(4) Rule 8–22, adopted on June 1, 1994.

* * * * *

[FR Doc. 95–3864 Filed 2–15–95; 8:45 am]

BILLING CODE 6560–50–W

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

[BPD–424–F]

RIN 0938–AE94

Medicare Program; Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations to provide Medicare coverage for prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. This rule reflects the enactment of section 1861(s)(2)(J) of the Social Security Act that provides Medicare coverage for prescription drugs used in immunosuppressive therapy for a period of up to 1 year from the date of discharge from an inpatient hospital stay during which the Medicare-covered organ or tissue transplant was performed.

This final rule also implements section 13565 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66) and section 160 of the Social Security Act Amendments of 1994 (Public Law 103–432) that, beginning January 1, 1995, expand Medicare coverage for prescription drugs used in immunosuppressive therapy from 1 year to a phased-in period of 3 years from the date of discharge from a hospital stay during which the Medicare-covered organ or tissue transplant was performed.

DATES: These regulations are effective January 1, 1995, the effective date of the statute.

FOR FURTHER INFORMATION CONTACT: Debra McKeldin, (410) 966–9671.

SUPPLEMENTARY INFORMATION:

I. Background

Before enactment of section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99–509, there was no specific Medicare benefit that provided for Medicare Part B coverage of prescription drugs used in immunosuppressive therapy.

OBRA '86 added subparagraph (J) to section 1861(s)(2) of the Social Security Act (the Act) to provide Medicare coverage for immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period not to exceed 1 year after the transplant procedure. Coverage of these drugs under Medicare Part B began January 1, 1987.

We published a proposed rule with a 60-day public comment period (53 FR 1383) on January 19, 1988, which we discuss below. Before its publication, however, the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, was enacted and effective December 22, 1987, revised section 1861(s)(2)(J) of the Act so that the scope of coverage was expanded from coverage of ''immunosuppressive drugs'' to coverage of ''prescription drugs used in immunosuppressive therapy.'' We issued the proposed rule before changes could be made to reflect this new terminology. We did propose, however, coverage that would include, in addition to immunosuppressive drugs, other drugs used in conjunction with immunosuppressive therapy. In addition, in April 1988, we issued manual instructions to Medicare contractors that reflected the new terminology.

Also, section 202 of the Medicare Catastrophic Coverage Act of 1988, Public Law 100–360, enacted on July 1, 1988, extended coverage of drugs used in immunosuppressive therapy to include drugs furnished in subsequent years after the first year following a covered transplant. It also extended coverage to include drugs used following a noncovered transplant irrespective of any prescribed time limitations. This extended coverage, which was to be effective on January 1, 1990, was part of the outpatient drug coverage set forth in section 202(a) of Public Law 100–360. On December 19, 1989, however, these provisions of the law were repealed as part of the Medicare Catastrophic Coverage Repeal Act of 1989, Public Law 101–234. As a result, the extended Medicare coverage of drugs used in immunosuppressive therapy set forth in Public Law 100–360 never became effective.

Since publication of the proposed rule, section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93), Public Law 103–66, amended section 1861(s)(2)(J) of the Act. In accordance with OBRA '93, the coverage period for prescription drugs used in immunosuppressive therapy will be extended to 18 months from the hospital discharge date following a covered transplant procedure for drugs furnished in 1995; 24 months for drugs furnished in 1996; 30 months for drugs furnished in 1997; and 36 months for drugs furnished after 1997. Subsequently, section 160 of the Social Security Act Amendments of 1994, Public Law 103–432, enacted on October 31, 1994, allows us to administer the OBRA '93 provision in such a way that coverage would be continued consecutively.

Since this provision is self-executing, we have issued it as part of this final rule, rather than in proposed form.

II. Provisions of the Proposed Rule

In the January 1988 proposed rule, we proposed to amend 42 CFR part 410 (''Supplementary Medical Insurance (SMI) Benefits'') to incorporate the following:

- Cover immunosuppressive drugs under Medicare Part B by revising § 410.10 to include immunosuppressive drugs in the term ''medical and other health services'';
- Add a new § 410.31 to provide specifically for coverage of immunosuppressive drugs generally; and
- Add a new § 410.65 to provide Medicare coverage of drugs used in immunosuppressive therapy, that are furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period of up to 1 year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed (the proposed rule did not, of course, include the OBRA '93 phased-in extension to the coverage period that follows a Medicare approved transplant). We proposed that coverage include: (1) Those immunosuppressive drugs specifically labeled as immunosuppressive drugs and approved for marketing by the Food and Drug Administration (FDA) and (2) other drugs that FDA-approved labeling indicates are used in conjunction with immunosuppressive drug therapy.

III. Discussion of Comments

We received 11 timely comments in response to the January 1988 proposed rule. The comments were from representatives of hospitals, medical centers, national associations representing health care professionals, and a university. The specific comments and our responses follow:

Comment: Several commenters suggested that coverage of immunosuppressive drugs be extended beyond 1 year.

Response: As stated earlier, since the publication of the proposed rule, OBRA

'93 has authorized phased-in extensions to the Medicare coverage period for prescription drugs used in immunosuppressive therapy. In accordance with this new legislation, the period after the hospital discharge date in which a Medicare beneficiary is eligible to receive Part B coverage of prescription drugs used in immunosuppressive therapy has been extended as follows:

- For drugs furnished during 1995, a Medicare beneficiary is eligible for coverage within 18 months after the date of discharge from an inpatient stay during which the covered transplant was performed.
- For drugs furnished during 1996, a Medicare beneficiary is eligible for coverage within 24 months after the date of discharge from an inpatient stay during which the covered transplant was performed.
- For drugs furnished during 1997, a Medicare beneficiary is eligible for coverage within 30 months after the date of discharge from an inpatient stay during which the covered transplant was performed.
- For drugs furnished after 1997, a Medicare beneficiary is eligible for coverage within 36 months after the date of discharge from an inpatient stay during which the covered transplant was performed.

Thus, the extension provides a range of coverage extending from 12 to 36 months depending on the date of discharge from an inpatient stay during which the covered transplant was performed.

For example, if prescription drugs used in immunosuppressive therapy are furnished to a beneficiary who received a covered transplant and was discharged on February 1, 1994, the initial coverage period is for 12 months (February 1, 1994 to January 31, 1995). In accordance with OBRA '93, on January 1, 1995, the coverage period for prescription drugs used in immunosuppressive therapy will be extended to 18 months from the hospital discharge date following a covered transplant procedure. Therefore, the initial 12-month coverage period is extended to July 31, 1995 because section 13565 of OBRA '93 extends coverage for drugs furnished in 1995 to 18 months. Subsequently, the eligibility for coverage for drugs furnished in 1996 is extended to 24 months after the discharge date. Because January 31, 1996 is 24 months after the discharge date of the covered transplant procedure in this example, the beneficiary is eligible for an additional month of coverage beginning January 1, 1996 and ending on January 31, 1996. Thus, the beneficiary will receive a total of 19 months of coverage for prescription drugs used in immunosuppressive therapy.

The following chart illustrates how the extension periods prescribed by OBRA '93 will be phased in using a discharge date of the first day of each month.

PHASED-IN BENEFIT PERIODS FOR IMMUNOSUPPRESSIVE DRUG THERAPY

Discharge date	Coverage period ends	Coverage period resumes	Coverage period ends	Total months of coverage
08/1/93	07/31/94	01/1/95	01/31/95	13
09/1/93	08/31/94	01/1/95	02/28/95	14
10/1/93	09/30/94	01/1/95	03/31/95	15
11/1/93	10/31/94	01/1/95	04/30/95	16
12/1/93	11/30/94	01/1/95	05/31/95	17
01/1/94	06/30/95	.....	.....	18
02/1/94	07/31/95	01/1/96	01/31/96	19
03/1/94	08/31/95	01/1/96	02/29/96	20
04/1/94	09/30/95	01/1/96	03/31/96	21
05/1/94	10/31/95	01/1/96	04/30/96	22
06/1/94	11/30/95	01/1/96	05/31/96	23
07/1/94	06/30/96	.....	.....	24
08/1/94	07/31/96	01/1/97	01/31/97	25
09/1/94	08/31/96	01/1/97	02/28/97	26
10/1/94	09/30/96	01/1/97	03/31/97	27
11/1/94	10/31/96	01/1/97	04/30/97	28
12/1/94	11/30/96	01/1/97	05/31/97	29
01/1/95	06/30/97	.....	.....	30
02/1/95	07/31/97	01/1/98	01/31/98	31
03/1/95	08/31/97	01/1/98	02/28/98	32
04/1/95	09/30/97	01/1/98	03/31/98	33
05/1/95	10/31/97	01/1/98	04/30/98	34
06/1/95	11/30/97	01/1/98	05/31/98	35
07/1/95	06/30/98	.....	.....	36

As illustrated in the chart, the statutory construction of the provision in OBRA '93 that prescribed the phased-in extension of coverage for drugs used in immunosuppressive therapy resulted in gaps in the coverage period. However, as stated earlier, section 160 of the Social Security Act Amendments of 1994 allows us to administer this provision in such a way that consecutive months of coverage are furnished provided the total number of months of coverage allowed by OBRA '93 are the same. Thus, in the above example, the beneficiary who was discharged on February 1, 1994 will receive 19 consecutive months of coverage (through August 31, 1995) for prescription drugs used in immunosuppressive therapy.

The periods of consecutive coverage for prescription drugs used in immunosuppressive therapy are illustrated in the following chart. The chart demonstrates how the OBRA '93 provisions would be phased in using a discharge date of the first day of each month.

PHASED-IN CONSECUTIVE BENEFIT PERIODS FOR IMMUNOSUPPRESIVE DRUG THERAPY

Discharge date	Coverage period ends	Total months of coverage
08/1/93	08/31/94	13
09/1/93	10/31/94	14
10/1/93	12/31/94	15
11/1/93	02/28/95	16
12/1/93	04/30/95	17
01/1/94	06/30/95	18
02/1/94	08/31/95	19
03/1/94	10/31/95	20

PHASED-IN CONSECUTIVE BENEFIT PERIODS FOR IMMUNOSUPPRESIVE 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.

Comment: One commenter recommended that all payments, including those to hospital outpatient departments, should be made under Part B on a reasonable charge basis. The commenter maintained that payments based on costs do not allow the hospital to be paid a reasonable rate for pharmaceutical services and overhead and that many hospitals maintain separate inventory and purchasing practices for drugs used in the outpatient setting.

Response: The statute mandates that the outpatient department of a hospital be paid based on the lower of reasonable cost or customary charges as established in the following sections of the Act:

- Sections 1832(a)(2)(B) and 1861(s)(2)(J), which establish that drugs used in immunosuppressive therapy furnished in a provider are a covered medical service.
- Section 1833(a)(2)(B), which states that payment is based on the lesser of the reasonable cost of hospital outpatient department services as determined under section 1861(v), or the customary charges with respect to these services.
- Section 1861(u), which defines a provider of services to include a hospital.
- Section 1862(a)(14), which states, in part, that no payment may be made under Part A or Part B for any expenses incurred for items or services, other than for statutorily specified exceptions, that are furnished to an individual who is a patient of a hospital by an entity other than the hospital or under arrangements with the hospital. (''Patient'' means inpatients and outpatients of a hospital.)

Therefore, if a patient is an outpatient of a hospital and receives prescription drugs from the hospital pharmacy, payment would have to be made to the hospital pharmacy according to the mandate of section 1833(a)(2)(B) of the Act. That section establishes that payment to any provider of services (in this case, the outpatient pharmacy department of a hospital) must be the lesser of the reasonable cost of these services, as determined under section 1861(v) (which includes recognition of both direct and indirect costs), or the customary charges with respect to these services.

Comment: One commenter suggested that we improve our communication with fiscal intermediaries, because some intermediaries are unaware that they should be paying for prescription drugs used in immunosuppressive therapy.

Response: We have taken steps to ensure that all contractors processing claims for prescription drugs used in immunosuppressive therapy are aware of current Medicare coverage and payment policies. We have not been informed of any specific problems in this area of program administration.

IV. Provisions of This Final Rule

The provisions of this final rule restate the provisions of the January 1988 proposed rule. The final rule differs from the proposed rule in that we have changed the term ''immunosuppressive drugs,'' wherever it appears, to ''prescription drugs used in immunosuppressive therapy'' to conform with section 4075 of OBRA '87. Also, we have redesignated the proposed § 410.65 as § 410.31. The final rule also differs from the proposed rule in that we have specified that drugs also will be covered if they have been determined, by a Part B carrier in processing a Medicare claim, to be reasonable and necessary (that is, safe and effective) for the purpose of treating or preventing the rejection of a patient's transplanted organ or tissue, or for use in conjunction with these immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. The carriers make these determinations by considering factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications. This change makes the policy governing drugs used in immunosuppressive therapy consistent with Medicare's general drug coverage policy.

An additional point of clarification is that the coverage of prescription drugs for transplants under this rule includes prescription drugs used in immunosuppressive therapy furnished to an individual who receives a bone marrow tissue transplant for which Medicare payment is made. For purposes of this rule, we consider bone marrow tissue transplants to be subsumed within the term ''organ transplant'' under section 1861(s)(2)(J) of the Act. Medicare currently covers heart, kidney, bone marrow, and certain liver transplants.

The final rule also differs from the proposed rule in that OBRA '93 requires phased-in extensions (up to 3 years) to the coverage period for prescription drugs used in immunosuppressive therapy.

V. Collection of Information Requirements

This notice does not impose information collection or recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C 3501 *et seq.*).

VI. Regulatory Impact Statement

A. Introduction

This final rule amends the regulations to provide Medicare coverage for prescription drugs used in immunosuppressive therapy following an inpatient hospital stay during which a Medicare-covered organ transplant was performed. OBRA '86 amended section 1861(s)(2) of the Act to provide Part B coverage for a period not to exceed 1 year beginning July 1, 1987. As a result of OBRA '93, the period of coverage of prescription drugs used in immunosuppressive therapy after the discharge from a hospital has been increased to 18 months for drugs furnished in 1995, 24 months for drugs furnished in 1996, 30 months for drugs furnished in 1997, and 36 months for drugs furnished after 1997. The following table shows the estimated additional expenditures as a result of the extended coverage.

ESTIMATED ADDITIONAL COST BECAUSE OF EXTENDED COVERAGE OF DRUGS FOR IMMUNOSUPPRESSIVE THERAPY—ROUNDED TO THE NEAREST $5 MILLION

FY 1995	FY 1996	FY 1997	FY 1998	FY 1999
$20	$60	$90	$110	$120

The use of immunosuppressive drug therapy is indicated for the prevention of organ rejection when an organ or tissue transplant is performed. The estimated number of transplants that will be performed in CY 1994 is 10,125, some of which will have an effect on immunosuppressive drug therapy expenditures in CYs 1995 and 1996. The estimated 10,850 transplants that will be performed in CY 1995 will have an effect on drug therapy costs in CYs

1996, 1997, and 1998. We estimate that the annual drug cost following transplantation for a full time user of immunosuppressive drugs will be as follows:

ESTIMATED ANNUAL COST OF IMMUNOSUPPRESSIVE DRUGS FOR EACH TRANSPLANT PATIENT

CY 1995	CY 1996	CY 1997
$5580	$5910	$6275

This final rule also differs from the proposed rule in that the term ''immunosuppressive drugs'' has been changed to ''prescription drugs used in immunosuppressive therapy'' to conform with section 4075 of OBRA '87. This expanded coverage will allow payment for other necessary drugs used in conjunction with immunosuppressive drugs.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmacists, physicians who perform transplantation services, and manufacturers of covered pharmaceuticals are considered to be small entities. Although pharmaceutical manufacturers are frequently not considered to be small entities, the possibility exists that certain manufacturers affected by this final rule may meet the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Because of the high cost of a majority of the drugs used for immunosuppressive therapy and the extended time that beneficiaries are required to take the drugs to ensure that the transplanted organ is not rejected, all Medicare transplant patients and many small entities will benefit by this regulation. In many cases, 1 year of immunosuppressive therapy is not sufficient. Also, it is possible that we may avoid the additional cost of a second transplant if a patient is kept on immunosuppressive drug therapy beyond the original 12 month coverage period.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 410

Medical and other health services, Medicare.

For the reasons set forth in the preamble, 42 CFR chapter IV, part 410 is amended as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 410.10, the introductory text is republished and a new paragraph (u) is added to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, ''medical and other health services'' includes the following services:

* * * * *

(u) Prescription drugs used in immunosuppressive therapy.

3. A new § 410.31 is added to read as follows:

§ 410.31 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, 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 immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Period of eligibility.* Coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who receives an organ or tissue transplant for which Medicare payment is made, for the following periods:

(1) For drugs furnished before 1995, for a period of up to 1 year beginning with the date of discharge from the hospital during which the covered transplant was performed.

(2) For drugs furnished during 1995, within 18 months after the date of discharge from the hospital during which the covered transplant was performed.

(3) For drugs furnished during 1996, within 24 months after the date of discharge from the hospital during which the covered transplant was performed.

(4) For drugs furnished during 1997, within 30 months after the date of discharge from the hospital during which the covered transplant was performed.

(5) For drugs furnished after 1997, within 36 months after the date of discharge from the hospital during which the covered transplant was performed.

(c) *Coverage.* Drugs are covered under this provision irrespective of whether they can be self-administered.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: January 9, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Approved: February 9, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–3835 Filed 2–15–95; 8:45 am]

BILLING CODE 4120–01–P