
Medicare Hospital Manual

Department of Health and
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HEALTH CARE FINANCING
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HEADER SECTION NUMBERS

210.3 – 210.3 (Cont.)

PAGES TO INSERT

23 – 23.1 (2 pp.)

PAGES TO DELETE

23 – 23.1 (2 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: August 6, 2001*

Section 210.3, Drugs and Biologicals, is revised to update the definition to reflect mergers and successor publications to the original sources listed in §1861(t) of the Social Security Act.

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

210.2 Nursing and Other Services.--Nursing and other related services, use of hospital facilities, and medical social services ordinarily furnished by the hospital for the care and treatment of inpatients are covered.

NOTE: The services of a private-duty nurse or other private-duty attendant are not covered.--Private-duty nurses or private-duty attendants are registered professional nurses, licensed practical nurses, or any other trained attendant whose services ordinarily are rendered to, and restricted to, a particular patient by arrangement between the patient and the private-duty nurse or attendant. Such persons are engaged or paid by an individual patient or by someone acting on his behalf, including a hospital that initially incurs the cost and looks to the patient for reimbursement for such noncovered services.

Where the hospital acts on behalf of a patient, the services of the private-duty nurse or other attendant under such an arrangement are not inpatient hospital services regardless of the control which the hospital may exercise with respect to the services rendered by such private-duty nurse or attendant.

A. Anesthetist Services.--If the hospital engages the services of a nurse anesthetist or other nonphysician anesthetist (either on a salary or fee-for-service basis) under arrangements which provide for billing to be made by hospital, the cost of the service when provided to an inpatient is covered under Part A.

B. 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 hospital; (b) appropriate action to obtain case work services to assist in resolving problems in these areas; (c) assessment of the patient's medical and nursing requirements, his home situation, his financial resources, and the community resources available to him in making the decision regarding his discharge.

210.3 Drugs and Biological.--Drugs and biological for use in the hospital, which are ordinarily furnished by the hospital for the care and treatment of inpatients, are covered.

Three basic requirements must be met for a drug or biological furnished by a hospital to be included as a covered hospital service:

- o The drug or biological must represent a cost to the institution in rendering services to the beneficiary.

- o The drug 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; or be approved by the pharmacy and drug therapeutics or equivalent committee of the medical staff of the hospital for use in the hospital.

- o Use of the drug or biological must be safe and effective and otherwise reasonable and necessary as specified in §260.

Drugs or biological approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this last requirement when used for indications specified on the labeling. Therefore, use of an FDA-approved drug or biological is covered if:

- o it was injected on or after the date of the FDA's approval;
- o it is reasonable and necessary for the individual patient; and
- o all other applicable coverage requirements are met.

Drugs and biological which have not received final marketing approval by the FDA are not covered unless you receive instructions from HCFA to the contrary. For specific guidelines of Group C cancer drugs and other covered/non-covered drug issues refer to the Coverage Issues Manual.

However, FDA-approved drugs are used for indications other than those specified on the labeling. As long as the FDA has not specified such use as nonapproved, coverage is determined taking into consideration the generally accepted medical practice in the community. For example, the labeling of certain chemotherapeutic drugs indicates their use in the therapy of specified types of cancer. However, based on experience and empirical evidence, physicians may prescribe these drugs for a wider range of cancer treatments than what is indicated in the labeling. Under these conditions, these drugs would be covered unless the PRO has determined that such use is not medically reasonable and necessary in the individual case.

A. Drugs Included in the Drug Compendia.--Coverage is provided only for those drugs and biological included, or approved for inclusion, in the latest official edition or revision 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 biological are considered "approved for inclusion" in a compendium if approved under the procedure established by the professional organization responsible for revision of the compendium.

B. Approval by Pharmacy and Drug Therapeutics Committee.--A pharmacy and drug therapeutics or equivalent committee is a medical staff committee which confers with the hospital pharmacist in the formulation of policies pertaining to drugs. Drugs and biological approved for use in the hospital by such a committee are covered only if the committee develops and maintains a formulary or list of drugs accepted for use in the hospital. The committee need not function exclusively as a pharmacy and drug therapeutics committee but may also carry on other medical staff function.

Drugs and biological are considered approved for use in the hospital if selected for inclusion in the hospital drug list or formulary under the procedure of the committee established for that purpose. Express approval is required; the fact that a drug or biological has not been specifically determined to be unacceptable for use in the hospital does not constitute approval.