Medicare
Intermediary Manual
Part 3 - Claims Process

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 1934

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
3112.4 (Cont.) - 3112.5	3-38.3 - 3-38.4c (5 pp.)	3-38.3 - 3-38.4b (4 pp.)
3613 - 3613 (Cont.)	6-133 - 6-134 (2 pp.)	6-133 - 6-134 (2 pp.)
3660.7 (Cont.) - 3660.9 (Cont.)	6-341.6 - 6-342.3 (5 pp.)	6-341.6 - 6-342.2 (4 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: December 21, 2000*
IMPLEMENTATION DATE: April 1, 2002

This manualizes transmittal numbers AB-99-98.60 and AB-01-10.60 dated December 12, 1999 and January 24, 2001, respectively.

Section 3112.4, Outpatient Therapeutic Services and Section 3660.8, Immunosuppressive Drugs Furnished to Transplant Patients, are revised to provide updated coverage, billing and payment instructions for immunosuppressive drugs. Some of this updated information was previously released to you through your regional offices. Also, it allows a 22X bill type for skilled nursing facilities to bill for immunosuppressive drugs. In addition, it incorporates instructions previously released in Program Memorandum AB-99-98, Change Request 1069 dated December 1999, and in Program Memorandum AB-01-10, Change Request 1513, dated January 24, 2001.

Section 3613, Heart Transplants, removes the coverage narrative and adds a cross-reference narrative for billing and payment instructions for immunosuppressive drugs furnished to transplant patients.

Do not search your history for claims denied, but adjust any improperly denied claims brought to your attention.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

Because the FDA has not yet completed its identification of drug products that are still on the market, existing FDA efficacy decisions must be applied to all similar products once they are identified. The complete FDA listing comprises, for the most part, self-administered drugs. The listing that follows includes only those drugs which cannot be self-administered and which therefore could otherwise be covered under the Medicare program.

DESI DRUG PRODUCTS AND KNOWN RELATED DRUG PRODUCTS THAT LACK SUBSTANTIAL EVIDENCE OF EFFECTIVENESS AND ARE SUBJECT TO A NOTICE OF OPPORTUNITY FOR HEARING

TRADE NAME	ACTIVE INGREDIENT	DOSAGE FORM/ROUTE	FIRM
Vasodilan	Isoxsuprine Hydrochloride	Sol/IM	Mead Johnson

2. Hemophilia Clotting Factors.--Blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors are covered under Part B. Coverage is effective for such items and services purchased on or after July 18, 1984. Prior to the enactment of the Deficit Reduction Act of 1984 (P.L. 98-369), all drugs and biologicals which were of the type that could be self-administered were excluded from coverage. The coverage of blood clotting factors is an exception to the exclusion.

The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision will be based on the historical utilization pattern or profile developed by the contractor for each patient. It is expected that the treating source; e.g., a family physician or Comprehensive Hemophilia Diagnostic and Treatment Center, will have such information. From this data, the contractor should be able to make reasonable projections concerning the quantity of clotting factors anticipated to be needed by the patient over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents, inpatient hospital stays, etc., will change this base line data and should be appropriately considered. In addition, changes in a patient's medical needs over a period of time will require adjustments in the profile.

Payment under this provision may be conditioned by the Part B blood deductible, see §3235.2.

3. Immunosuppressive Drugs.--Until January 1, 1995, immunosuppressive drugs are covered under Part B for a period of 1 year following discharge from a hospital for a Medicare covered organ transplant. CMS interprets the 1-year period after the date of the transplant procedure to mean 365 days from the day on which an inpatient is discharged from the hospital. Beneficiaries are eligible to receive additional Part B coverage within 18 months after the discharge date for drugs furnished in 1995; within 24 months for drugs furnished in 1996; within 30 months for drugs furnished in 1997; and within 36 months for drugs furnished after 1997. Beginning January 1, 2000, §227 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 extended coverage to eligible beneficiaries whose coverage for drugs used in immunosuppressive therapy expires during the calendar year to receive an additional 8 months of coverage beyond the current 36 month period. This benefit does not extend Medicare entitlement or eligibility to ESRD only Medicare beneficiaries. These beneficiaries will continue to lose their Medicare coverage for immunosuppressive drug therapy 36 months after discharge from a hospital following a covered transplant.

Section 113 of the BIPA 2000 by eliminates the time limit for coverage of immunosuppressive drugs under the Medicare program. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no longer any time limit for Medicare benefits. This policy applies to all Medicare entitled beneficiaries who meet all of the other program requirements for coverage

under this benefit. Therefore, for example, currently entitled beneficiaries who had been receiving benefits for immunosuppressive drugs in the past, but whose immunosuppressive drug benefit was terminated solely because of the time limit described above for non-ESRD beneficiaries, would now resume receiving that benefit for immunosuppressive drugs furnished on or after December 21, 2000.

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA, as well as those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered.

You are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and to share this information with your providers. The FDA has identified and approved for marketing only the following specifically labeled immunosuppressive drugs:

- Sandimmune (cyclosporine), Sandoz Pharmaceutical (oral or parenteral form);
- Imuran (azathioprine), Burroughs-Wellcome (oral);
- Atgam (antithymocyte/globuline), Upjohn (parenteral);
- Orthoclone (OKT3 (muromonab-CD3), Ortho Pharmaceutical (parenteral);
- Prograf (tacrolimus), Fujisawa USA, Inc.; and
- Cellcept (mycophenolate mofetil), Roche Laboratories.
- Daclizumab (Zenapax)
- Cyclophosphamide (Cytoxan)
- Prednisone
- Prednisolone

For coverage of immunizations, etc., see §3157.

4. Epoetin Alfa (EPO).--Epoetin Alfa is a biologically engineered protein which stimulates the bone marrow to make new red blood cells. The FDA approved labeling for EPO states that it is indicated in the treatment of anemia associated with chronic renal failure. Medicare patients with this condition include end stage renal disease (ESRD) patients on dialysis and other beneficiaries who have chronic renal failure, but who are not on dialysis. Chronic renal failure patients with symptomatic anemia considered for EPO therapy should have a hematocrit less than 30%.

EPO is covered for Medicare beneficiaries with chronic renal failure who are not on dialysis when it is administered for the treatment of anemia "incident to" a physician's service.

Section 3644.2 contains instructions for submitting claims for EPO, including the requirements for providing the hematocrit reading and the number of units of EPO administered. It is expected that the outpatient department of a hospital will maintain the following information in each patient's medical record to permit the review of the medical necessity of EPO.

- o Diagnostic coding;
- o Most recent creatinine prior to initiation of EPO therapy;

- o Date of most recent creatinine prior to initiation of EPO therapy;
- o Most recent hematocrit (HCT) prior to initiation of EPO therapy;
- o Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
- o Dosage in units/kg.;
- o Weight in kgs.; and
- o Number of units administered.

5. Oral Anti-Cancer Drugs.--Effective January 1, 1994, Medicare Part B coverage is extended to include oral anti-cancer drugs that are prescribed as anti-cancer, chemotherapeutic agents providing they have the same active ingredients and are used for the same indications as anti-cancer, chemotherapeutic agents which would be covered if they were not self-administered and they were furnished incident to a physician's service as drugs and biologicals.

This provision applies only to the coverage of anti-neoplastic, chemotherapeutic agents. It does not generally apply to oral drugs and/or biologicals used to treat toxicity or side effects such as nausea or bone marrow depression. However, effective January 24, 1996, Medicare will cover anti-neoplastic, chemotherapeutic agents, the primary drugs which directly fight the cancer, and self-administered antiemetics which are necessary for the administration and absorption of the anti-neoplastic, chemotherapeutic agents when a high likelihood of vomiting exists. The substitution of an oral form of an anti-neoplastic drug requires that the drug be retained for absorption. The antiemetics drug is covered as a necessary means for administration of the oral drug (similar to a syringe and needle necessary for injectable administration). Oral drugs prescribed for use with the primary drug which enhance the anti-neoplastic effect of the primary drug or permit the patient to tolerate the primary anti-neoplastic drug in higher doses for longer periods are not covered. Self-administered antiemetics to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption.

In order to assure uniform coverage policy, you must be apprised of carriers' anti-cancer drug medical review policies which may impact on future medical review policy development. Carrier's current and proposed anti-cancer drug medical review polices should be provided by carrier medical directors or your medical directors, upon request.

For an oral anti-cancer drug to be covered under Part B, it must:

- o Be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer, chemotherapeutic agents;

- o Be a drug or biological that has been approved by the Food and Drug Administration (FDA);

- o Have the same active ingredients as a non-self-administrable, anti-cancer, chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's Approved Drug Products (Orange Book), Physician's Desk Reference (PDR), or an authoritative drug compendium;

  -- or, effective January 1, 1999, be a prodrug, which is an oral drug ingested into the body that metabolizes into the same active ingredient that is found in the non-self-administrable form of the drug;

- o Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and

- o Be reasonable and necessary for the individual patient.

6. Oral Anti-Nausea Drugs.--Section 4557 of the Balanced Budget Act of 1997 amends §1861(s)(2) by extending the coverage of oral anti-emetic drugs under the following conditions:

o Coverage is provided only for oral drugs approved by the FDA for use as anti-emetics;

o The oral anti-emetic(s) must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;

o Oral anti-emetic drug(s) administered with a particular chemotherapy treatment must be initiated within 2 hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time; and

o The oral anti-emetic drug(s) provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.

Only drugs pursuant to a physician's order at the time of the chemotherapy treatment, qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within 2 hours of that treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy. However, more than one oral anti-emetic drug may be prescribed and will be covered for concurrent usage within these parameters if more than one oral anti-emetic is needed to fully replace the intravenous drugs that would otherwise have been given.

Oral drugs that are not approved by the FDA for use as anti-emetics and which are used by treating physicians adjunctively in a manner incidental to cancer chemotherapy are not covered by this benefit and are not reimbursable within the scope of this benefit.

It is recognized that a limited number of patients will fail on oral anti-emetic drugs. Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to patients who fail on oral anti-emetic therapy.

This coverage, effective for services on or after January 1, 1998, is subject to regular Medicare Part B coinsurance and deductible provisions.

NOTE: Existing coverage policies authorizing the administration of suppositories to prevent vomiting when oral cancer drugs are used are unchanged by this new coverage.

C. Other Covered Services and Items.--Covered services and items provided by the hospital in connection with the clinic visit or the physician's treatment of outpatients include the use of the following:

o Hospital facilities, including the use of the emergency room;

o Services of nurses, nonphysician anesthetists, psychologists, technicians, therapists, and other aides; and

o Medical supplies such as gauze, oxygen, ointments and other supplies used by physicians or hospital personnel in the treatment of outpatients.

Additional examples of covered items are surgical dressings; splints, casts, and other devices used for reduction of fractures and dislocations; prosthetic devices; leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes. (See §§3110.3 - 3110.5 for details on coverage of these items and §3101.9B for additional coverage rules for occupational therapy.)

3112.5 Sleep Disorder Clinics.--Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. circumstances is covered under provisions of the law different from those for coverage of therapeutic services. Sleep disorder clinics may provide some diagnostic or therapeutic services which are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.

A. Criteria for Coverage of Diagnostic Tests.--All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:

o The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician.

o Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders.

o The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

- If the beneficiary lives east of the Mississippi, excluding Minnesota, send the copy to:

  Blue Cross and Blue Shield
  of South Carolina
  Medicare Immunosuppressive Drug Unit
  Pen Claims
  P.O. Box l02401
  Columbia, SC 29224

See §3718.1 for the message about immunosuppressive drug reimbursement to include in the notice.

3613. HEART TRANSPLANTS

A. Background.--On April 6, 1987, HCFA Ruling 87-1, "Criteria for Medicare Coverage of Heart Transplants" was published in the **Federal Register**. For Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria. Facilities that wish to obtain coverage for their Medicare patients submit an application and documentation showing their initial and ongoing compliance with each criterion.

The facility mails the application to the address below in a manner which provides it with documentation that it was received, e.g., return receipt requested.

Administrator
Health Care Financing Administration
c/o Office of Executive Operations
Room 777 East High Rise
6325 Security Blvd.
Baltimore, MD 21207

If you have any questions concerning the effective or approval dates of your hospitals, contact your RO.

B. Artificial Hearts and Related Devices.--An artificial heart can be used either as a permanent replacement for a human heart or as a temporary life-support system (bridge to transplant) until a human heart becomes available. Ventricular assist devices (VAD) also are used as temporary support systems. Charges for artificial heart ventricular assist devices and related services are reported as noncovered except in the following situations (effective May 5, 1997):

1. The VAD must be used in accordance with the FDA approved labeling instructions. This means that the VAD is used as a temporary mechanical circulatory support for approved transplant candidates as a bridge to cardiac transplantation.

2. The patient is approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center.

3. The implanting site, if different than the Medicare approved transplant center, must receive written permission from the Medicare approved heart transplant center under which the patient is listed prior to implantation of the VAD (effective January 1, 2001).

All of the above criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant. Medicare does not cover this device when used as an artificial heart. (See §65-15 of the Coverage Issues Manual for further detail.)

ICD-9-CM procedure code 37.66, Implantation of an implantable pulsatile heart assist system, is and will continue to be listed as a noncovered procedure in the Medicare Code Editor (MCE) due to the

stringent conditions that must be met by hospitals in order to receive payment. If this procedure is listed in accordance with the above criteria, payment is appropriate and you are to override the MCE noncovered edit.

C. Drugs.--See §3660.8 concerning billing and payment instructions for immunosuppressive drugs furnished to transplant patients.

D. Noncovered Transplants.--Medicare does not cover transplants or retransplants in facilities which have not been approved as meeting the facility criteria. If a beneficiary is admitted for and receives a heart transplant from a facility that is not approved, neither physician's services nor inpatient services associated with the transplantation procedure are covered.

When a beneficiary has received a heart transplant from a hospital (which has not been approved as meeting the facility criteria) and later requires medical and hospital services as a result of the noncovered transplant, the services are covered when they are reasonable and necessary in all other respects.

E. Bill Review Procedures.--Take the following actions to process heart transplant bills. You may accomplish them manually or you may modify your MCE and Grouper interface programs to handle the processing.

F. Change MCE Interface.--The MCE creates an exception for procedure code 375 (heart transplant). Where this procedure code is identified by MCE, check the provider number to determine if the provider is an approved transplant center. Check the effective approval date. If payment is appropriate (i.e., the center is approved and the service is on or after the approval date) override the noncovered OR procedure edit.

G. Grouper.--If the discharge is October 1, 1987 or later, process the bill through Grouper and Pricer. If the discharge is before October 1, 1987, Pricer does not have the proper DRG weight. Assign a weight of 14.9944 and process to payment. Use a 51 day outlier threshold for discharges before October 1, 1987.

H. Handling Heart Transplant Billings From Nonapproved Hospitals.--Where a heart transplant and covered services are provided by a nonapproved hospital, the bill data processed through Grouper and Pricer must exclude transplant procedure codes and related charges. (See §3656.1.)

I. Effective Dates.--Coverage is effective for discharges no earlier than October 17, 1986, for facilities which applied by July 6, 1987.

J. Approved Heart Transplant Facilities.--The facilities listed following subsection K have been approved as Medicare heart transplant facilities. The effective date for each is shown. If you have any questions, contact your RO.

K. Charges for Heart Acquisition Services.--Applicable services (see §§3178-3178.19) are billed to the transplant (implant) hospital by the excising hospital). A billing form is not submitted from the excising hospital to you. The transplant hospital keeps an itemized statement that identifies the services rendered, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges are reflected in the transplant hospital's heart acquisition cost center and are used in determining the hospital's standard charge for acquiring a live donor's heart. The standard charge is not a charge representing the acquisition cost of a specific heart; rather, it is a charge which reflects the average cost associated with each type of heart acquisition. Also, it is an all inclusive charge for all services required in the acquisition of a heart, i.e., tissue typing, post-operative evaluation, etc.

standardized information relative to the provider and the benefit. Mass immunizers attach a standard roster to a single pre-printed Form HCFA-1450, which will contain the variable claims information regarding the service provider and individual beneficiaries.

The roster must contain, at a minimum, the following information:

- Provider name and number;
- Date of service;
- Patient name and address;
- Patient date of birth;
- Patient sex;
- Patient health insurance claim number; and
- Beneficiary signature or stamped "signature on file".

NOTE: A stamped "signature on file" can be used in place of the beneficiary's actual signature for all institutional providers that roster bill from an inpatient or outpatient department provided the provider has a signed authorization on file to bill Medicare for services rendered. In this situation they are not required to obtain the patient signature on the roster. However, you have the option of reporting "signature on file" in lieu of obtaining the patient's actual signature.

The roster should contain the following language to be used by providers as a precaution to alert beneficiaries prior to administering the PPV.

WARNING: The beneficiary's vaccination status must be verified before administering the PPV. It is acceptable to rely on the patient's memory to determine prior vaccination status. If the patient is uncertain whether they have been vaccinated within the past 5 years, administer the vaccine. If patients are certain that they have been vaccinated within the past 5 years, do not revaccinate.

For providers using the simplified billing procedure, the modified Form HCFA-1450 shows the following preprinted information in the specific form locators (FLs):

- The words "See Attached Roster" in FL 12, (Patient Name);
- Patient Status code 01 in FL 22 (Patient Status);
- Condition code M1 in FLs 24-30 (Condition Code);
- Condition code A6 in FLs 24-30 (Condition Code);
- Revenue code 636 in FL 42 (Revenue Code), along with HCPCS code 90732 in FL 44 (HCPCS Code);
- Revenue code 771 in FL 42 (Revenue Code), along with HCPCS code G0009 in FL 44 (HCPCS Code);
- "Medicare" on line A of FL 50 (Payer);
- The words "See Attached Roster" on line A of FL 51 (Provider Number); and
- Diagnosis code V03.82 in FL 67 (Principal Diagnosis Code).

Providers conducting mass immunizations are required to complete the following FLs on the preprinted Form HCFA-1450:

- FL 4 (Type of Bill);

- o FL 47 (Total Charges);
- o FL 85 (Provider Representative); and
- o FL 86 (Date).

NOTE: Medicare Secondary Payer (MSP) utilization editing is by-passed in CWF for all mass immunizer roster bills. However, if the provider knows that a particular group health plan covers the PPV and all other MSP requirements for the Medicare beneficiary are met, the primary payer must be billed. First claim development alerts from CWF are not generated for PPV.

Use the beneficiary roster list to generate Form HCFA-1450s to process PPV claims by mass immunizers indicating condition code M1 in FLs 24-30 to avoid MSP editing. Standard System Maintainers will develop the necessary software to generate Form HCFA-1450 records that will process through their system.

Providers that do not mass immunize must continue to bill for PPV using the normal billing method, i.e., submission of a Form HCFA-1450 or electronic billing for each beneficiary.

M. Inpatient Roster Billing.--The following billing instructions apply to hospitals that roster bill for the influenza virus vaccine and PPV provided to inpatients under the procedures outlined in subsection J and L:

- o Hospitals do not have to wait until patients are discharged to provide the vaccine. They may provide it anytime during the patient's stay;

- o The roster should reflect the actual date of service;

- o The requirement to provide the vaccine to five or more patients at the same time to meet the requirements for mass immunizers will be waived when vaccines are provided to hospital inpatients. Therefore, the roster may contain fewer than five patients or fewer than five patients on the same day; and

- o The roster should contain information indicating that the vaccines were provided to inpatients to avoid questions regarding the number of patients or various dates.

N. Electronic Roster Claims.--As for all other Medicare-covered services, you pay electronic claims more quickly than paper claims. For payment floor purposes, roster bills are paper bills and may not be paid as quickly as EMC. (See §3600.1.) If available, you must offer free, or at-cost, electronic billing software and ensure that the software is as user friendly as possible for the influenza virus vaccine benefit.

3660.8 Immunosuppressive Drugs Furnished to Transplant Patients.--Payment of FDA-approved immunosuppressive drugs is made under Part B. Medicare pays the reasonable cost of these drugs furnished in skilled nursing facilities (SNFs) and for claims with dates of service prior to August 1, 2000, in hospital outpatient departments. Medicare pays for claims with dates of service on or after August 1, 2000, for hospital outpatient departments under the outpatient prospective payment system. Effective for services on and after October 1, 2000, obtain prices for immunosuppressive drugs from the carrier with jurisdiction over the facility location. Payment is based on 95 % of AWP as determined by the carrier for RDF and inpatient Part B hospital claims. SNFs continue to be paid based on cost. Payment is made for those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. Those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen are reflected in FDA-approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered. (See §3112.4 for Coverage Criteria.) Deductible and coinsurance apply.

Coverage of immunosuppressive drugs received as a result of a transplant is contingent upon the transplant being covered by Medicare. (See §3613.)

Pay for immunosuppressive drugs which are provided outside the approved benefit period if they are covered under some other provision of the law (e.g., when the drugs are covered as inpatient hospital services or are furnished incident to a physician's service).

During a covered stay, include payment for these drugs in your payment to the provider. If the same patient receives a subsequent transplant operation the immunosuppressive coverage period begins anew (even if the patient is mid-way through the coverage period when the subsequent transplant operation was performed).

The FDA has identified and approved for marketing only the specifically labeled immunosuppressive drugs. (See §3112.4 for a list of covered drugs and discussion of coverage of other drugs.)

Prescription drugs used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA-approved labeling for immunosuppressive drugs are also covered. You are expected to keep informed of FDA additions to the list of the immunosuppressive drugs. Prescriptions generally should be non-refillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, do not consider a supply of drugs in excess of 30 days to be reasonable and necessary. Deny payment accordingly.

A. Billing Requirements.--The provider bills on Form HCFA-1450 with bill type 12X, 13X, 22X, 83X, or 85X, as appropriate. For claims with dates of service prior to April 1, 2000, providers report the following entries:

- o Occurrence code 36 and date in FLs 32-35;
- o Revenue code 250 in FL 42; and
- o Narrative description in FL 43

For claims with dates of service on or after April 1, 2000, providers report:

- o Occurrence code 36 and date in FLs 32-35;
- o Revenue code 636 in FL 42;
- o HCPCS code of the immunosuppressive drug in FL 44;
- o Number of units in FL 46 (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. For example, if fifty 10 mg. Prednisone tablets are dispensed, bill J7506, 100 units (l unit of J7506 = 5 mg).

The provider completes the remaining items in accordance with regular billing instructions.

B. MSN Messages.--If the claim for an immunosuppressive drug is denied because the benefit period has expired, state on the MSN the following message;

4.2 "This service is covered up to (insert appropriate number) months after transplant and release from the hospital."

If the claim for an immunosuppressive drug is partially denied because of the 30 day limitation, use the following message;

4.3 "Prescriptions for immunosuppressive drugs are limited to a 30-day supply."

If the claim for an immunosuppressive drug is denied because a transplant was not covered, use the following message;

6.1 "This drug is covered only when Medicare pays for the transplant."

If the claim for an immunosuppressive drug is denied because it was not approved by the FDA, use the following message :

6.2 "Drugs not specifically classified as effective by the Food and Drug Administration are not covered."

C. Remittance Advice Messages.--If the claim is denied because the immunosuppressive drug is not approved by the FDA, you use existing American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message 114, Procedure/product not approved by the Food and Drug Administration.

If the claim is denied because the benefit period has expired or because of the 30 day limitation, you use existing ANSI X-12-835 claim adjustment reason code/message 35, Benefit maximum has been reached.

If the claim is denied for the immunsuppressive drug because a transplant was not covered, you use existing ANSI X-12-835 claim adjustment reason code/message 107, Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

3660.9 Payment for CRNA or AA Services.--Anesthesia services furnished on or after January 1, 1990, at a qualified rural hospital by a hospital employed or contracted CRNA or AA can be paid on a reasonable cost basis. Determine the hospital's qualification using the following criteria.

The hospital must be located in a rural area (as defined for PPS purposes) to be considered. A rural hospital that qualified and was paid on a reasonable cost basis for CRNA or AA services during calendar year 1989 can continue to be paid on a reasonable cost basis for these services furnished during calendar year 1990 if it can establish before January 1, 1990, that it did not provide more than 500 surgical procedures, both inpatient and outpatient, requiring anesthesia services during 1989.

A rural hospital that was not paid on a reasonable cost basis for CRNA or AA services during calendar year 1989 can be paid on a reasonable cost basis for these services furnished during calendar year 1990 if it establishes before January 1, 1990, that:

- As of January 1, 1988, it employed or contracted with a CRNA or AA (but not more than one full-time equivalent CRNA or AA); and

- In both 1987 and 1989, it had a volume of 500 or fewer surgical procedures, including inpatient and outpatient procedures, requiring anesthesia services.

Each CRNA or AA employed by, or under contract with the hospital, must agree in writing not to bill on a fee schedule basis for services furnished at the hospital. A rural hospital can qualify and continue to be paid on a reasonable cost basis for qualified CRNA or AA services for a calendar year beyond 1990 if it can establish before January 1 of that year that it did not provide more than 500 surgical procedures, both inpatient and outpatient, requiring anesthesia services during the preceding year. For a calendar year beyond 1990, it must make its election after September 30, but

before January 1. Determine the number of anesthetics by annualizing the number of surgical procedures for the 9-month period ending September 30.

A rural hospital that first elects reasonable cost payment for CRNA services for a calendar year after 1990 must demonstrate that:

- It had a volume of 500 or fewer surgical procedures, including inpatient and outpatient, requiring anesthesia services in the preceding year; and

- It meets the criteria that would have been met by a rural hospital first electing reasonable cost in calendar year 1990.

Inform carriers of the names of CRNAs or AAs, the hospitals which they have agreements with, and the effective dates to prevent duplicate payments. If the CRNA or AA bills Part B for anesthesia services furnished prior to the hospital's election of reasonable cost payments, the carrier must recover the overpayment from the CRNA or AA.