

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

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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 Budget 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