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Centers for Medicare & Medicaid Services

Over-the-Counter Drug Reference File Frequently Asked Questions (FAQ)

Q1. Are Over-the-Counter (OTC) drugs coverable under the Medicare Part D program?

A1. OTC drugs are excluded from Medicare Part D coverage per section 1860D-2(e)(2)(A) of the Social Security Act. However, as referenced in Section 10.10 of Chapter 6 and Section 60.2 of Chapter 7 of the Medicare Prescription Drug Benefit Manual, CMS permits Part D sponsors to offer OTC drugs as part of a drug utilization management program. Part D sponsors choosing to do so must account for the OTC costs under their administrative cost structure and provide them at no cost to their beneficiaries. Part D sponsors electing to offer OTCs must do so for the full contract year and cannot limit their use to certain phases of the benefit.

Q2. What is the OTC Drug Reference File and what types of medications are included?

A2. The OTC Reference File is a list of OTC drugs that could reasonably be utilized as an alternative to a more expensive Part D drug, either through a general drug utilization management program or as part of a step therapy protocol for a Part D formulary drug.

Similar to the Formulary Reference File, each row of the OTC 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 (if applicable), active ingredient, strength and dose form (e.g., multiple package sizes and/or manufacturers can be represented by a single RXCUI). Since there may be multiple manufacturers and brand names available for an OTC drug, each drug on the OTC Drug Reference File is listed under a common ingredient, strength and dosage form.

Q3. How often is the OTC 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 OTC Reference File for a plan year once it is posted.

Q4. Where is the OTC Reference File located?

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

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

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

- **RXCUI** – The RXCUI on the OTC Reference File represents a unique proxy identifier for each drug record on the file. Only RXCUIs contained on the OTC Reference File will be valid codes for formulary submissions. For the purposes of the file, each RXCUI represents a 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 OTC Reference File include SCD (Semantic Clinical Drug). [1,2]
- **RxNorm Name** – This field provides a description of the drug represented by the SCD for a given RXCUI which includes the ingredient, strength, and dosage form.
- **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 OTC Drug Reference File?

A6. Part D plans choosing to offer OTCs, either as part of a general drug utilization management program or as part of a step therapy protocol for Part D formulary drugs, can use the OTC Reference File to assist in the development of their OTC supplemental file submission to CMS. The OTC supplemental file is a plan-specific list of the OTC drugs a Part D sponsor submits to CMS as part of its bid if the plan intends to offer OTCs to their beneficiaries during the contract year. Unlike some of the other formulary supplemental files that can be updated during the contract year, the OTC supplemental file is not available to be updated following final bid approval, absent extraordinary circumstances.

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

A7. CMS collects OTC supplemental files from Part D plans that indicate that they offer OTC drugs as part of their drug utilization management strategy. The OTC supplemental file submitted by the Part D sponsor will contain a list of the OTC drugs offered by the plan. Participating Part D plan sponsors can refer to the HPMS Formulary Submission Module and Reports Technical Manual located in HPMS for the OTC supplemental file layout.

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1 Since there may be multiple manufacturers and brand names available for an OTC drug, each drug can be represented by a single RXCUI representing the ingredient, strength, and dose form.

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