

## CHAPTER 7 SECTION 7.1

### DRUGS AND MEDICINES

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#### I. POLICY

A. Drugs and medications, including "unlabeled or off-label use", whether administered by a physician or obtained by prescription, are covered when all of the following conditions are met:

1. The drug is medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice. Approval for "unlabeled or off-label use" requires medical review for medical necessity. The review for medical necessity must include demonstrations from medical literature, national organizations, or national technology assessment bodies, that the "off-label or unlabeled" use of the drug is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. If the "off-label or unlabeled" use of the drug does not meet all the above requirements, cost-sharing of the drug will be denied.

2. The drug is approved by the U.S. Food and Drug Administration for commercial marketing. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be cost-shared as if FDA approved. A drug that is approved for testing in humans is not covered. Information concerning FDA approved drugs may be obtained by calling (301) 827-4573.

3. By law of the United States, the drug requires a physician's or other authorized individual professional provider's prescription (acting within the scope of their license) and are ordered or prescribed by a physician or other authorized individual professional provider.

4. The drug is prescribed and dispensed in accordance with state law and licensing requirements.

5. The drug is not prescribed or furnished by a member of the patient's immediate family. For information concerning immunizations, see [Chapter 1, Section 9.1](#). For information concerning processing of prescription drugs and medicine claims, see the [OPM Part Two, Chapter 1, Section V.C.5.h.\(4\)](#).

B. Insulin is covered for diabetic patients, regardless of whether a prescription is required under state law.

C. Vitamins may be covered only when used in accordance with nationally accepted standards of practice in the medical community as a specific treatment of a medical condition.

D. Drugs which previously required a prescription but which are now deemed safe by the FDA for use without a doctor's prescription, and are available over-the-counter, can not be cost-shared.

E. The current FDA-approved label supersedes the information contained in this policy.

## II. POLICY CONSIDERATIONS

A. The following is a list of drugs that will or will not be cost-shared for "unlabeled or off-labeled" uses as specifically stated.

1. ACTH (adrenocorticotrophic hormone) is covered when used in the treatment of multiple sclerosis and rheumatoid arthritis.

2. Adrenal cortex extract injections are not covered.

3. Anti-inhibitor coagulant complex (Autoplex®) is covered only when administered to hemophiliacs who have developed antibodies to antihemophilic factor. It is usually used in the treatment of massive bleeding or when surgery is necessary. All claims require a determination that the drug was medically necessary and that other appropriate means of dealing with the situation were not available.

4. Autogenous vaccines are not covered.

5. Azathioprine (Imuran®) is covered:

a. For prophylaxis of organ rejections in patients receiving liver, liver-kidney, heart, lung, and heart-lung transplants, effective January 1, 1989.

b. When used to induce and maintain remission of the symptoms of active inflammatory bowel disease, including Crohn's disease. Because of potential adverse effects, use of this drug requires thorough patient education and close physician supervision, effective July 15, 1995.

6. Botulinum Toxin Type A (Botox®), see [Chapter 1, Section 11.1](#).

7. Calcitriol (Rocaltrol®) is covered for the treatment of osteoporosis, effective June 1, 1995.

8. Chymopapain is covered only for the treatment of herniated lumbar intervertebral discs in accordance with FDA requirements. See [Chapter 3, Section 15.9](#).

9. Cladribine, 2CdA (Leustatin®) and Cyclophosphamide (Cytosan®) are covered for the treatment of Waldenström's macroglobulinemia, effective February 26, 1993. These drugs may be administered subcutaneously or intravenously.

10. Cyclophosphamide (Cytosan<sup>®</sup>, Neosar<sup>®</sup>) is covered for the treatment of lupus nephritis, effective March 1, 1986.
11. Cyclosporine (Sandimmune<sup>®</sup>) is covered for the prophylaxis of rejection in patients receiving bone marrow transplantation.
12. Disodium edetate (EDTA), see Chapter 1, Section 11.3.
13. Dimethyl sulfoxide (DMSO), is covered when used in the treatment of interstitial cystitis.
14. Epogen (EPO, erythropoietin, Eprex, Procrit, Epoetin Alfa) may be covered for patients diagnosed with orthostatic hypotension (dysautonomia).
15. Epoprostenol Sodium (FLOLAN<sup>®</sup>) is covered for the management of severe secondary pulmonary hypertension for patients who have been authorized for lung transplant and are awaiting transplant, effective May 1, 1996.
16. Gemcitabine (Gemzar<sup>®</sup>) is not covered for the treatment of non-small cell lung cancer.
17. Group C Drugs are not eligible for cost-sharing.
18. Heparin therapy in the treatment of pregnant patients who have systemic lupus erythematosus (SLE) or who have lupus anticoagulant (LA) is not covered.
19. High dose calcitriol and/or interferon gamma in the treatment of malignant osteopetrosis is not covered.
20. High dose chemotherapy (HDC), see Chapter 3, Section 6.1.
21. Human chorionic gonadotropin (HCG), or any other drug, administered for purposes of weight control is not covered.
22. Hycamtin (Topotecan<sup>®</sup>) is covered for treatment of glioblastoma multiforme (brain tumors), effective February 1, 1996.
23. Interferon alfa-2a (Roferon<sup>®</sup>-A) is covered for the treatment of metastatic renal cell carcinoma, effective March 1, 1994.
24. Interferon alfa-2b (Intron<sup>®</sup>A) is covered for the treatment of:
  - a. Chronic myelogenous leukemia (CML), effective March 1, 1994.
  - b. Children with malignant melanoma when prescribed as adjuvant to surgical treatment, effective December 5, 1995.
25. Interferon alfa-2b for treatment of bladder cancer is not covered.
26. Interferon Gamma for the treatment of scleroderma is not covered.

27. Intravenous injections of Gamma Globulin for pregnancy rejection and polycystic ovarian disease is not covered.

28. Intravenous Immune Globulin (IVIG) (Venoglobulin®):

a. Is covered when used with aspirin to decrease coronary artery aneurysm formation and other manifestations of Kawasaki syndrome,

b. Is not covered in the treatment of multiple sclerosis.

29. Irinotecan (Camptosar®) may be covered for the treatment of glioblastoma multiforme, effective June 14, 1996.

30. Isotretinoin (Accutane®) is covered when used in combination with other drugs that are FDA-approved for chemotherapy to treat squamous cell carcinoma of the skin. It is not covered as a single-agent treatment nor for maintenance of remission of squamous cell carcinoma of the skin.

31. Laetrile (amygdalin, sarcocarpinase, vitamin B-17) and all other drugs characterized as a "nitrilide," are not recognized to be safe and effective for any therapeutic use and are not covered.

32. Leuprolide acetate (Lupron®) for uterine leiomyomata is covered when any of the following conditions are present in women of reproductive age: infertility; nearing menopause; patients scheduled for myomectomy, or who might be candidates for hysterectomy, upon medical determination that the total uterine volume could be sufficiently reduced with use of the drug, effective December 1989.

*NOTE: No medication has been shown to safely cause complete regression or disappearance of leiomyoma uteri; however, studies have shown that approximately 50% of patients experience a decrease in total uterine volume by about 50% following treatment with leuprolide acetate. Response to treatment is usually achieved by the 12th week of treatment. Since use of leuprolide acetate beyond six months increases the risk of hypogonadism, and leads to osteoporosis (thus appearing to outweigh the beneficial effects), in no event will reimbursement extend beyond six months for treatment with leuprolide acetate.*

33. Methotrexate for systemic lupus erythematosus is not covered.

34. Methotrexate for unruptured ectopic pregnancies is covered, effective December 1, 1990.

35. Methylprednisolone acetate suspension (Depo-Medrol®) is covered for the treatment of multiple sclerosis.

36. Mitomycin-C (Mutamycin®) is not covered when used in trabeculectomy (glaucoma filtering surgery).

37. Mitoxantrone (Novantrone®) is covered when used in the treatment of intermediate and high grade non-Hodgkin's lymphomas.

**38. Mycophenolate Mofetil (Cellcept®) for the prophylaxis of organ rejection in patients receiving heart transplantation or liver transplantation is not covered.**

39. Paclitaxel (Taxol®) is covered for the following treatments:

a. Metastatic ovarian cancer after failure of first-line or subsequent chemotherapy, effective December 29, 1992.

b. Non-small cell lung cancer as primary treatment choice when the tumor is inoperable or as adjuvant treatment in patients following surgical removal of a lung to impede regional or distant metastases, effective March 3, 1993.

c. Breast cancer in patients who have not responded to first-line metastatic chemotherapy or who have relapsed after chemotherapy, effective April 21, 1994.

40. Paclitaxel (Taxol®) for the treatment of malignant melanoma is not covered.

41. Pamidronate (Aredia®) for the treatment of osteoporosis is not covered.

42. Potassium preparations ordered by a physician and obtained by prescription are covered when the medical necessity is documented and verified by medical review.

43. Tacrolimus (Prograf®), formerly known as FK506, is covered for prophylaxis of organ rejection in patients receiving allogeneic liver transplants, lung transplants, heart transplants, and kidney transplants, effective April 8, 1994.

44. Terbutaline Sulfate to induce and maintain tocolysis for the management of preterm labor is covered in the inpatient setting, see [Chapter 3, Section 13.2](#).

45. Transdermal nicotine patch for the treatment of ulcerative colitis is not covered.

46. Treatment Investigational New Drugs (INDs) are not approved by the FDA for commercial marketing and therefore are not eligible for coverage. Medical care related to the use of Treatment INDs may be covered when the care is provided in accordance with nationally accepted standards of practice in the medical community.

47. Vinorelbine Tartrate (Navelbine®) is covered for the treatment of metastatic breast cancer, effective April 1, 1995.

B. The above list is not all-inclusive and will be updated as required.

### III. EXCLUSIONS

Placebo injections and drugs are not covered under any circumstances.

#### IV. EFFECTIVE DATE

Cost-sharing of drugs is as follows:

- A. Labeled uses. The effective date of FDA approval for the specific labeled indication/use.
- B. Off-labeled uses. The effective date of the FDA approval for the latest specific labeled indication/use; or if medical literature supports prior safety and efficacy, the first effective date of FDA approval of the drug for general use in humans may be used.
- C. Orphan drugs. The effective date of FDA's marketing approval (MA) for the proposed use. Orphan drugs are defined as a drug or biological product which are used for the diagnosis, treatment or prevention of a rare disease or condition. A rare disease is one which affects fewer than one in 200,000 persons in the U.S.

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