

**Centers for Medicare and Medicaid (CMS) Clarification Regarding
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 <i>(Listing is NOT all-inclusive)</i>	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

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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.

Product/Drug/Drug Category <i>(Listing is NOT all-inclusive)</i>	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
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: ▪ *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)
Fioricet® (Bultalbital, 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
Guaiifenesin (RX)	Yes	

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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
Lorbitol® (Amitriptyline/chlordiazepoxide)	Yes	See Commercially Available Combination Product Policy

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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.
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

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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.

Product/Drug/Drug Category <i>(Listing is NOT all-inclusive)</i>	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
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

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