DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

Date: April 26, 2019

To: All Part D Sponsors

From: Amy Larrick Chavez-Valdez
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Subject: CY 2020 Part D Formulary Submission Information

The initial Contract Year (CY) 2020 Formulary Reference File (FRF) has been posted in the CY 2019 HPMS Formulary Submission Module and will be posted in the CY 2020 Formulary Submission Module upon the module's release. An updated FRF will be posted in the CY 2020 Formulary Submission Module in mid- to late-May. The following information is provided to assist Part D sponsors with the submission of CY 2020 formularies. In lieu of a Formulary Submission Part C & D User Call, this memorandum highlights the updates to the formulary submission process for CY 2020. For additional information about 2020 formulary requirements, please see the CY 2020 Final Call Letter released on April 1, 2019.

Annual Formulary Submission Updates

Formulary Submission Window Dates

Important dates regarding the CY 2020 formulary submission are listed below. Sponsors are encouraged to submit formulary files in advance of the deadline, in order 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 deadline.

Important dates related to the CY 2020 Formulary Submission:

- May 13, 2019 – CY 2020 HPMS Formulary Submission Module released
- June 3, 2019 at 11:59 p.m. PDT – Deadline for the following submissions:
    - Initial formulary submission
    - Transition attestation and policy submission
    - Formulary attestations (Pharmacy and Therapeutic Committee and Prior Authorization/Step Therapy)
    - Formulary crosswalk

- On or about June 5, 2019 – Supplemental formulary and Additional Demonstration Drug (ADD) file submission window opens
- June 7, 2019 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 10, 2019 – Stage 1 review concerns communicated
- On or about June 21, 2019 – Stage 2 review concerns communicated
- On or about July 12, 2019 – Stage 3 review concerns communicated
- Late July – Early August 2019 – Summer limited update window
- September 2019 – Formulary update window for limited enhancements and generic substitutions only

Indication-Based Formulary Design

As announced in the HPMS memo "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020" released on August 29, 2018, beginning in 2020, the Centers for Medicare & Medicaid Services (CMS) is providing Part D sponsors with the flexibility to utilize indication-based formulary design (IBFD). This will enable them to better negotiate for prescription drugs, especially high-cost drugs, while providing Part D beneficiaries access to the drugs they need to treat their disease states. Consequently, there are changes to the formulary submission process to accommodate this type of formulary design.

When submitting a new formulary, a new question will be added to the Formulary Information page asking if any drugs on your formulary submission are limited to certain indications. "Yes" should be selected for this question if you are implementing an indication-based formulary design for CY 2020. There will be a corresponding question in the Plan Benefit Package (PBP), and the answer must match the answer in the Formulary Submission Module.

CMS will publish an Indication Reference File (IRF) to enable Part D sponsors to submit IBFD information for review. This file will contain condition indication codes and a description for each code. Only condition indication codes that are listed on the IRF will be permitted. The initial IRF will be shared with HPMS-identified primary and secondary formulary contacts via email. It will also be posted in the CY 2020 Formulary Submission Module upon the module's release. An updated IRF will be posted in the CY 2020 Formulary Submission Module if necessary.

Part D sponsors adopting IBFD must submit an Indication-Based Coverage (IBC) file to CMS. This file must be in a tab-delimited text (.txt) format and must not contain a header record. The file will consist of two columns: RxCUI and Condition Indication Code (from the IRF). The file should contain the RxCUIs and the condition indication codes for the FDA-approved indications for which each RxCUI is considered on-formulary. For example, if an RxCUI will be considered on-formulary for five separate indications, the unique RxCUI-condition indication code combination should be submitted on five separate lines for each covered indication, excluding any indications you do not intend to cover. Note that the IBC files cannot be loaded until the organization has successfully submitted its related bids and the bid has migrated to "desk

review" in the HPMS system on or about June 5th. Only one IBC file may be submitted for each formulary. Please note that IBC submissions apply only to FDA-approved indications. The files should not contain off-label uses for formulary RxCUIs.

Only allowable changes can be made to the IBC files during the monthly formulary update windows. These changes include: the addition of an RxCUI(s) new to the FRF, the complete removal of an RxCUI(s) from the IBC file (i.e., you must remove all the lines associated with this RxCUI from the file), and the addition of a condition indication code to an RxCUI(s) pre-existing on the IBC file. The removal of an indication from the formulary will not be permitted during the plan year.

We would like to remind sponsors that all current formulary requirements as outlined in 42 CFR §423.120(b)(2) and detailed in Chapter 6 of the Medicare Prescription Drug Benefit Manual will still apply.

Detailed IBC file submission processes are outlined in the CY 2020 HPMS Formulary Submission Module & Reports Technical Manual.

Prior Authorization (PA) File Update

In order to accommodate IBFD as part of the PA process, there will be changes to the PA file layout. Please note the change in the PA file applies to all submissions, regardless of whether a sponsor intends to implement IBFD. The two newly-added fields, "PA_Indication_Indicator" and "Off-Label_Uses" replace the previous "Covered Uses" field on the PA file.

The "PA_Indication_Indicator" field is used to describe the indications for which the PA will be approved. A value of 1, 2, 3, or 4 is required in this field.

- 1 = All FDA-Approved Indications. This value cannot be used if the drug that requires PA is subject to Indication-Based Coverage (IBC).
- 2 = Some FDA-Approved Indications Only. This value is to be submitted for drugs that are subject to IBC.
- 3 = All Medically-Accepted Indications. This value identifies drugs for which the PA will be approved for all Part D medically-accepted indications (FDA-approved and compendia-supported).
- 4 = All FDA-Approved Indications, Some Medically-Accepted Indications. If the PA will only be approved for specific off-label uses in addition to FDA-approved uses, a 4 should be submitted. The additional off-label uses should be submitted in the subsequent "Off-Label Uses" field. This is a free text field that is only required if the "PA_Indication_Indicator" field contains a 4.

For the full file format, please see the CY 2020 HPMS Formulary Submission Module & Reports Technical Manual, Table 12: Prior Authorization File Instructions.

Excluded Drug Reference File

The initial CY 2020 Excluded Drug Reference File (ERF) has been posted in the CY 2019 HPMS Formulary Submission Module, and will be posted in the CY 2020 Formulary Submission Module upon the module's release. An updated ERF, if applicable, will be posted in the CY 2020 Formulary Submission Module in mid- to late-May. As set forth in the CY 2020 Call Letter, Excluded Drug File submission will be RxCUI-based for CY 2020 and only RxCUIs that are listed on the ERF will be successfully validated. Please refer to the ERF posted in the CY 2020 Formulary Submission for Excluded Drug RxCUIs. Submissions based on NDC will no longer be accepted.

Prior Authorization/Step Therapy (PA/ST) Criteria Change Request Update

Starting in CY 2020, sponsors can request to change PA/ST criteria in HPMS in lieu of submitting change request templates to umcriteriarequests@cms.hhs.gov for the monthly utilization management (UM) criteria updates. This process will only be used for the monthly updates and does not apply to the annual UM criteria review. Additional information regarding this change will be forthcoming in the CY 2020 formulary information memo (anticipated issuance December 2019); however, sponsors are encouraged to review the CY 2020 HPMS Formulary Submission Module & Reports Technical User Manual for instructions on submission of PA/ST criteria change requests.

Additional Information

Formulary Training Video

CMS created a training video for plan users that provides a high-level overview of the Health Plan Management System (HPMS) formulary submission process for the current plan year (CY 2019). The Formulary Training Video is available on the CMS YouTube channel (CMSHHSgov). While the information in this video is from CY 2019 and does not include the key updates for CY 2020, it may still be a useful resource, especially for new users.

Technical Manual

The CY 2020 HPMS Formulary Submission Module & Reports Technical User Manual was posted within the "HPMS News and Announcements" section of the HPMS homepage on April 11, 2019, and provides additional detail regarding formulary submission and the updates contained in this memo.

If you have questions regarding the CY 2020 formulary submission process, please email PartDFormularies@cms.hhs.gov.