
Medicare

Intermediary Manual

Part 3 - Claims Process

Department of Health and
Human Services (DHHS)
HEALTH CARE FINANCING
ADMINISTRATION (HCFA)

Transmittal 1838

Date: JUNE 22, 2001

CHANGE REQUEST 1748

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
3101.3 – 3101.3 (Cont.)	3-28.3 – 3-28.4 (2 pp.)	3-28.3 – 3-28.4 (2 pp.)
3133.5 – 3133.5 (Cont.)	58.1 – 58.2 (2 pp.)	58.1 – 58.2 (2 pp.)

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

Sections 3101.3 and 3133.5, Drugs and Biologicals, is revised to update these definitions 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.

These instructions should be implemented within your current operating budget.

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 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 costs 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 the hospital, the cost of the service when provided to an inpatient would be covered under Part A.

B. Medical Social Services to Meet the Patient's Medically Related Social Needs.--Medical social services are 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 to his home situation, his financial resources, and the community resources available to him in making the decision regarding his discharge.

3101.3 Drugs and Biologicals.--Drugs and biologicals 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 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.

Drugs or biologicals 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 in the labeling. Therefore, use of an FDA-approved drug or biological is covered if:

- o It was administered 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 biologicals 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 determines that such use is not medically reasonable and necessary in the individual case.

Determinations as to whether use of a drug or biological is reasonable and necessary for an individual patient are the responsibility of the Peer Review Organization (PRO).

A hospital stay solely for the purpose of use of a drug or biological that is determined not reasonable and necessary is not covered.

A. Drugs Included in the Drug Compendia.--Cover only those drugs and biologicals included, or approved for inclusion, in the latest official edition or revision of the compendia as previously listed.

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 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 biologicals 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 functions.

3133.4 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 to his home situation, his financial resources, and the community resource available to him in making the decision regarding his discharge.

3133.5 Drugs and Biologicals.--Drugs and biologicals for use in the facility which are ordinarily furnished by the facility for the care and treatment of inpatients are covered. Such drugs and biologicals are not limited to those routinely stocked by the skilled nursing facility but include those obtained for the patient from an outside source, such as a pharmacy in the community. Where a facility does not bill for such drugs and biologicals or include their costs in its cost reporting forms, the intermediary should bring the matter to the attention of the regional office for referral to the State agency for consideration whether the facility is in substantial compliance with the conditions of participation. 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.

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.

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary as specified in section 3151. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this last requirement. Therefore, you may pay for the use of an FDA-approved drug or biological, if (1) it was administered on or after the date of the FDA's approval; (2) it is reasonable and necessary for the individual patient; and (3) all other applicable coverage requirements are met. Payment may not be made for particular uses of drugs that the FDA has expressly disapproved or that are designated as not covered in the Coverage Issues Appendix.

If you have reason to question whether the FDA has approved a drug or biological for marketing, you should obtain satisfactory evidence of FDA's approval. Acceptable evidence includes a copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA); or listing of the drug or biological in the FDA's Approved Drug Products or FDA Drug and Device Product Approvals; or a copy of the manufacturer's package insert, approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it. When necessary, the Medicare regional office may be able to help in obtaining information.

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 edition or revision of the compendia listed above.

The exclusion from coverage of drugs and biologicals unfavorably evaluated in AMA Drug Evaluations (the successor publication to New Drugs) or Accepted Dental Therapeutics (the successor publication to Accepted Dental Remedies) applies to those drugs and biologicals which have been unfavorably evaluated for all medicinal uses. If a drug or biological has been unfavorably evaluated for one or more, but not all, medicinal uses, the exclusion applies only where the drug has been unfavorably evaluated for the medicinal use to which it is being put.

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.

B. Drugs Not Included in the Compendia.--Drugs not included, or approved for inclusion, the drug compendia are nevertheless covered if such drug (1) was furnished the patient during his prior hospitalization, (2) was approved for use in the hospital by the hospital's pharmacy and drug therapeutics (or equivalent) committee, (3) is required for the continuing treatment of the patient in the skilled nursing facility, and (4) is reasonable and necessary.

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.