

PHASED-IN CONSECUTIVE BENEFIT PERIODS FOR IMMUNOSUPPRESSIVE DRUG THERAPY—Continued

Discharge date	Coverage period ends	Total months of coverage
04/1/94	12/31/95	21
05/1/94	02/29/96	22
06/1/94	04/30/96	23
07/1/94	06/30/96	24
08/1/94	08/31/96	25
09/1/94	10/31/96	26
10/1/94	12/31/96	27
11/1/94	02/28/97	28
12/1/94	04/30/97	29
01/1/95	06/30/97	30
02/1/95	08/31/97	31
03/1/95	10/31/97	32
04/1/95	12/31/97	33
05/1/95	02/28/98	34
06/1/95	04/30/98	35
07/1/95	06/30/98	36

Comment: One commenter recommended that each patient be given a card showing eligibility dates for immunosuppressive drug therapy.

Response: We have not adopted this suggestion because it would add an unnecessary paperwork burden without a commensurate benefit to the program. This information is contained in the Medicare Handbook.

The Medicare contractors processing claims for prescription drugs used in immunosuppressive therapy are prepared to implement the extended periods of coverage. The claims processing systems are capable of determining the periods for which Part B coverage is available beginning with the date of discharge from a hospital stay during which a covered transplant was performed.

Comment: One commenter requested that we define several classes of drugs, such as treatment related drugs (for example, prednisone, antihypertensives, and cardiac medicines) that, in his opinion, would be eligible for payment. This classification would provide guidelines for coverage of each type of drug. Another commenter urged that there be flexible criteria to permit providers to use a full range of drug therapy, including drugs prescribed for unapproved indications, rather than limiting coverage to "other drugs that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen."

Response: Section 1861(s)(2)(J) of the Act provides for coverage of only prescription drugs used in immunosuppressive therapy. We interpret this to mean that coverage is limited to those drugs that are medically necessary and appropriate for the specific purpose of preventing or treating the rejection of a transplanted

organ or tissue by suppressing a patient's natural immune responses. To meet this definition, a drug must be approved by the FDA, be available only through a prescription, and belong to one of the following three categories:

- It is a drug approved for marketing by the FDA and is labeled as an immunosuppressive drug.
- It is a drug, such as a corticosteroid, that is approved by the FDA and is labeled for use in conjunction with immunosuppressive drugs to treat or prevent the rejection of a patient's transplanted organ or tissue.
- It is a drug that a Part B carrier, in processing a Medicare claim, determined to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with those immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue.

Accordingly, drugs that are used for the treatment of conditions that may result from an immunosuppressive drug regimen (for example, antibiotics, antihypertensives, analgesics, vitamins, and other drugs that are not directly related to organ rejection) are not covered under this benefit.

Comment: One commenter suggested that we clarify the statement in the proposed rule (53 FR 1383) that implied that corticosteroids may be covered by Medicare only if used in association with Sandimmune (that is, cyclosporine).

Response: The statement in the proposed rule was meant as an example of a drug treatment regimen that included corticosteroids. It was not our intention to imply that corticosteroids would not be covered if prescribed in conjunction with another immunosuppressive, or alone, to prevent rejection of an organ or tissue transplant.

Comment: One commenter concluded that our statement that commonly prescribed immunosuppressive drugs are available at substantial discounts from prices listed in the Red Book (an annual publication that lists drugs and their wholesale prices) is wrong because the drugs we listed (with the exception of prednisone) are sole source drugs and there is no competition to reduce the prices.

Response: Since publication of the proposed rule in January 1988, payment for Medicare Part B drugs was modified by the November 25, 1991 final rule for the fee schedule for physicians' services (56 FR 59502). Section 405.517 states that payment for drugs (other than those

paid on a cost or prospective basis) is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined by individual carrier surveys of actual invoice prices paid for the drug. If physicians or pharmacies receive price discounts, the reductions are reflected in their invoice costs.

Comment: One commenter objected to our statement in the preamble to the proposed rule (53 FR 1385) that mail service pharmacies "offer reduced prices that minimize beneficiaries' coinsurance liability," on the grounds that it amounted to a "commercial" on behalf of mail service pharmacies.

Response: Our intent was not to endorse one source of drugs over another, but to make the public aware of the alternative of mail service pharmacies.

Comment: One commenter expressed concern that ordering drugs through the mail eliminates patient-pharmacist contact.

Response: The absence of face-to-face contact is one of the many things a beneficiary would want to consider in deciding from whom he or she will obtain prescribed drugs.

Comment: One commenter suggested that we buy drugs from manufacturers and have them shipped directly to participating transplant centers.

Response: We lack the legal authority to do this. We administer the Medicare program at the national level as authorized by the law. We are not empowered to participate in the delivery of health care services.

Comment: One commenter asked that we update prices for immunosuppressive drugs.

Response: Medicare carriers use the Red Book or a similar publication that is updated periodically during the year for current prices.

Comment: One organization suggested that our payment policy cover not only the costs of drugs, but also pharmaceutical care services. The organization explained that in addition to traditional drug distribution services, contemporary pharmaceutical services include clinical functions that ensure the safe and effective use of drug therapy. Examples of these functions, which were characterized by the commenter as "pharmacy" services, are providing patient education, assessing patient compliance, and monitoring for therapeutic effectiveness and adverse effects.

Response: Payment for functions furnished by pharmacists is included in the amount that Medicare pays for the drugs.