

Medicare Part B Versus Part D Coverage Issues

This document is not a statement or promise of coverage, but rather a discussion of when something *may* be covered under Parts A, B or D, if all other coverage requirements are met.

Introduction

Beneficiaries who are inpatients of hospitals or skilled nursing facilities during covered stays may receive drugs as part of their treatment. Typically, the payment for drugs is bundled into the Medicare Part A payments made to these types of facilities. Under the hospice benefit, beneficiaries receive drugs that are medically necessary for symptom control or for pain relief. In general, references are seen in five major categories of Medicare Part B drug spending: 1. drugs billed by physicians and typically provided in physicians offices (such as chemotherapy drugs); 2. drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; 3. drugs billed by pharmacy suppliers and self-administered by the patient (such as immunosuppressive drugs and some oral anti-cancer drugs); 4. Separately billable drugs provided in Hospital Outpatient Departments; and 5. Separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO). Regional differences in Part B coverage policies for drugs can occur in the absence of a national coverage decision. A drug for which coverage is available under Part A or Part B, as it is being “prescribed and dispensed or administered” with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage. Please call 1-800-MEDICARE to discuss specific coverage issues.

Medicare Part A and Part B Covered Drugs

Part A/B Covered Drugs Set by Statute: Medicare Part B versus Part D Coverage Issues

Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:

- Durable Medical Equipment (DME) Supply Drugs. These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for *inhalation drugs*, which are administered through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). The other category of drugs Medicare covers as a DME supply are drugs for which administration with an *infusion pump* in the home is medically necessary (e.g. some chemotherapeutic agents).
- Immunosuppressive Drugs. Drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.

- Hemophilia clotting factors. Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.
- Oral Anti-Cancer Drugs. Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician's professional service.
- Oral Anti-emetic Drugs. Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.
- Pneumococcal vaccine. The vaccine and its administration to a beneficiary if ordered by a physician.
- Hepatitis B vaccine. The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.
- Influenza vaccine. The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.
- Antigens. These are prepared by a physician (usually an allergist) for a specific patient. The physician or physician's nurse generally administers them in the physician's office. In some cases the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home.
- Erythropoietin (EPO). EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.
- Parenteral Nutrition. Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. Parenteral nutrition is administered intravenously and is regulated as a drug by the FDA.
- Intravenous Immune Globulin Provide in the Home. The MMA created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. Coverage is provided if a physician determines that the administration of IVIG in the patient's home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product.

Part B Covered Drugs in the Context of a Professional Service

- Drugs furnished "Incident To" a Physician's Service. These are injectable or intravenous drugs that are administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service. The statute limits coverage to drugs that are not usually self-administered.
- Separately Billable ESRD Drugs. Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs are for erythropoietin (EPO) which is covered for dialysis beneficiaries when it is furnished by independent and hospital-based ESRD facilities, as well as when it is furnished by physicians.

- Separately billable drugs provided in Hospital Outpatient Departments. For Calendar Year 2005, Medicare continues to pay separately for drugs, biologicals and radiopharmaceuticals whose median cost per administration exceeds \$50, while packaging the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per administration is less than \$50 into the procedures with which they are billed.
- Drugs covered as Supplies or - “Integral to a Procedure.” Some drugs are covered as supplies that are an integral part of a procedure which is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. Other examples of drugs covered under the “integral to a procedure” provision include eye drops administered before cataract surgery.
- Blood. Medicare does make separate payment for blood and blood products and these products are regulated as biological agents by the FDA.
- Drugs furnished as a part of a service in these provider settings. 1. Drugs packaged under the Hospital Outpatient Prospective Payment System; 2. Drugs furnished by ESRD facilities and included in Medicare’s ESRD composite rate; 3. osteoporosis drugs provided by home health agencies under certain conditions; 4. Drugs furnished by Critical Access Hospitals’ (CAH) Outpatient Departments; 5. Drugs furnished by a Rural Health Clinic (RHC); 6. Drugs furnished by Federally Qualified Health Centers (FQHC); 7. Drugs furnished by Community Mental Health Centers (CMHC); 8. Drugs furnished by Ambulances; 9. Separately billable drugs provided in Comprehensive Outpatient Rehabilitation Facilities (CORF).

Part D Covered Drugs

Definition of a Part D Covered Drug

A Part D covered drug is available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication. A covered Part D drug includes prescription drugs, biological products, and insulin. The definition also includes “medical supplies associated with the injection of insulin.” Medicare defines the medical supplies to include syringes, needles, alcohol swabs, and gauze.

Part D Excluded Drugs

The definition of a covered Part D drug excludes any drug for which as prescribed and dispensed or administered to an individual, payments would be available under Parts A or B of Medicare for that individual. In addition, the definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:

1. Agents when used for anorexia, weight loss, or weight gain.
2. Agents when used to promote fertility
3. Agents when used for cosmetic purposes or hair growth.
4. Agents when used for the symptomatic relief of cough and colds

5. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
6. Nonprescription drugs
6. Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
7. Barbiturates
8. Benzodiazepines

* While these drugs or uses are excluded from basic Part D coverage, drug plan sponsors can generally include them as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug.