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Centers for Medicare & Medicaid Services

Excluded Drug Reference File Frequently Asked Questions (FAQ)

Q1. What drugs are excluded from coverage under the Medicare Part D program?

A1. As referenced in Section 20.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Medicare Part D does not cover drugs, or their medical uses, which are excluded from coverage or otherwise restricted per section 1860D-2(e)(2)(A) of the Social Security Act. Those drugs include the following:

- Agents when used for anorexia, weight loss or gain (even if used for non-cosmetic purposes, for example: morbid obesity).
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for symptomatic relief of cough and colds .
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Covered outpatient drugs where the manufacturer seeks to require as a condition of sale that associated test or monitoring services be purchased exclusively from the manufacturer or its designee.
- Drugs when used for the treatment of sexual or erectile dysfunction, unless such drugs were used to treat a condition other than sexual or erectile dysfunction for which the drugs have been approved by the Food and Drug Administration.

Q2. What is the Excluded Drug Reference File?

A2. The Excluded Drug Reference File is a list of drugs that may be excluded from coverage under the Medicare Part D program. Similar to the Formulary Reference File, each row on the Excluded Drug Reference File represents a single drug as identified by an RxNorm concept unique identifier (RXCUI). RxNorm (RxNorm hyperlink) is a normalized drug naming system that is produced by The National Library of Medicine (NLM). RXCUIs serve as a unique identifier which can represent multiple National Drug Codes (NDCs) for similar drug products with the same brand name, active ingredient, strength and dose form (e.g., multiple package sizes and/or manufacturers can be represented by a single RXCUI).

Q3. How often is the Excluded Drug Reference File updated?

A3. CMS updates this file annually prior to the bid deadline. Generally, changes are not made to the final version of the Excluded Drug Reference File for a plan year once it is posted.

Q4. Where is the Excluded Drug Reference File located?

A4. Participating Part D plan sponsors can access the Excluded Drug Reference File that is posted in the Health Plan Management System (HPMS). Beginning in 2020, the Excluded Drug Reference File will also be posted on the CMS.gov website (RxContracting Formulary Guidance hyperlink).

Q5. What is the Excluded Drug Reference File format and what do the fields represent?

A5. The Excluded Drug Reference File is comprised of the following fields:

- **RXCUI** – The RXCUI on the Excluded Drug Reference File represents a unique proxy identifier for each drug record on the file. Only RXCUIs contained on the Excluded Drug Reference File will be valid codes for formulary submissions. For the purposes of the file, each RXCUI represents a unique branded name product (where applicable), clinical name, strength, and dose form of a drug product.
- **Term Type (TTY)** – This field contains the TTY for the RXCUI. The possible values for the Excluded Drug Reference File include SBD (Semantic Branded Drug) and SCD (Semantic Clinical Drug).[1,2]
- **RxNorm Description** – This field provides a description of the drug represented by the SBD or SCD for a given RXCUI which includes the ingredient, strength, dosage form and where applicable the brand drug name.
- **Related Brand Name (BN)** – This field contains the brand name that is related to a given RXCUI. This field will be null for products that do not have a branded name.
- **Related Semantic Clinical Drug Component (SCDC)** – The field contains the active ingredient(s) and strength(s) for each RXCUI.
- **Related Dose Form (DF)** – This field contains the dose form for each RXCUI.

Q6. How do Part D plan sponsors use the Excluded Drug Reference File?

A6. Part D plans offering an enhanced alternative benefit design may choose to offer these "excluded drugs" as part of a supplemental Part D benefit. The Excluded Drug Reference File is used by Part D sponsors to assist in the development of their Excluded Drug supplemental file submission to CMS. The Excluded Drug supplemental file is a plan-specific list of the Excluded Drugs a Part D sponsor intends to offer to their beneficiaries during the contract year. Unlike some of the other formulary supplemental files that can be updated during the contract year, the Excluded Drug supplemental file is not available to be updated following final bid approval, absent extraordinary circumstances.

Q7. How does CMS oversee the use of an Excluded Drug Reference File?

A7. CMS collects and reviews an Excluded Drug supplemental file submitted by Part D sponsors that plan to offer excluded drugs as part of an enhanced prescription drug benefit. The Excluded Drug supplemental file submitted by the Part D sponsor includes a list of the excluded drugs offered by the plan, along with any utilization management criteria (i.e. quantity limits, step therapy or prior authorization) that will be applied at the point of sale. Participating Part D plan sponsors can refer to the

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[1] This represents the ingredient, strength, and dose form, plus brand name.

[2] This represents the ingredient, strength, and dose form.

HPMS Formulary Submission Module and Reports Technical Manual located in HPMS for the Excluded Drug supplemental file layout.

Q8. Can medications on the Excluded Drug Reference File also be included in a plan's formulary?

A8. Yes, but only when the drug also meets the definition of a Part D drug. A drug may appear on both the plan's formulary and the Excluded Drug supplemental file when it has multiple FDA labeled indications, one or more of which are covered under Part D and another that is excluded under section 1860D-2(e)(2)(A). Chapter 6 of the Prescription Drug Benefit Manual, Section 20.1 describes such an example for drugs when used for the treatment of sexual or erectile dysfunction (ED). 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).