DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: April 13, 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: CY 2022 Part D Formulary Submission Information

This memorandum provides information to assist Part D sponsors with the submission of Contract Year (CY) 2022 formularies.

Formulary Reference File

The initial CY 2022 Formulary Reference File (FRF) has been posted in the CY 2021 Health Plan Management System (HPMS) Formulary Submission Module. An updated CY 2022 FRF will be posted in the CY 2022 Formulary Submission Module in mid- to late May.

Annual Formulary and Benefits Submission Window Dates

Important dates regarding the CY 2022 formulary submission are listed below. We encourage sponsors 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 7, 2021 submission deadline. Prior to this deadline, we encourage organizations to utilize the HPMS Two Drug Review Report. This report will list categories and classes within your formulary submission that appear to have less than two Part D drugs. CMS provides access to this report in an effort to assist you in the correction of inadvertent submission errors.

Important dates related to the CY 2022 Formulary Submission:

- May 17, 2021 – CY 2022 HPMS Formulary Submission Module released
- June 7, 2021 at 11:59 p.m. PDT – Deadline for the following submissions:
    - Initial formulary submission
    - Transition attestation and policy submission
    - Formulary attestations (Pharmacy and Therapeutics Committee and Prior Authorization/Step Therapy)

    - Formulary crosswalk
- On or about June 9, 2021 – Supplemental formulary and Additional Demonstration Drug (ADD) file submission window opens
- June 11, 2021 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 11, 2021 – Stage 1 review concerns communicated
- On or about July 1, 2021 – Stage 2 review concerns communicated
- On or about July 21, 2021 – Stage 3 review concerns communicated
- Early August 2021 – Summer limited formulary update window
- Late September 2021 – Formulary update window for limited enhancements and generic substitutions only

Specialty Tier

Consistent with 42 C.F.R. § 423.104(d)(2)(iv)(D), Part D sponsors have the option of adding a preferred specialty tier for the 2022 plan year. Plan sponsors will see this second specialty tier included in the tier model options. Only drugs that have a 30-day equivalent ingredient cost that exceeds the specialty tier threshold are eligible for placement on either specialty tier. For CY 2022, the specialty tier threshold is $830. For additional information on changes to the methodology and calculation of the specialty-tier cost threshold please refer to 42 C.F.R. § 423.104(d)(2)(iv). We remind Part D sponsors that certain strengths of a drug can qualify for placement on a specialty tier, while other strengths may not, depending on usual dosing regimens.

Indication-Based Coverage File Submission

Part D sponsors that will be implementing Indication-Based Formulary Design (IBFD) for CY 2022 will indicate their intent in the HPMS formulary submission module. Previously, there was a corresponding question in the Plan Benefit Package (PBP) that needed to be answered consistently with the formulary question; however, that question has been removed from the PBP for CY 2022.

The process to submit Indication-Based Coverage (IBC) files for sponsors that choose to apply IBFD to their formulary remains the same as CY 2021. Sponsors do not need to wait until their bid is in "desk review" status to submit the IBC file. When the question about IBFD on the Formulary Information page is answered "Yes," the user will be prompted to submit the IBC file on the formulary submission file upload page in HPMS.

Plans that specify they will be using IBFD will be able to revise their IBC files during formulary revision for each submission window. During formulary revision, you will have the option to upload a new IBC file or use your current one. As a reminder, we generally would expect to see changes to IBC files only when a drug receives a new indication or a newly approved drug is added to the formulary.

Prior Authorization (PA), Step Therapy (ST), and Quantity Limits (QL)

The PA/ST criteria change request file layout will remain the same for CY 2022. The following fields are required in the PA/ST criteria change request file:

- Formulary ID
- Reason for Utilization Management (UM) change. The submitter should continue to submit one of the reason codes provided in the file layout.
- Current UM type. This should be PA or ST.
- Current UM group description.

For CY 2022, the PA/ST criteria review status will continue to be available in HPMS. Part D sponsors should use the Utilization Management Group Description (UMGD) Review Detail Report and the UMGD Status Report to determine the review status of submitted criteria. When each criteria element in a UMGD is in an approved status, the criteria can be posted on plan websites in accordance with posting deadlines. Part D sponsors will not receive an email stating that all UM criteria are approved.

The UMGD criteria response file layout has a new field for formulary gate opening requests. Formulary gate opening requests should only be used during the annual review, since all formulary gates are open during the monthly review. Formulary gate openings should be requested for removal of a UM group description, or to align the formulary file for ST criteria review concerns.

Please also note that the criteria ID displayed on the UMGD Review Detail Report will remain the same across formulary versions throughout the plan year.

With respect to QL submissions, please ensure that you have identified the appropriate QL type for each RXCUI that has a QL restriction on your formulary. Changes in QL types during the staged reviews are considered non-allowable changes.

Part B Before Part D Step Therapy

If a formulary is crosswalked to an MA-PD plan, and there will be a step therapy requirement for the beneficiary to utilize a Part B drug under the plan before a Part D drug, the MA-PD plan must ensure that these requirements are clearly outlined in the Part D PA criteria for the affected Part D drugs. In addition, in the "Other Criteria" field of the PA criteria, please include the statement for the applicable PA Group descriptions "Part B before Part D Step Therapy." Further, if the same formulary ID is crosswalked to both a PDP and MA-PD plan, criteria that are specific to the trial of a Part B drug prior to a Part D drug cannot be applied to PDP enrollees. If this scenario exists, the following statement must also be submitted in the "Other Criteria" field "Applies only to beneficiaries in an MA-PD plan."

Expedited Generic Substitution

Part D sponsors that plan to implement immediate brand-generic substitutions in CY 2022 should answer "Yes" to the question "Will this formulary be subject to expedited generic substitution, as

outlined in 42 C.F.R. § 423.120(b)(5)(iv)?" during initial formulary submission in the HPMS formulary submission module.

Tier Model Changes

All tier model options that include a specialty tier have been maintained, and additional options containing a preferred specialty tier will also be available. As such, some tier options now include a seventh tier.

Part D Supplemental Files

When creating HPMS formulary submissions for the CY 2022 plan year, sponsors should be mindful that supplemental Part D files are submitted at the formulary ID level. This is unchanged and applies to most plans, including Medicare-Medicaid Plans (MMPs).

All plans tied to a formulary ID must use the same versions of the various supplemental file types, if applicable to their benefit design, with the exception of value-based insurance design (VBID) file and Part D Senior Savings (PDSS) Model files. In other words, this means that the content of supplemental files shared by plans with the same formulary ID must be identical. Please note however that this one-to-one relationship does NOT mean that all plans tied to a single formulary ID are required to utilize supplemental files at all, nor are they required to utilize the same number or type of supplemental files. Sponsors should plan accordingly when determining the number of formularies to submit to ensure that they can accommodate the one-to-one relationship of supplemental files to formulary IDs.

The HPMS Formulary Submission Module & Reports Technical Manual Section XXI provides additional details and examples of the specific scenarios that would result in a plan being unable to share a formulary ID. Please note that the VBID supplemental file is unique in that it includes a field for contract and plan ID and, as such, is an exception to the one-to-one ratio system requirement. Plans that share a formulary ID can have a VBID supplemental file with content that varies by plan, due to this unique file layout. The PDSS Model supplemental file is also submitted at a contract and plan ID level. Plans that offer identical plan selected Model drug coverage (RxCUIs and Cohorts) may use the same PDSS supplemental file.

As a reminder, all supplemental files that are submitted and accepted as part of the bid must contain at least one drug throughout the contract year. Additionally, files that are tier specific, such as the partial gap supplemental file, must contain at least one drug on each tier indicated in the PBP. Therefore, if you submit a file with only one drug, you will be unable to remove that drug from the file or possibly be unable to move it to another tier, unless you add another drug in its place. HPMS will not allow an empty file or a tier without a supplemental file drug once a plan is approved with those conditions in place.

If you have questions regarding the CY 2022 formulary submission process, please email PartDFormularies@cms.hhs.gov.