

Dear Medicare Provider and Practitioner:

Enclosed are some basic tools to assist you in understanding Medicare drug coverage determinations under Part A, Part B and Part D of Medicare, and to clarify coverage for specific Part D products/drugs/categories.

There are three products. First is a chart, “Medicare Parts B/D Coverage Issues”, that describes frequent Medicare Part B drug and Part D drug coverage determinations. Accompanying this chart is a brief explanation of “Medicare Drug Coverage Under Part A, Part B and Part D” that details drug coverage under Medicare hospital, medical and prescription drug programs, and offers discussion points you can use in helping people with Medicare to understand their Medicare drug coverage. The third product is a chart “Part D Drugs/Part D Excluded Drugs” that describes which products/drugs/categories are and are not covered by Medicare under the statutory and regulatory requirements. While these documents address the most common scenarios/products, they do not address all situations. For a more extensive discussion, refer to the regulation, or go to www.cms.hhs.gov/PrescriptionDrugCovGenin/Downloads/PartBandPartDdoc_07.27.05.pdf for additional information.

Thank you for support to people with Medicare. We trust that you will find these documents useful in providing services to your Medicare patients.

Medicare Drug Coverage Under Part A, Part B, and Part D

Medicare Part A and Part B generally do not cover outpatient prescription drugs, most of which are now covered under Part D. This document and the attached chart are designed to help you determine which part of Medicare covers a drug in a particular situation, assuming all other requirements are met, e.g., a drug must still be medically necessary to be covered. This information is for people in the Original Medicare Plan. People who have a Medicare Advantage HMO or PPO Plan with prescription drug coverage get all their Medicare-covered health care from the plan, including prescription drugs.

Part A—Hospital Insurance

People with Medicare who are inpatients of hospitals or skilled nursing facilities (SNF) during covered stays may receive drugs as part of their treatment. Medicare Part A payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Under the Medicare hospice benefit, people receive drugs that are medically necessary for symptom control or pain relief.

Part B can pay hospitals and SNFs for most categories of Part B covered drugs if a person does not have Part A coverage, if Part A coverage for the stay has run out, or if a stay is not covered.

Part B—Medical Insurance

Medicare Part B covers a limited set of drugs. Medicare Part B covers injectable and infusible drugs that are not usually self-administered and that are furnished and administered as part of a physician service. If the injection is usually self-administered (e.g., Imitrex) or is not furnished and administered as part of a physician service, it may not be covered by Part B. Medicare Part B also covers a limited number of other types of drugs as shown in the attached chart.¹

(Regional differences in Part B drug coverage policies can occur in the absence of a national coverage decision. For more information on local coverage determinations, go to www.cms.hhs.gov/coverage.)

Part D—Prescription Drug Insurance

Part D-covered drugs are defined as: drugs available only by prescription, used and sold in the United States, and used for a medically accepted indication; biological products; insulin; and vaccines. The definition also includes medical supplies associated with the injection of insulin (syringes, needles, alcohol swabs, and gauze). Certain drugs or classes of drugs, or their medical uses, are excluded by law from Part D coverage. These drugs or classes of drugs are listed at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf. While these drugs or uses are excluded from basic Part D coverage, drug plans may choose to include them as part of supplemental benefits, not covered by Medicare.

¹ For example, Medicare Part B covers certain oral anti-cancer and oral anti-emetic drugs, immunosuppressive drugs for people who had a Medicare covered transplant, erythropoietin for people with end stage renal disease, parenteral nutrition for people with a permanent dysfunction of digestive tract, drugs requiring administration via a nebulizer or infusion pump in the home, and certain vaccines: influenza, Pneumococcal, and (for intermediate- to high-risk individuals) Hepatitis B.

If Medicare Part A or Part B would pay for a person's drug as prescribed and dispensed or administered, that drug cannot be covered for that person under Part D. The person may have to pay the deductible under Part B.

The attached chart provides more detail on specific situations in which Part B or Part D may apply.

The following discussion may help you explain to a person with Medicare which part of Medicare covers his or her drugs:

If Medicare is covering your stay in a hospital or skilled nursing facility, your drugs will be paid for under Medicare Part A. Part A will stop paying for your drugs when you leave the hospital or skilled nursing facility or when your benefit runs out, whichever comes first.

If you are in a Medicare-approved hospice program, Medicare Part A will pay for drugs for symptom control or pain relief. However, Medicare is not permitted to pay for prescriptions intended to treat your terminal illness. If you join a Medicare prescription drug plan (Part D), drugs unrelated to your terminal illness would be covered by that plan. For instance, if you need medicine to treat an infection unrelated to your terminal illness, it would be covered by your Medicare prescription drug plan (Part D).

If your drugs are currently covered by Part B, they will continue to be covered by Part B. You may want to join a Medicare drug plan (Part D) to help pay for other drugs you may be taking that are not currently covered by Part B.

If you live in a long-term care facility, any medications you receive under the DME benefit such as nebulizer drugs for lung disease will no longer be covered since that benefit by law is only for services delivered in the home. If you have Medicare prescription drug coverage (Part D), your plan may cover those prescriptions. [For this purpose, long term care facilities include skilled nursing facilities (after Part A coverage is exhausted or for stays not covered by Medicare), nursing homes which give skilled care, and institutions which give skilled care.]

IMPORTANT INFORMATION: If Part A or Part B would cover your prescription drug as it is prescribed and dispensed or administered, that drug will not be paid for by your Medicare drug plan (Part D).

For your drugs to be covered by Medicare Part B, you will need to make sure your pharmacy or supplier is a participating durable medical equipment (DME) provider in the Medicare Part B program or find a pharmacy or supplier that is a provider with the Medicare Part B Durable Medical Equipment Regional Carrier (DMERC). If you get your drugs covered by your Medicare Part D prescription drug plan, you will need to go to a pharmacy in your plan's network for your drugs to be covered.

Medicare Parts B/D Coverage Issues

This table provides a quick reference guide for the most frequent Medicare Part B drug and Part D drug coverage determination scenarios facing Part D plans and Part D pharmacy providers. It does not address all possible situations. For a more extensive discussion, please refer to “Medicare Part B vs. Part D Coverage Issues” at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf.

Part B Coverage Category	Part B Coverage Description	If Retail Pharmacy, Which Part Pays? ²	If LTC Pharmacy, Which Part Pays?	Comments
Durable Medical Equipment (DME) Supply Drugs Only available for people living at “home”³	Drugs that require administration via covered DME (e.g., inhalation drugs requiring a nebulizer, IV drugs “requiring” ⁴ a pump for infusion, insulin via infusion pump) ⁵	B	D	Blood glucose testing strips and lancets covered under Part B DME benefit are never available under Part D because they are not Part D drugs.
Drugs furnished “incident to” a physician service (i.e., the drug is furnished by the physician and administered either by the physician or by the physician’s staff under the physician’s supervision).	Injectable/intravenous drugs 1) administered incident to a physician service <u>and</u> 2) considered by Part B carrier as “not usually self-administered”	D	D	Not covered by Part B because a pharmacy cannot provide a drug incident to a physician’s service (i.e., only a physician office would bill Part B for “incident to” drugs).

² For purposes of this chart, retail pharmacies include home infusion pharmacies.

³ In addition to a hospital, a SNF or a distinct part SNF, the following LTC facilities cannot be considered a home for purposes of receiving the Medicare Part B DME benefit:

- A nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF)
- A Medicaid-only NF that primarily furnishes skilled care;
- A non-participating nursing home (i.e., neither Medicare nor Medicaid) that provides primarily skilled care; and
- An institution which has a distinct part SNF and which also primarily furnishes skilled care.

⁴ The DMERC determines whether or not an IV drug requires a pump for infusion.

⁵ The DMERC determines whether a nebulizer or infusion pump is medically necessary for a specific drug/condition.

Part B Coverage Category	Part B Coverage Description	If Retail Pharmacy, Which Part Pays? ²	If LTC Pharmacy, Which Part Pays?	Comments
Immunosuppressant Drugs	Drugs used in immunosuppressive therapy for people who received transplant from Medicare-approved facility and were entitled to Medicare Part A at time of transplant (i.e., "Medicare-Covered Transplant")	B or D: Part B for Medicare-Covered Transplant Part D for all other situations	B or D: Part B for Medicare-Covered Transplant Part D for all other situations	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Oral Anti-Cancer Drugs	Oral drugs used for cancer treatment that contain same active ingredient (or pro-drug) as injectable dosage forms that would be covered as 1) not usually self-administered and 2) provided incident to a physician's service	B or D: Part B for cancer treatment Part D for all other indications	B or D: Part B for cancer treatment Part D for all other indications	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Oral Anti-emetic Drugs	Oral anti-emetic drugs used as full therapeutic replacement for IV anti-emetic drugs within 48 hrs of chemo	B or D: Part B for use w/in 48 hrs. of chemo Part D all other situations	B or D: Part B for use w/in 48 hrs. of chemo Part D all other situations	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Erythropoietin (EPO)	Treatment of anemia for persons with chronic renal failure who are undergoing dialysis	B or D: Part B for treatment of anemia for people undergoing dialysis Part D all other situations	B or D: Part B for treatment of anemia for people undergoing dialysis Part D all other situations	EPO may also be covered under Part B for other conditions if furnished incident to a physician's service. (A physician, not a pharmacy, bills for "incident to" drugs.)

Part B Coverage Category	Part B Coverage Description	If Retail Pharmacy, Which Part Pays? ²	If LTC Pharmacy, Which Part Pays?	Comments
Prophylactic Vaccines	Influenza; Pneumococcal; and Hepatitis B (for intermediate to high-risk individuals)	<p>B or D: Part B for Influenza, Pneumococcal, & Hepatitis B (for intermediate to high risk)</p> <p>Part D for all others</p>	<p>B or D: Part B for influenza, pneumococcal, & Hepatitis B (for intermediate to high risk)</p> <p>Part D for all others</p>	Vaccines given directly related to the treatment of an injury or direct exposure to a disease or condition are always covered under Part B.
Parenteral Nutrition	Prosthetic benefit for individuals with “permanent” dysfunction of the digestive tract (must meet “permanence” test)	<p>B or D: Part B if “permanent” dysfunction of digestive tract</p> <p>Part D for all other situations</p>	<p>B or D: Part B if “permanent” dysfunction of digestive tract</p> <p>Part D for all other situations</p>	Part D does not pay for the equipment/supplies and professional services associated with the provision of parenteral nutrition or other Part D covered infusion therapy.

Part D Drugs/Part D Excluded Drugs February 7, 2006

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a “Part D drug” before drawing conclusions from this table. This table does not address B versus D coverage questions.

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ¹ and not covered under Medicare Parts A or B)	Comments
Advicor®	Yes	See Commercially Available Combination Product Policy
Agents when used for anorexia, weight loss, or weight gain	No	Prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded under such exclusion categories.
Agents when used for cosmetic purposes or hair growth	No	Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetic.
Agents when used for symptomatic relief of cough and colds	No	All agents when used for symptomatic relief of cough, cold, or cough and cold are excluded from Part D
Antihistamine/Decongestant Combinations (RX)	Yes, except when being used for symptomatic relief of cough and cold	
Barbiturates	No	
Benzodiazepines	No	
Blood glucose testing strips	No	NOT directly associated with injection of insulin
Commercially available combination prescription products	Yes, if it contains at least one Part D drug component <u>and</u> the product as a whole is not excluded from Part D for another reason (e.g. Used for cough and cold, Less-than-effective DESI drug)	Commercially available combination prescription drug products that contain at least one Part D drug component are part D drugs when used for a "medically accepted" indication, unless CMS makes a determination that such product, as a whole, belongs in one of the categories of drugs excluded from coverage under Part D. If CMS has not provided guidance to exclude a specific combination product, such combination product containing at least one part D drug component should be considered a Part D drug unless it is excluded from coverage under Part D for another reason.
Electrolytes/Replenishers: <ul style="list-style-type: none"> • *Potassium • Sodium • Calcium • Magnesium 	Yes	*Potassium Iodide products are excluded from Part D as Iodine products (minerals) because they are not used for potassium supplementation
Extemporaneous Compounds, including sterile compounding of IV's and TPN	Yes, but only costs for Part D drug components may be billed under Part D	Dispensing fee may include labor costs associated with mixing a compounded drug product that contains at least one Part D drug component Part D drug components used solely as vehicles in a compound may be covered under Part D (e.g. D5W, Normal Saline)

¹ Medically Accepted Indication for purposes of Part D is an FDA labeled indication or an indication supported by citation in either the American Hospital Formulary System (AHFS), USP-DI, or Drugdex.

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Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ¹ and not covered under Medicare Parts A or B)	Comments
Fioricet® (Bupropion, APAP, Caffeine)	No	See Commercially Available Combination Product Policy
Fioricet® with Codeine	Yes	See Commercially Available Combination Product Policy
Fiorinal® (Butalbital, APAP, Caffeine)	No	See Commercially Available Combination Product Policy
Fiorinal® with Codeine	Yes	See Commercially Available Combination Product Policy
Fosamax plus D	Yes	See Commercially Available Combination Product Policy
Guaifenesin (RX)	Yes	
Heparin/Saline Flushes	No	CMS clarified in the preamble to the final rule that although heparin is a Part D drug, a heparin flush is not used to treat a patient for a medically accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. It would therefore not be a Part D drug when used in a heparin flush. (70 FR 4232)
Injectable or IV Iron products such as Iron Dextran, Iron Sucrose and Sodium ferric gluconate	No	Prescription vitamin/mineral product
Insulin	Yes	
Insulin syringes	Yes	Syringes are NOT covered for injection of other Part D drugs
IV Solutions for hydration therapy	Yes	
Klonopin® (Clonazepam)	No	Benzodiazepine
Lancets	No	NOT directly associated with injection of insulin
Less-than-effective DESI Drugs (and those drugs identical, related or similar)	No	
Leucovorin Calcium	Yes	
Librax® (Clidinium/chlordiazepoxide)	No	Less-than-effective DESI drug
Limbitrol® (Amitriptyline/chlordiazepoxide)	Yes	See Commercially Available Combination Product Policy
Megestrol Acetate and Growth Hormone when used for AIDS wasting and cachexia	Yes	Prescription drug products that otherwise satisfy the definition of Part D drug are Part D drugs when used for AIDS wasting and cachexia if these conditions are "medically accepted" indications, as defined by section 1927(k)(6) of the Social Security Act (SSA), for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or agents used for cosmetic purposes, and therefore such products cannot be excluded from the Medicare Prescription Drug Benefit by reference to section 1927(d)(2) of the SSA.

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Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ¹ and not covered under Medicare Parts A or B)	Comments
Methadone	Yes, except when indicated for the treatment of opioid dependence	A Part D drug is partially defined as “a drug that may be dispensed only upon a prescription”. . . . Consequently, Methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy.
Mysoline® (Primidone)	Yes	NOT considered a barbiturate
Nonprescription/Over-the-counter (OTC) drugs ²	No, except Insulin and supplies associated with the injection of insulin	Supplies associated with the injection of insulin include syringes, alcohol wipes, insulin pens and pen needles, gauze, and alcohol
Omacor®	Yes	
Phenobarbital	No	Barbiturate
PhosLo®	Yes	
Polysaccharide Iron Complex	No	Prescription vitamin/mineral product
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations Examples: <ul style="list-style-type: none"> • B vitamins (Niacin*, Folic Acid, Cyanocobalamin) • Vitamin K (phytonadione) • Vitamin D (ergocalciferol and cholecalciferol) • Zinc (sulfate, acetate) • Iron • Iodine • Multivitamin additives for parenteral nutrition 	No	*CMS has determined that prescription Niacin products (e.g. Niaspan®, Niacor®) are prescription vitamins and therefore excluded from the definition of Part D drug in accordance with statutory requirements. The effective date of this decision is June 1, 2006 due to the ambiguity and unique circumstances surrounding prescription Niacin products. Prior to this effective date, Part D plans may treat prescription Niacin products as either excluded prescription vitamins or as Part D drugs. After May 31, 2006, prescription Niacin products will be universally excluded from the definition of Part D drug.
Smoking cessation drugs (OTC)	No	
Smoking cessation drugs (RX)	Yes	
Sterile Saline/water for Irrigation	Yes	
Suboxone®, Subutex®	Yes	
Vitamin D Analogs (Calcitriol, doxercalciferol, paricalcitol, and dihydrotachsterol)	Yes	NOT considered prescription vitamins

² Part D plans may include OTC drugs in step therapy protocols as part of their cost effective drug utilization management program. However, OTC drugs included in these step therapy protocols are considered administrative costs, not Part D drugs.