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

CENTER FOR MEDICARE

DATE: April 14, 2023

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 2024 Part D Formulary Submission Information

This memorandum provides information to assist Part D sponsors with the submission of Contract Year (CY) 2024 formularies.

Formulary Instructions

The CY 2024 Health Plan Management System (HPMS) Formulary Submission and Reports Technical Manual was released on March 28, 2023 in the memos section of HPMS. The Formulary Outlier Justification Submission Module User Manual will be available with the Formulary Submission Module on May 15, 2023.

Formulary Reference File

The initial CY 2024 Formulary Reference File (FRF) has been posted in the CY 2023 HPMS Formulary Submission Module. An updated CY 2024 FRF will be posted in the CY 2024 Formulary Submission Module in mid-to-late May.

Annual Formulary and Benefits Submission Window Dates

Important dates regarding the CY 2024 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 5, 2023 submission deadline.

Important dates related to the CY 2024 Formulary Submission:

- May 15, 2023 – CY 2024 HPMS Formulary Submission Module released

- June 5, 2023 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 7, 2023 – Supplemental formulary and Additional Demonstration Drug (ADD) file submission window opens
- June 9, 2023 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 12, 2023 – Stage 1 review concerns communicated
- On or about June 30, 2023 – Stage 2 review concerns communicated
- On or about July 19, 2023 – Stage 3 review concerns communicated
- Early August 2023 – Summer limited formulary update window
- Late September 2023 – Formulary update window for limited enhancements and generic substitutions only

Quantity Limits

As outlined in the Paperwork Reduction Act package, CMS-R-262 (OMB control number: 0938-0763), CMS will no longer require the Quantity Limit Type on the formulary submission file. The formulary submission file layout has been updated to reflect a Quantity Limit Yes/No field. This field is used to indicate if the RxCUI will have a quantity limit restriction. A "0" entered into this field means that a quantity limit does not apply. A "1" entered in this field means that a quantity limit applies.

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 fewer than two Part D drugs. CMS provides access to this report in an effort to assist you in the correction of inadvertent submission errors.

Prior Authorization (PA) and Step Therapy (ST) Submission

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 ST requirement to utilize a Part B drug before a Part D drug, the requirements must be clearly outlined in the Part D PA criteria for the affected Part D drugs. The PA file layout for CY 2024 includes an optional field called "Part B Prerequisite." This field applies when an MA-PD plan requires a Part B drug before a Part D drug as outlined above. When the formulary ID is associated to only an MA-PD plan, or both MA-PD plans and stand-alone Prescription Drug Plans (PDP), a "1" should be selected, indicating that the Part B prerequisite would only apply to the MA-PD plans. Plans are no longer required to add the statement "Part B before Part D step therapy" in the "Other Criteria" field. If a formulary ID will be associated to stand-alone PDPs only, a "0" should be submitted for the "Part B Prerequisite" field.

Step Therapy Submission Reminders:

- In order to improve efficiency of the reviews and decrease administrative burden, we remind sponsors to conduct a quality assurance check to ensure that the drugs listed in their ST criteria match the drugs that are submitted with ST on the formulary file for that specific ST group. CMS has seen multiple instances where the drugs listed on the ST criteria and the drugs flagged on the formulary file for that group description do not align.
- If the ST criteria cover both the brand and generic drug, please either list out both brand and generic drugs or refer to it as the generic name for the drug in the ST criteria.

Prior Authorization Submission Reminders:

- When including an off-label indication in PA criteria, please ensure that the off-label indication is supported by one or more citations included in Part D recognized compendia.
- If the PA Indication Indicator field contains "All FDA approved indications," sponsors do not need to list out the diagnosis in the PA criteria for each FDA approved indication unless there are corresponding criteria for the specific diagnosis.
- Please ensure that the coverage duration is addressed in the PA criteria for all drugs and indications associated with the PA group.

Expedited Generic Substitution

Part D sponsors that plan to implement immediate brand-generic substitutions in CY 2024 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.

Bid Outlier Justification Module

The Bid Outlier Justification module was introduced in CY 2023. CMS has continued to improve and expand the module for CY 2024. Improvements include expanding the view of the Plan Comments field on the submission page and adding a Bid Outlier Justification History report. We have also added an additional sub-review to the module to address review concerns with notes entries in the Plan Benefit Package.

Other review concerns will continue to be addressed via email as in years past. Plans will continue to have access to the training video from last year, however this will not reflect the updates described above. The Bid Outlier Justification Training can be found at the following path in HPMS: HPMS Home Page > Plan Bids > Bid Outlier Justification > CY 2024 > Documentation > Bid Outlier Justification Submission Training.

If you have questions regarding the CY 2024 formulary submission process, please email PartDFormularies@cms.hhs.gov. If you have questions regarding the CY 2024 supplemental files or Bid Outlier Justification module, please email PartDBenefits@cms.hhs.gov.