIST OF SEPARATELY PAYABLE OPPS DRUGS WITH GENERIC ALTERNATIVES APPROVED BETWEEN OCTOBER 2001 AND DECEMBER 2002

APC	Description	Date of Generic Approval by the FDA	43% of AWP	2004 Median cost (with dampening if applicable)
0832	Idarubicin hcl injection	May 2002	\$190.08	\$188.25
0831	Ifosfomide injection	May 2002	68.07	115.46
0863	Paclitaxel injection	May 2002	74.27	116.61
0730	Pamidronate disodium	May 2002	120.34	184.40
0857	Bleomycin sulfate injection	October 2001	130.98	169.28
0820	Daunorubicin hcl injection	November 2001	35.46	89.65

6. Orphan Drugs

In response to last year's proposed rule, many commenters explained that many orphan drugs were life-saving therapies used solely for the treatment of rare disorders where no other treatment was available. They further stated that many of these drugs would be received by very few Medicare beneficiaries and that if we packaged these drugs into other procedures, our payment rates would be insufficient to recognize their high cost, thus impairing the access of beneficiaries who needed the drugs. These commenters also stated that the claims data we used to set payment rates for 2003 did not accurately reflect the cost of these drugs. We shared these concerns, and in the November 1, 2002 final rule (67 FR 66772), we set forth the following payment policy:

We identified orphan drugs that are used solely for orphan conditions by applying the following criteria:

- The drug is designated as an orphan drug by the FDA and approved by the FDA for treatment of only one or more orphan condition(s).

- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s). Payment for drugs that met these criteria was made outside of OPPS under reasonable cost.

In that same rule, we identified four orphan drugs (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) as meeting these criteria. Therefore, we excluded them from payment under OPPS and paid for them at reasonable cost in 2003.

We received several comments in response to the final rule, stating that we had not identified all drugs that qualified for special payment as orphans under our criteria. After reviewing these comments, we have identified 7

additional drugs that meet our criteria.

These drugs are: J2355 Injection, oprelvekin, 5 mg; J3240 Injection, thyrotropin alpha, 0.9 mg; J7513 Daclizumab parenteral, 25 mg; J9015 Aldesleukin, per vial; J9160 Denileukin diftitox, 300 mcg; J9216 Interferon, gamma 1-b, 3 million units; and Q2019 Injection, basiliximab, 20 mg.

We have now identified a total of 11 drugs that meet our orphan drug criteria, and we expect to identify more such drugs in the future. Last year's policy was intended to narrowly target a very small number of drugs received by very few Medicare beneficiaries in order to ensure beneficiary access to life saving therapies. The aggregate number of Medicare beneficiaries who will receive the 11 drugs that meet our criteria for orphans is significantly higher than the number who receive the 4 we identified last year. Furthermore, as we identify more drugs that meet our criteria, we expect the number of beneficiaries who receive these drugs to grow. As the number of beneficiaries who receive these drugs increases, so do total payments for the drugs. Therefore, we no longer believe that paying for these drugs at reasonable cost, outside of OPPS, is appropriate. Our goal is to pay for as many hospital outpatient department (OPD) services as possible under the OPPS system. We believe that any payments made outside of OPPS should remain relatively small and, as in the case of vaccines, be made because it is unlikely our claims data will reflect the cost of the item or service (see discussion of vaccines below).

In the case of orphan drugs, we believe that our claims data for April 1, 2002 through December 31, 2002 do reflect the cost of orphan drugs, and we are concerned about the potential of making ever increasing payments for these drugs outside of the OPPS. Furthermore, we believe that many of the concerns expressed by commenters would be addressed if we continue to make separate payment for these drugs.

Therefore, we propose the following payment policy for orphan drugs:

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

We solicit comment on each of these proposals and request that commenters submit information meeting the same criteria as comments for other drugs (as discussed above).

7. Vaccines

Outpatient hospital departments administer large amounts of the vaccines for influenza (flu) and pneumococcal pneumonia (PPV), typically by participating in immunization programs. In recent years, the availability and cost of some vaccines (particularly the flu vaccine) have fluctuated considerably. As discussed in the November 1, 2002 final rule (67 FR 66718), we were advised by providers that OPPS payment was insufficient to cover the costs of the flu vaccine and that access of Medicare beneficiaries to flu vaccines might be limited. They cited the timing of updates to OPPS rates as a major concern. They said that our update methodology, which uses 2-year-old claims data to recalibrate payment rates would never be able to take into account yearly fluctuations in the cost of the flu vaccine. We agreed with this concern and decided to pay hospitals for influenza and pneumococcal pneumonia vaccines based on a reasonable cost methodology. As a result of this change, hospitals, home health agencies (HHAs), and hospices,