Medicare Hospital Manual

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

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
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NEW/REVISED MATERIAL--*EFFECTIVE DATE: December 21, 2000*
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This manualizes Transmittal Numbers AB-99-98 (CR 1069) and AB-01-10 (CR1513) dated December 12, 1999 and January 24, 2001, respectively.

Section 230.4, Outpatient Therapeutic Services, and Section 439, Billing for Immunosuppressive Drugs Furnished to Transplant Patients, provides updated coverage, billing and payment instructions for immunosuppressive drugs. This information was previously released to you by your intermediary.

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.

1. Less Than Effective Drugs.--Payment may not be made for a less than effective drug. This is a drug that has been determined by the FDA to lack substantial evidence of effectiveness for all labeled indications. Also, a drug that has been the subject of a Notice of an Opportunity for a Hearing (NOOH) published in the **Federal Register** before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medical need, is considered less than effective. This includes any other drug product that is identical, similar, or related. 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 other than Epoetin 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 is 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, has such information. From this data the contractor is 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., change this base line data and are appropriately considered. In addition, changes in a patient's medical needs over a period of time require adjustments in the profile. (Also see §§160.1B and 210.3.)

Payment under this provision may be conditioned by the Part B blood deductible. (See §222.)

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 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. 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.

Your intermediary is expected to keep you informed of FDA additions to the list of the immunosuppressive drugs. 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 §260.7.

4. Epoetin (EPO).--EPO 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 induced by the drug zidovudine (commonly called AZT), anemia associated with chronic renal failure, and anemia induced by chemotherapy in patients with non-myeloid malignancies. EPO is covered for these indications when it is furnished incident to a physician's service. Patients with anemia associated with chronic renal failure include all ESRD patients whether or not they are on dialysis. Chronic renal failure patients with symptomatic anemia considered for EPO therapy should have a hematocrit less than 30 percent or a hemoglobin less than 10.

In addition to coverage incident to a physician's service, EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:

- o It is administered in the renal dialysis facility; or

- o It is self administered in the home by any dialysis patient (or patient caregiver) who is determined competent to use the drug and meets the other conditions detailed below.

NOTE: Payment may not be made for EPO under the incident to provision when EPO is administered in the renal dialysis facility.

For payment of EPO, see §2710.3 of the Provider Reimbursement Manual, Part I.

Medicare covers EPO including items related to its administration for dialysis patients who use EPO in the home when the following conditions are met.

a. Patient Care Plan.--A dialysis patient who uses EPO in the home must have a current care plan (a copy of which must be maintained by the designated back-up facility for Method II patients) for monitoring home use of EPO which includes the following:

(1) Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;

(2) Review of medications to ensure adequate provision of supplemental iron;

(3) Ongoing evaluations of hematocrit and iron stores;

(4) Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;

(5) Method for physician and facility (including back-up facility for Method II patients) follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;

(6) Training of the patient to identify the signs and symptoms of hypotension and hypertension; and

(7) The decrease or discontinuance of EPO if hypertension is uncontrollable.

b. Patient Selection.--The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) Pre-selection monitoring. The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) Conditions the patient must meet. The assessment must find that the patient meets the following conditions:

(a) Is a dialysis patient;

(b) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(i) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.

(ii) For a patient who has been receiving EPO from the facility or the physician, between 30 and 36 percent; and

(c) Is under the care of:

(i) A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(ii) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) The assessment must find that the patient or a caregiver meets the following conditions:

(a) Is trained by the facility to inject EPO and is capable of carrying out the procedure;

(b) Is capable of reading and understanding the drug labeling; and

(c) Is trained in, and capable of observing, aseptic techniques.

(4) Care and storage of drug. The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

c. Responsibilities of Physician or Dialysis Facility.--The patient's physician or dialysis facility must:

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO;

(3) Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply; and

(4) Maintain adequate records to allow quality assurance for review by the network and State survey agencies. For Method II patients, current records must be provided to and maintained by the designated back-up facility.

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 apply to oral drugs and/or biologicals used to treat toxicity or side effects such as nausea or bone marrow depression. 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, regional carriers and intermediaries must be apprised of local carriers' anti-cancer drug medical review policies which may impact on future medical review policy development. Local carrier's current and proposed anti-cancer drug medical review polices should be provided by local carrier medical directors to regional carrier or intermediary medical directors, upon request.

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

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

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

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

- Be reasonable and necessary for the individual patient.

C. Immunizations.--Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. In cases where a vaccination or inoculation is excluded from coverage, deny the entire charge.

1. Pneumococcal Pneumonia Vaccinations.--Part B of Medicare pays 100 percent of the reasonable charge for pneumococcal pneumonia vaccine and its administration to a patient if it is ordered by a physician who is a doctor of medicine or osteopathy. This includes revaccination of patients at highest risk of pneumococcal infection.

A physician does not have to be present to meet the physician order requirement if a previously written physician order (standing order) is on hand and it specifies that for any person receiving the vaccine: (1) the person's age, health and vaccination status must be determined; (2) a signed consent must be obtained; (3) an initial vaccine may be administered only to persons at high risk of pneumococcal disease; (4) revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years have passed since receipt of a previous dose of pneumococcal vaccine; and (5) a record indicating the date the vaccine was given must be presented to each patient.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. Routine revaccination of people age 65 or older who are not at highest risk is not appropriate.

To help avoid potentially unnecessary doses, every patient should be given a record of their vaccination. Nevertheless, those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable for them to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about their vaccination history in the past 5 years, the vaccine should be given. However, if the patient is certain he/she was vaccinated in the last 5 years, the vaccine should not be given. If the patient is certain that the vaccine was given and that more than 5 years have passed since receipt of the previous dose, revaccination is not appropriate unless the patient is at highest risk.

D. Other Covered Services and Items.--Covered services and items provided by you in connection with the clinic visit or the physician's treatment of outpatients include the use of hospital facilities, i.e., the emergency room and the services of nurses, non-physician anesthetists, psychologists, technicians, therapists, and other aides, and medical supplies such as gauze, oxygen, ointments and other supplies used by physicians or hospital personnel in the treatment of outpatients.

439. BILLING FOR IMMUNOSUPPRESSIVE DRUGS FURNISHED TO TRANSPLANT PATIENTS

Part B of Medicare covers the reasonable cost of FDA-approved immunosuppressive drugs for claims with dates of service prior to August 1, 2000, and under the outpatient prospective payment system for claims with dates of service on or after August 1, 2000. Inpatient Part B claims for immunosuppressive drugs are paid based on 95 % of AWP as determined by the carrier with jurisdiction over your area. Your intermediary obtains the price from the appropriate carrier. 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 §230.4 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.

Medicare pays 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, payment for these drugs is included in Medicare's Part A payment to you. 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).

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.

Your intermediary is expected to keep you 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, your intermediary does not consider a supply of drugs in excess of 30 days to be reasonable and necessary and denies payment accordingly.

A. Billing Requirements.--Bill on HCFA-1450 or its electronic equivalent with bill type 12X, 13X, 83X or 85X, as appropriate. For claims with dates of service prior to April 1, 2000, report the following entries:

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

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

- Occurrence code 36 and date in FLs 32-35;
- Revenue code 636 in FL 42;
- HCPCS code of the immunosuppressive drug in FL 44; and
- 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).

Complete 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, your intermediary states on the MSN to the beneficiary:

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, the following message is used:

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, the following message is use:

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, your intermediary states on the MSN to the beneficiary:

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