



CENTER FOR MEDICARE

DATE: July 29, 2020

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 2021 Formularies

CY 2021 Formulary Timelines and Processes

CMS is currently granting conditional approvals for CY 2021 formularies and is in the process of contacting those organizations that still have outstanding formulary issues. CMS reminds all plans of the importance of resolving any outstanding formulary concerns in an expeditious manner.

Summer Update Window for CY 2021 Formulary Submissions

Only formularies that are in an approved status within the Health Plan Management System (HPMS) are 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 2021 formulary submissions from **12:00 a.m. EDT August 6, 2020 through 5:00 p.m. EDT August 10, 2020**. A CY 2021 Formulary Reference File (FRF) change report is attached for your reference. The new FRF will be available within the CY 2021 HPMS Formulary Submission Module on or about July 31, 2020.

During the summer update window, Part D sponsors will be able to add new FRF drugs to their approved formularies. Part D sponsors may also submit negative changes to existing formulary drugs, if an equivalent generic or therapeutically similar drug is available on the FRF and is submitted on the corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management (UM) than what was applied to the existing formulary drug. We do not expect sponsors to make significant enhancements or significant negative changes to existing formulary drugs during this window, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. Plan sponsors will also be able to update step therapy (ST) criteria files if other formulary updates necessitate a change (e.g., adding a new generic to an existing ST group). Plan sponsors are reminded to evaluate the CY 2021 FRF update for the

addition of drugs within the protected classes prior to the submission of their formulary update.

Step Therapy (ST) File Updates

If there are existing ST group descriptions that need to be revised, sponsors should submit the request through HPMS. The following fields are required in the PA/ST criteria change request file:

- a) Formulary ID
- b) Reason for UM change
- c) Current UM Type. This will be ST as only step therapy criteria may be updated during this summer window.
- d) Current ST group description

ST criteria change requests may be submitted by plans from August 3, 2020 through 5:00 p.m. on August 5, 2020. During the summer update window, you should submit a partial ST file containing an “UPD” record for revising existing ST group description(s). Any PA and ST group descriptions that are being added to the partial PA or ST file need to contain an “ADD” record for new UM group description(s). PA and ST group descriptions that are being deleted based on your formulary file submission will automatically be deleted from the PA/ST files if they are deleted from the formulary (i.e., a deletion record, “DEL”, should not be uploaded on the partial PA or ST files). You will receive a confirmation of these deletions in the “Formulary Processing Results” email.

During the update window, Part D sponsors will select the “Revise Formulary” option in HPMS to submit their partial formulary files. Following the update window, Part D sponsors should check the status of formulary approvals in HPMS. Formulary approvals will be entered into HPMS by August 25, 2020.

If you have any questions regarding this summer update window, please email PartDFormularies@cms.hhs.gov.