DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: April 14, 2022

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

FROM: Amy Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: CY 2023 Part D Formulary Submission Information

This memorandum provides information to assist Part D sponsors with the submission of Contract Year (CY) 2023 formularies.

Formulary Instructions

The CY 2023 Health Plan Management System (HPMS) Formulary Submission and Reports Technical Manual was released on April 4, 2022 in the memos section of HPMS. The Formulary Outlier Justification Submission Module User Manual will be available with the Formulary Submission Module on May 16, 2022.

Formulary Reference File

The initial CY 2023 Formulary Reference File (FRF) has been posted in the CY 2022 HPMS Formulary Submission Module. An updated CY 2023 FRF will be posted in the CY 2023 Formulary Submission Module in mid-to-late May.

Annual Formulary and Benefits Submission Window Dates

Important dates regarding the CY 2023 formulary submission are listed below. We encourage Part D sponsors to submit formulary files in advance of the deadline in order to provide time to address any technical issues with their submissions that may arise. Please note that an initial formulary must be submitted and successfully validated prior to the formulary submission deadline. The initial formulary and transition policy submissions may be revised and updated until the June 6, 2022 submission deadline.

Important dates related to the CY 2023 Formulary Submission:

- May 16, 2022 – CY 2023 HPMS Formulary Submission Module released

- June 6, 2022 at 11:59 p.m. PDT – Deadline for the following submissions:
    - Initial formulary submission
    - Transition attestation and policy submission
    - Formulary attestations (Pharmacy and Therapeutics Committee and Prior Authorization/Step Therapy)
    - Formulary crosswalk
- On or about June 8, 2022 – Supplemental formulary and Additional Demonstration Drug (ADD) file submission window opens
- June 10, 2022 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 13, 2022 – Stage 1 review concerns communicated
- On or about July 1, 2022 – Stage 2 review concerns communicated
- On or about July 20, 2022 – Stage 3 review concerns communicated
- Early August 2022 – Summer limited formulary update window
- Late September 2022 – Formulary update window for limited enhancements and generic substitutions only

Two Drug Review Report

We encourage organizations to utilize the HPMS Two Drug Review Report. This report will list categories and classes within your formulary submission that appear to have less than two Part D drugs. CMS provides access to this report in an effort to assist you in the correction of inadvertent submission errors.

Part B Before Part D Step Therapy

When a formulary is associated to a Medicare Advantage Prescription Drug (MA-PD) plan, and there is a step therapy requirement to utilize a Part B drug before a Part D drug, the submission must ensure that these requirements are clearly outlined in the Part D prior authorization (PA) criteria for the affected Part D drugs.

The PA file layout for CY 2023 has been updated to include an optional field called "Part B Prerequisite." This field applies when an MA-PD requires a Part B drug before a Part D drug as outlined above. When the formulary ID is associated to only an MA-PD, or both MA-PD and stand-alone Prescription Drug Plans (PDP), a "1" should be selected, and the Part B prerequisite would only apply to the MA-PD plans. Plans will no longer be required to add the statement "Part B before Part D step therapy" in the "Other Criteria" field.

Formulary Outlier Justification Submission

The Formulary Outlier Justification Submission (OJS) process has been updated for CY 2023 to improve the efficiency by which plan sponsors can submit justifications. The system update enables sponsors to upload justifications for multiple formulary IDs using a mass update file that is submitted from the OJS Outlier Justification Upload page. The OJS Upload File has 3 required fields named the following: "Outlier ID", "Resubmission? (Y/N)", and "Resubmission Comment/Justification". A justification may be submitted for an outlier ID, provided that the

user has access to the corresponding formulary in HPMS, and the justification gate is open. Please refer to the CY 2023 Formulary Outlier Justification Submission Module User Manual for additional information.

Expedited Generic Substitution

Part D sponsors that plan to implement immediate brand-generic substitutions in CY 2023 must answer "Yes" to the question "Will this formulary be subject to expedited generic substitution, as outlined in 42 C.F.R. § 423.120(b)(5)(iv)" with the initial HPMS formulary submission.

Part D Supplemental Files

When creating unique HPMS formulary submission IDs for the CY 2023 plan year, Part D sponsors should be mindful that supplemental Part D formulary files are submitted at the formulary ID level with a few exceptions noted below. All plans associated with a formulary ID must use the same versions of the various supplemental file types, if applicable to their benefit design. Please note that this one-to-one relationship does NOT mean that all plans tied to a single formulary ID are required to utilize supplemental files at all, nor are they required to utilize the same number or type of supplemental files. Sponsors should plan accordingly when determining the number of formularies to submit to ensure that they can accommodate the one-to-one relationship of supplemental files to formulary IDs.

The HPMS Formulary Submission Module & Reports Technical Manual Section XXI provides additional details and examples of the specific scenarios that would result in a plan being unable to share an HPMS formulary ID. As a reminder, all supplemental files that are submitted and accepted as part of the bid must contain at least one drug throughout the contract year. Additionally, files that are tier specific, such as the partial gap supplemental file, must contain at least one drug on each tier indicated in the PBP. Therefore, if you submit a file with only one drug, you will be unable to remove that drug from the file or possibly be unable to move it to another tier, unless you add another drug in its place. HPMS will not allow an empty file or a tier without a supplemental file drug once a plan is approved with those conditions in place.

Exceptions:
1. Value-Based Insurance Design (VBID) file: this file is unique in that it includes a field for contract and plan ID. Plans that share a formulary ID can have a VBID supplemental file with content that varies by plan, due to this unique file layout.
2. Part D Senior Savings (PDSS) Model files: this file is submitted at the contract and plan ID level. Plans that offer identical plan-selected Model drug coverage (RxCUIs and Cohorts) may use the same PDSS supplemental file. In addition, the PDSS Model supplemental file must contain at least one RxCUI in each cohort based on the cohort number established in the PBP. Once submitted and approved as part of the bid, cohorts may not be changed, and are required to contain at least one drug throughout the contract year.

New Bid Outlier Justification Module

New for CY 2023, plans sponsors will have access to a Bid Outlier Justification module to view and respond to potential CMS Part D benefits review concerns. CMS is piloting this process with two sub-reviews: crosscheck and PDP meaningful difference. Other review concerns will continue to be addressed via email as in years past. CMS intends to release a training video that will walk plan sponsors through the new process. Additional details regarding the training video will be forthcoming.

If you have questions regarding the CY 2023 formulary submission process, please email PartDFormularies@cms.hhs.gov. If you have questions regarding the CY 2023 supplemental files or Bid Outlier Justification module, please email PartDBenefits@cms.hhs.gov.