

Erectile Dysfunction (ED) drugs

Q: Are Erectile Dysfunction (ED) drugs covered under Part D?

A: For Contract Year (CY) 2006 ED drugs met the definition of a Part D drug and were available on Plan Sponsor formularies. On October 26, 2005, Section 1860D-2(e)(2)(A) of the Social Security Act (the Act) was amended excluding from the definition of a Part D drug, “a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration (FDA)”. Subsequently, beginning CY 2007, ED drugs, when prescribed for the treatment of sexual or erectile dysfunction, will be excluded from coverage under Part D.

As with other excluded drugs, Part D sponsors may only continue coverage of ED drugs as long as they do so as supplemental benefits through enhanced alternative coverage. 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 for other off-label uses not approved by the FDA. This includes non-FDA approved uses included in one of the compendia listed in section 1927(g)(1)(B)(i) of the Act : American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, and DRUGDEX Information System.