

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director  
Medicare Drug Benefit and C & D Data Group

SUBJECT: Summer Update Window for CY 2019 Formulary Submissions

DATE: July 26, 2018

### **CY 2019 Formulary Timelines and Processes**

CMS is currently granting conditional approvals for CY 2019 formularies and is in the process of contacting those organizations that still have outstanding formulary issues to schedule a negotiation call. CMS will make every effort to accommodate all negotiation requests within the existing time and resource constraints at this stage of the 2019 formulary review process. Given these constraints, organizations with a smaller number of formulary issues will receive the first negotiation calls and as a result are more likely to be eligible for the summer update window. CMS reminds all plans of the importance of resolving any outstanding formulary concerns in an expeditious manner. Plan sponsors that do not receive conditional approval prior to the summer update window will not be eligible to take advantage of this update opportunity. No exceptions will be granted.

Part D sponsors must have a conditionally approved formulary to be eligible for a CY 2019 Part D contract. Organizations that failed to meet CY 2019 Stage 1, 2, or 3 formulary review resubmission deadlines, as well as those organizations whose formulary resubmissions contained unauthorized negative changes during the staged reviews, will be reviewed after CMS completes its review of all other timely formulary submissions. Any Part D sponsor that has not received conditional approval of its CY 2019 Part D formulary by August 17, 2018 will not have its plan included in the Medicare & You Handbook. Part D sponsors must resolve all outstanding issues and receive conditional approval for their CY 2019 formulary no later than 5:00 p.m. EDT on August 31, 2018. Failure to attain conditional approval by this deadline may result in the Part D sponsor not receiving a Part D contract, making it ineligible to offer Part D benefits during CY 2019.

## Summer Update Window for CY 2019 Formulary Submissions

Only sponsors that have received prior CMS conditional formulary approval will be permitted to submit an update during the summer update window. Part D sponsors will have the opportunity to make limited updates, as outlined below, to their conditionally approved CY 2019 formulary submissions from **12:00 a.m. EDT August 6, 2018 through 5:00 p.m. EDT August 8, 2018**. An updated CY 2019 Formulary Reference File (FRF) will be available within the CY 2019 HPMS Formulary Submission Module on or around July 30, 2018.

The CY 2019 summer update window cannot be used for making significant changes to conditionally approved formulary submissions. The summer update window will allow for the following types of formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, 2) the submission of 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, 3) enhancements to existing formulary drugs including changes to a lower cost-sharing tier or removal of UM, and 4) prior authorization (PA) edit and criteria changes to incorporate indication-based UM strategies addressed in the July 25, 2018 HPMS memorandum. Plan sponsors will also be able to update PA and step therapy (ST) criteria files if other formulary updates necessitate a change (e.g., adding a new generic to an existing ST group).

### Prior Authorization (PA) and Step Therapy (ST) File Updates

If there are existing PA or ST group descriptions that need to be revised, sponsors should submit the UM Criteria Change Request template (attached) prior to the summer update window. The group descriptions included on the template **must exactly match** the group descriptions from the formulary file, including spacing, commas, hyphen, and other characters. If the group description does not exactly match, the HPMS PA and/or ST gates will not open.

The template must be completed as follows:

- a) **FID:** enter only one valid 5-digit CY 2019 formulary ID per line item. However, you may enter more than one FID per template.
- b) **UM Type (PA/ST):** from a drop-down menu, select either PA or ST type.
- c) **UM Group Description:** enter the Group Description that was submitted with the formulary submission for CY 2019.

Submit the completed template to the CMS UM Criteria Requests mailbox:

[umcriteriarequests@cms.hhs.gov](mailto:umcriteriarequests@cms.hhs.gov) by 5:00 p.m. EDT on August 1, 2018. During the summer update window you should submit a partial PA and/or ST file containing an “UPD” record for revising existing UM 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 must check the status of formulary approvals in HPMS. Only approved formularies can be included in your communication materials for contract year 2019. Original or updated formulary submissions that have not yet been approved will be suppressed in Medicare Plan Finder. For these reasons, CMS emphasizes that Part D sponsors should not attempt to make a significant number of changes because it could delay approval of their formulary updates.

If you have any questions regarding this summer update window, please email [PartDFormularies@cms.hhs.gov](mailto:PartDFormularies@cms.hhs.gov).