



Guiding Principles
USP Medicare Model Guidelines v7.0
Medicare Model Guidelines Subcommittee
March 22, 2016

- ❖ *The Healthcare Quality Expert Committee retains the goal of the original Model Guidelines Expert Committee (2004) – to strike a balance of assuring beneficiary access to the safe and effective drugs that they need with the flexibility that Part D sponsors need to offer an affordable and effective benefit.*
- ❖ *The USP Medicare Model Guidelines utilize pharmacotherapeutic evidence for an FDA-approved agent to create categories and classes. The USP Medicare Model Guidelines are composed of two organizational levels—USP Categories and USP Classes—which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class.^{i ii}*
- ❖ *USP Categories and USP Classes are defined as follows:*
 - *A USP Category is the broadest classification of the USP Medicare Model Guidelines, and provides a high level formulary structure designed to include all potential therapeutic agents for diseases and conditions of Part D beneficiaries.*
 - *A USP Class is a more granular classification, occurring within a specific USP Category in the USP Model Guidelines, which provides for therapeutic or pharmacologic groupings of FDA approved medications, consistent with current U.S. healthcare practices and standards of care.*
- ❖ *USP Medicare Model Guidelines v7.0 includes a list of associated drug examples that aligns with the Part D drugs on the Centers for Medicare & Medicaid Services (CMS) Formulary Reference File (FRF).*
 - *A drug in the associated list may appear in more than one USP Category or USP Class if there is a scientifically valid and clinically meaningful patient care issue.*
 - *Combination productsⁱⁱⁱ, and specific dosage forms/formulations/delivery systems, are generally not listed, but may be included in the associated list if there is a valid and clinically meaningful patient care issue.*
- ❖ *USP will advise CMS on issues it discovers during the revision process that are relevant to implementing the USP Medicare Model Guidelines.*

ⁱ The Law states in Section 1860D-4(b)(3)(C) that: (D) Plan design.—(i) In general.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan. (ii) Use of categories and classes in formularies.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

ⁱⁱ The Law states in Section 1860D-11(e)(2)(D) that (C) Inclusion of drugs in all therapeutic categories and classes.—(i) In general.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.(ii) Model guidelines.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.(iii) Limitation on changes in therapeutic classification.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

ⁱⁱⁱ The CMS Part D prescription benefit manual Chapter 6, Section 10.3 states that 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 the 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, so long as it contains 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).