Medicare
Carriers Manual
Part 3 - Claims Process

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

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CHANGE REQUEST 1748

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
2049.2 – 2049.3	2-18.1 – 2-18.2 (2 pp.)	2-18.1 – 2-18.2 (2 pp.)

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

Section 2049.1, Definition of Drug or 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.

These instructions should be implemented within your current operating budget.

2049. DRUGS AND BIOLOGICALS

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- o They meet the definition of drugs or biologicals (see §2049.1);
- o They are of the type that cannot be self-administered (see §2049.2);
- o They meet all the general requirements for coverage of items as incident to a physician's services (see §§2050.1 and 2050.3);
- o They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §2049.4);
- o They are not excluded as immunizations (see §2049.4.B); and
- o They have not been determined by the FDA to be less than effective. (See §2049.4 D.)

Drugs that can be self-administered, such as those in pill form, or are used for self-injection, are generally not covered by Part B. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §§2100.5 and 2130.D for coverage of drugs which are necessary to the effective use of DME or prosthetic devices.)

2049.1 Definition of Drug or Biological.--Drugs and biologicals must be determined to 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.

2049.2 Determining Self-Administration of Drug or Biological.--Whether a drug or biological is of a type which cannot be self-administered is based on the usual method of administration of the form of that drug or biological as furnished by the physician. Thus, where a physician gives a patient pills or other oral medication, these are excluded from coverage since the form of the drug given to the patient is usually self-administered. Similarly, if a physician gives a patient an injection which is usually self-injected (e.g., insulin or calcitonin), this drug is excluded from coverage, unless administered to the patient in an emergency situation (e.g., diabetic coma). Where, however, a physician injects a drug which is not usually self-injected, this drug is not subject to the self-administrable drug exclusion (regardless of whether the drug may also be available in oral form) since it is not self-administrable in the form in which it was furnished to the patient.

Whole blood is a biological which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied. (See §2455 on Part B blood deductible.)

2049.3 Incident-to Requirements.--In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must be of a form that cannot be self-administered and must be furnished by a physician and administered by him/her or by auxiliary personnel employed by him/her under his/her personal supervision. The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§2154, 2156, 2158 and 2160 for specific instructions.)

2049.4 Reasonableness and Necessity.--Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See §2303.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, you may pay for the use of an FDA approved drug or biological, if:

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

Deny coverage for drugs and biologicals which have not received final marketing approval by the FDA unless you receive instructions from HCFA to the contrary. For specific guidelines on coverage of Group C cancer drugs, see the Coverage Issues Manual.

If there is reason to question whether the FDA has approved a drug or biological for marketing, 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 RO may be able to help in obtaining information.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritive medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §2049.4.C.

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice.