DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: April 16, 2024

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

FROM: Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: CY 2025 Part D Formulary Submission Information

This memorandum provides information to assist Part D sponsors with the submission of Contract Year (CY) 2025 formularies.

Formulary Instructions

The CY 2025 Health Plan Management System (HPMS) Formulary Submission and Reports Technical Manual was released on March 20, 2024 in the memos section of HPMS. The Formulary Outlier Justification Submission Module User Manual will be available with the Formulary Submission Module on May 13, 2024.

Formulary Reference File

The initial CY 2025 Formulary Reference File (FRF) is posted in the CY 2024 HPMS Formulary Submission Module. An updated CY 2025 FRF will be posted in the CY 2025 Formulary Submission Module in mid-to-late May.

Annual Formulary and Benefits Submission Window Dates

Important dates regarding the CY 2025 formulary submission are listed below. We encourage Part D sponsors to submit formulary files in advance of the deadline 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 3, 2024 submission deadline.

Important dates related to the CY 2025 formulary submission:

- May 13, 2024 – CY 2025 HPMS Formulary Submission Module released

- June 3, 2024 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 5, 2024 – Supplemental formulary and Additional Demonstration Drug (ADD) file submission window opens
- June 7, 2024 at 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 10, 2024 – Stage 1 Review concerns are communicated
- On or about June 28, 2024 – Stage 2 Review concerns are communicated
- On or about July 19, 2024 – Stage 3 Review concerns are communicated
- Early August 2024 – Summer limited formulary update window
- Late September 2024 – Formulary update window for limited enhancements and immediate substitution-type changes only

Formulary File Submission Reminders

If you intend for an FRF RxCUI to be considered a formulary drug, that RxCUI must be included in the HPMS Submission. Submissions should include each formulation, strength and dosage form that will be a covered formulary drug. Further, generic and brand products of the same drug have separate RxCUIs and should be included on the formulary submission to accurately reflect coverage.

Two Drug Review Report

We encourage organizations to utilize the HPMS Two Drug Review Report under the HPMS Formulary Reports module to identify potential Two Drug Review Concerns. 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 to assist in the correction of inadvertent submission errors. As a reminder, this report is available to plan sponsors during the initial formulary submission period and after the initial submission window closes. While this report may not always reflect what CMS has approved via the Two Drug Review, it can serve as a reference for sponsors.

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

Part B before Part D Step Therapy: When a formulary is associated with 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 2025 continues to include an optional field called "Part B Prerequisite" that must be utilized for this purpose. Only formularies that are associated to an MA-PD, or both an MA-PD and stand-alone Prescription Drug Plans (PDP), must include a "1" in this field, indicating that the Part B prerequisite would only apply to the MA-PD plans. If a

formulary ID is associated with PDPs only, a "0" should be submitted for the "Part B Prerequisite" field.

Step Therapy Submission Reminders:

- To improve the efficiency of reviews and decrease administrative burden, we remind sponsors to conduct a quality assurance check to ensure that drugs listed in the 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 the drug as the generic name in the ST criteria to reduce review concerns.
- When submitting ST criteria for CY 2025, please review current FDA-approved labeling for recent updates such as new or expanded indications.

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 the 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 a specific diagnosis.
- Please ensure that the coverage duration is addressed in the PA criteria for all drugs and indications associated with the PA group.
- When submitting PA criteria for CY 2025, please review current FDA-approved labeling for recent updates such as new or expanded indications.

Prior Authorization Prerequisite Therapy Criteria: To ensure timely access to treatment and improve clarity for patients and providers, when requiring prerequisite therapy as part of PA criteria, please list the requirements in the "Required Medical Information" or "Other Criteria" fields. This includes instances where the FDA label includes prerequisite therapy as part of the indication. The specific prerequisite requirements for each indication of the drug should be clearly described. Vague statements without additional context that specifies what is necessary for approval will require modification and delay the review process.

Immediate Substitutions

Part D sponsors that plan to immediately substitute a generic or authorized generic for a brand name drug; an interchangeable biosimilar for a reference product; or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product for the brand name biological product in CY 2025 must answer "Yes" to the question "Will this formulary be subject to immediate substitutions, as outlined in 423.120(e)(2)(i) and (f)" with the initial HPMS formulary submission.

Supplemental File Submission Changes

With the elimination of the coverage gap phase in 2025, there will no longer be an option to submit a partial gap supplemental file. In addition, there is no longer a coverage gap field in the excluded drug supplemental file. If your organization is preparing an excluded drug supplemental file using your prior year file, please ensure you remove the coverage gap field before uploading to avoid a validation error.

Bid Outlier Justification Module

Bid review concerns will continue to be addressed via the Bid Outlier Justification Module and email as in previous years. Plans will continue to have access to the training video from CY 2023. The Bid Outlier Justification Training can be found at the following path in HPMS: HPMS Home Page > Plan Bids > Bid Outlier Justification > CY 2025 > Documentation > Bid Outlier Justification Submission Training.

If you have questions regarding the CY 2025 formulary submission process, please email PartDFormularies@cms.hhs.gov. If you have questions regarding the CY 2025 supplemental files or Bid Outlier Justification module, please email PartDBenefits@cms.hhs.gov.