

Chapter 6 – Appendix B

Part D Drugs/Part D Supplementary Drugs

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 Part B versus Part 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”³ and not covered under Medicare Parts A or B) | Comments |
|--|--|---|
| 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 | Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds. For example, when cough medications are used for a medically accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold, CMS does not consider these cough medications as excluded drugs [such as the treatment of cough to alleviate bronchospasm in |

³ 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 its successor publications), 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”³ and not covered under Medicare Parts A or B) | Comments |
|--|--|---|
| | | asthma]. |
| 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 |
| 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. |
| Erectile (ED) Dysfunction Drugs | No | Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration. In addition, ED drugs will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. However, ED drugs will not meet the definition of a Part D drug when used off-label, even if the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act. |
| Extemporaneous Compounds, including sterile compounding of IV's and total parenteral nutrition | 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) |

| Product/Drug/Drug Category (Listing is NOT all-inclusive) | May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B) | Comments |
|---|--|--|
| Fioricet® (Bultalbital, APAP, Caffeine) | No | See Commercially Available Combination Product Policy Section 10.3 |
| Fioricet® with Codeine | Yes | See Commercially Available Combination Product Policy Section 10.3 |
| Fiorinal® (Butalbital, ASA, Caffeine) | No | See Commercially Available Combination Product Policy Section 10.3 |
| Fiorinal® with Codeine | Yes | See Commercially Available Combination Product Policy Section 10.3 |
| Fosamax plus D | Yes | See Commercially Available Combination Product Policy Section 10.3 |
| Heparin/Saline Flushes | No | See Section 10.6. |
| 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 | See Section 10.9 |
| Leucovorin Calcium | Yes | |
| Librax® | No | Less-than-effective DESI drug |
| Limbitrol® (Amitriptyline/chlordiazepoxide) | Yes | See Commercially Available Combination Product Policy Section 10.3 |

| Product/Drug/Drug Category (Listing is NOT all-inclusive) | May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B) | Comments |
|--|--|---|
| 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. |
| Primidone (Mysoline®) | Yes | NOT considered a barbiturate |
| Nonprescription/Over-the-counter (OTC) drugs ⁴ | 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 |

⁴ 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”³ and not covered under Medicare Parts A or B) | Comments |
|---|--|---|
| Prescription niacin products | Yes | Prescription niacin products are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program. |
| Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations Examples: B vitamins (Folic Acid, Cyanocobalamin) Vitamin K (phytonadione) Vitamin D (ergocalciferol and cholecalciferol) Zinc (sulfate, acetate) Iron Iodine Multivitamin additives for parenteral nutrition | No | |
| 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 dihydrotachysterol) | Yes | NOT considered prescription vitamins |