



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: July 28, 2021

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: Summer Update Window for CY 2022 Formularies

CMS is currently granting conditional approvals for CY 2022 formularies and is in the process of contacting those organizations that still have outstanding formulary issues. CMS reminds all Part D sponsors of the importance of resolving any outstanding formulary concerns in an expeditious manner.

Formularies that are in an approved status within the Health Plan Management System (HPMS) will be eligible for updating during the summer update window. Part D sponsors will have the opportunity to make limited updates, as outlined below, to their conditionally approved CY 2022 formulary submissions from **12:00 a.m. EDT August 5, 2021 through 5:00 p.m. EDT August 9, 2021**. A revised CY 2022 Formulary Reference File (FRF) and accompanying change report are available within the CY 2022 HPMS Formulary Submission Module.

During the summer update window, Part D sponsors will be permitted to make the following changes to previously approved CY 2022 formularies:

1. Adding drugs added to the updated CY 2022 FRF.¹
2. Negative changes to an existing formulary drug, if an equivalent generic or therapeutically similar drug is available on the FRF and is submitted 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 was applied to the existing formulary drug.
3. Other limited formulary enhancements (e.g., formulary additions, reduction in cost share tier, removal of utilization management edits).

¹ New FRF protected class drugs must be added during this submission window.

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

Revisions to existing utilization management criteria should be limited to Step Therapy (ST) criteria changes that are necessary as a result of allowable formulary changes described in this memo. ST criteria may only be updated when the addition of a new drug(s) to an existing step therapy 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 August 2, 2021 and 5:00 p.m. EDT on August 4, 2021. Please refer to the HPMS Formulary Submission Module & Reports Technical Manual for detailed submission instructions:

HPMS Homepage > Plan Formularies > Formulary Submission Module > CY 2022 > Documentation > Formulary Instructions

Following the update window, Part D sponsors should check the status of formulary approvals in HPMS. Approval of formulary updates will be entered into HPMS by August 24, 2021. If you have any questions regarding this summer update window, please email PartDFormularies@cms.hhs.gov.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.