Medicare
Skilled Nursing Facility Manual

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

Transmittal 371 **Date: NOVEMBER 7, 2001**

CHANGE REQUEST 1934

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
230.5 – 230.6 (Cont.) 542 – 542 (Cont.)	2-39 – 2-42 (4 pp.) 5-25.22 – 5-25.23 (2 pp.)	2-39 – 2-42 (4 pp.) 5-25.22 – 5-25.23 (2 pp.)

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

This manualizes Transmittals Numbers AB-99-98 (CR 1069) and AB-01-10 (CR 1513) dated December 12, 1999 and January 24, 2001, respectively.

Section 230.5, Drugs and Biologicals, and Section 542, 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.

230.4 Medical Social Services to Meet the Patient's Medically Related Social Needs.--Medical social services are those social services which contribute meaningfully to the treatment of a patient's condition. Such services include, but are not limited to: (a) assessment of the social and emotional factors related to the patient's illness, his need for care, his response to treatment, and his adjustment to care in the facility; (b) appropriate action to obtain case work services to assist in resolving problems in these areas; (c) assessment of the relationship of the patient's medical and nursing requirements his home situation, his financing resources, and the community resources available to him in making the decision regarding his discharge.

The rendering of medical social services by an SNF is optional. Even though skilled nursing facilities can participate in the Medicare program without offering such services, Medicare will continue to allow, as an element of cost, expenditures for medical social services provided by a facility or its inpatients. However, skilled nursing facilities that continue to render social services must comply with the staffing and other standards for social services presently in the regulations (Conditions of Participation: Skilled Nursing Facilities. Regulation 405.1130).

Although furnishing medical social services is not mandatory, many facilities have found that the social worker performs a valuable services both to the facility staff and the patient. The staff has often been helped by the social worker to better understand the medically related social needs of the patient. Adjustment by the patient is facilitated by the social worker who can also aid the family to avail itself of appropriate community resources.

230.5 Drugs and Biologicals.--(See also §230.6 for blood.) Drugs and biologicals for use in the facility which are ordinarily furnished by the facility for the care and treatment of inpatients are covered.

Three basic requirements must be met for a drug or biological furnished by a facility to be included as a covered SNF service. (1) The drug or biological must represent a cost to the institution in rendering services to the beneficiary. (2) The drugs or biological must meet the statutory definition. Under the statute, payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia-National Formulary (USP-NF), the United States Pharmacopoeia Drug Information (USP DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia. Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium. (3) The drug or biological must be reasonable and necessary as specified in §280.1.

Such drugs and biologicals are not limited to those routinely stocked by the facility but include those obtained for the patient from an outside source such as a pharmacy in the community. Since the provision of drugs and biologicals is considered an essential part of skilled nursing care, a facility must assure their availability to inpatients in order to be found capable of furnishing the level of care required for participation in the program. When a facility secures drugs and biologicals from an outside source, their availability is assured only if the facility assumes financial responsibility for the necessary drugs and biologicals; i.e., the supplier looks to the facility, not the patient, for payment.

A. Drugs Included in the Drug Compendia.--Coverage is provided only for those drugs and biologicals included, or approved for inclusion, in the latest official editions or revisions of the compendia listed above.

Where a drug is excluded from coverage because it is unfavorably evaluated in either the AMA Drug Evaluations or Accepted Dental Therapeutics, the exclusion applies to all uses for which the drug or biological was so unfavorably evaluated.

Drugs and biologicals are considered "approved for inclusion" in a compendium of approved under the procedure established by the professional organization responsible for revision of the compendium.

B. Drugs Not Included in the Compendia.--Drugs not included, or approved for inclusion, in the drug compendia are nevertheless covered if such drug (1) was furnished the patient during his prior hospitalization; and (2) was approved for use in the hospital by the hospital's pharmacy and drug therapeutics (or equivalent) committee; and (3) is required for the continuing treatment of the patient in the skilled nursing facility.

C. Combination Drugs.--Combination drugs are covered if the combination itself or all the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the designated drug compendia. Under the limited circumstances mentioned in B above, a combination drug approved by a hospital pharmacy and drug therapeutics committee may also be covered as an extended care service.

D. Drugs for Use Outside the Facility.--Drugs and biologicals furnished by a facility to an inpatient for use outside the facility are, in general, not covered as extended care services. However, if the drug or biological is deemed medically necessary to permit or facilitate the patient's departure from the facility, and a supply is required until he can obtain a continuing supply, the drugs or biologicals would be covered as an extended care service. Drugs and biologicals furnished to outpatients of skilled nursing facilities are not covered.

E. 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 immunosuppressive drugs in the past, but whose immunosuppressive drug benefit was terminated 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 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.

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.A.7.

230.6 Blood.--Extended care services covered under Part A include unreplaced blood (after satisfaction of the 3 pint blood deductible) and processing costs beginning with the first pint. However, blood transfusions are ordinarily performed by hospitals and not by SNF's. Thus, in the usual case, when an SNF patient needs blood, a participating hospital will provide the blood and the laboratory services and perform the transfusion for SNF. In such a case, the hospital's charge for such blood and services is a blood cost and/or blood processing cost to the SNF. (See D below for rules on distinguished between blood processing costs where blood is obtained from an outside source.) The SNF's charges to the beneficiary must be in accordance with C below. (**NOTE:** Ambulance transportation of the patient between the hospital and SNF for the purpose of obtaining a blood transfusion is covered under Part if the conditions for coverage of ambulance services are met. See §§ 262ff.)

In the unusual situation where the SNF stores, cross-matches, or types blood, rather than having this done by a qualified hospital or independent laboratory, the SNF must, as a condition of participation, meet Standard (j) of section 405.l028 of the Regulations on Conditions of Participation for Hospitals. Where the SNF only transfuses blood to inpatients, it would be required to meet only factors (1), (3), (4), and (6) and (9) of sections 405.1029(j). (See section 405.1128 of Regulations on Conditions of Participation for Skilled Nursing Facilities.) (42 CFR 405. Subpart K.)

A. Application of the Blood Deductible.--Program payment may not be made for the first three pints of whole blood or equivalent units of packed red cells received by a beneficiary in a benefit period. However, payment may be made for any blood processing costs (i.e., administration, storage, etc.) incurred by an SNF beginning with the first pint or unit in a benefit period. (See §524, Item l9A for rules on distinguishing between blood charges and blood processing charges.)

The blood deductible applies only to the first three pints of blood furnished in a benefit period, even if more than one SNF furnished blood. The blood deductible is in addition to any other applicable deductible and coinsurance amounts for which the patient is responsible.

To be covered as an extended care service or to count toward the Part A blood deductible, the blood must be furnished to an SNF inpatient on a day which counts toward the l00 extended care benefit days available in a benefit period. For example, whole blood is not covered by Part A and does not

count toward the Part A blood deductible when furnished to an SNF inpatient after he has exhausted his benefit days in a benefit period. However, where the patient is discharged on his first day of entitlement or on the SNF's first day of participation, the SNF is permitted to submit a billing form with no accommodation charge, but with ancillary charges including blood. (See § 242.4.)

B. Items Subject to the Blood Deductible.--The blood deductible applies only to whole blood and packed red cells. The term whole blood means human blood from which none of the liquid or cellular components have been removed. Where packed red cells are furnished, a unit of packed red cells is considered equivalent to a pint of whole blood. Other components of blood such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin are not subject to the blood deductible. However, these components of blood are covered as biologicals.

C. Obligation of the Beneficiary to Pay for or Replace Deductible Blood.-A provider may charge the beneficiary or a third party its customary charge for whole blood or units of packed red cells which are subject to either the Part A or Part B blood deductible, unless the individual, another person, or a blood bank replaces the blood or arranges to have it replaced.

1. Replacement.--For replacement purposes, a pint of whole blood is considered equivalent to a unit of packed red cells. A deductible pint of whole blood or unit of packed red cells is considered replaced when a medically acceptable pint or unit is given or offered to the provider or, at the provider's request, to its blood supplier. Accordingly, where an individual or a blood bank offers blood as a replacement for a deductible pint or unit furnished a Medicare beneficiary, the provider may not charge the beneficiary for the blood, whether or not the provider or its blood supplier accepts the replacement offer. Thus a provider may not charge the beneficiary for the blood, whether or not the provider or its blood supplier accepts the replacement offer. Thus a provider may not charge a beneficiary merely because it is the policy of the provider or its blood supplier not to accept blood from a particular source which has offered to replace blood on behalf of the beneficiary. However, a provider would not be barred from charging a beneficiary for deductible blood, if there is a reasonable basis for believing that replacement blood offered by or on behalf of the beneficiary would endanger the health of a recipient or that the prospective donor's health would be endangered by making a blood donation. Once a provider accepts a pint of replacement blood from a beneficiary or another individual acting on his behalf, the blood is deemed to have been replaced, and, the beneficiary may not be charged for the blood, even though the replacement blood is later found to be unfit and has to be discarded.

When a provider accepts blood donated in advance, in anticipation of need by a specific beneficiary, whether the beneficiary's own blood, that is, an autologous donation, or blood furnished by another individual or blood assurance group, such donations are considered replacement for pints or units subsequently furnished the beneficiary.

2. Adjustment of Provider's Cost Reimbursement to Reflect Deductible Amounts Collected.--At the end of the year when program reimbursement for blood is being computed, the cost of all unreplaced deductible and unreplaced nondeductible blood supplied will be reduced by the amount the provider collected from beneficiaries or other parties for unreplaced deductible pints. If more blood is donated by, or on behalf of, a beneficiary than is needed for full replacement on a pint-for-pint or unit basis, the value of the excess blood is not deducted from the amount payable to the provider. But, such donations would tend to reduce the cost of blood to the provider.

D. Distinction Between Blood Costs and Blood Processing Costs.--Since the blood deductible applies only to blood costs, and does not apply to blood processing costs, it is necessary that SNF's distinguish between those two costs for purpose of Medicare cost reporting in accordance with the following rules:

542. BILLING FOR IMMUNOSUPPRESSIVE DRUGS FURNISHED TO TRANSPLANT PATIENTS

A. Immunosuppressive Drugs Furnished to Transplant Patients.-- Part B of Medicare covers the reasonable cost of FDA-approved immunosuppressive drugs for inpatient Part B claims. 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.

B. Billing Requirements.--Bill on Form HCFA-1450 or its electronic equivalent with bill type 22x for claims with dates of service prior to April 1, 2000 with the following entries:

- Occurrence code 36 and date in FLs 32-35;
- Revenue code 0636 in FL 42;
- 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 0636 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.

C. 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 used:

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."

(the next page is 5-27)