



CENTER FOR MEDICARE

DATE: July 22, 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: Summer Update Window for CY 2025 Formularies

CMS is currently in the process of granting conditional approvals for CY 2025 formularies and contacting those organizations that still have outstanding formulary issues. We remind Part D sponsors of the importance of resolving any outstanding formulary concerns promptly.

Formularies that are in an approved status in the Health Plan Management System (HPMS) will be eligible to be updated during the summer update window. Part D sponsors will have the opportunity to make limited updates, as outlined below, to their conditionally approved CY 2025 formulary submissions from **12:00 a.m. EDT on August 5, 2024, through 5:00 p.m. EDT on August 7, 2024**. A revised CY 2025 Formulary Reference File (FRF) and accompanying change report are available in the CY 2025 HPMS Formulary Submission Module.

During the summer update window, Part D sponsors can make the following changes to previously approved CY 2025 formularies:

1. Addition of drugs new to the updated CY 2025 FRF;¹
2. Negative changes to an existing formulary drug, if an equivalent generic, biosimilar, or other therapeutically similar drug is available on the FRF and the sponsor has submitted the alternative drug on the corresponding formulary file update within the same category and class, at the same or lower cost share tier, and with no more restrictive utilization management (UM) than what the sponsor applied to the existing formulary drug; and
3. Other limited formulary enhancements (e.g., formulary additions, reduction in cost share tier, removal of UM edits).

¹ Sponsors must add new protected class drugs on the FRF during this submission window.

We do not expect sponsors to make significant formulary enhancements or significant negative changes during this window, as the sponsor developed the Part D bid using the formulary that they initially submitted to CMS for review.

Revisions to existing UM criteria should be limited to Step Therapy (ST) criteria changes that are necessary due to allowable formulary changes described in this memo. Sponsors may only update ST criteria when the addition of new drug(s) to an existing ST group description necessitates wording changes within the ST Criteria field. In this case, sponsors should submit a PA/ST Criteria Change Request File via HPMS between 12:00 a.m. EDT on July 31, 2024, and 5:00 p.m. EDT on August 2, 2024. Please refer to the HPMS Formulary Submission Module & Reports Technical Manual for detailed submission instructions:

HPMS Homepage > Plan Formularies > Formulary Submission Module > CY 2025 > Documentation > Formulary Instructions

Following the update window, Part D sponsors should check the status of formulary approvals in HPMS. CMS will enter approval of formulary updates into HPMS by August 27, 2024. If you have any questions regarding this summer update window, please email PartDFormularies@cms.hhs.gov.