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**DATE:** April 28, 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  
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**SUBJECT:** CY 2021 Part D Formulary Submission Information

The following information is provided to assist Part D sponsors with the submission of Contract Year (CY) 2021 formularies. CMS is issuing this memorandum in lieu of the Formulary Submission Part C & D User Call that was scheduled for April 15, 2020. This memorandum highlights the updates to the formulary submission process for CY 2021 and addresses common issues encountered during the Part D formulary and benefits submission.

### **Formulary Reference File**

The initial CY 2021 Formulary Reference File (FRF) has been posted in the CY 2020 Health Plan Management System (HPMS) Formulary Submission Module. An updated CY 2021 FRF will be posted in the CY 2021 Formulary Submission Module in mid- to late-May.

### **Annual Formulary and Benefits Submission Window Dates**

Important dates regarding the CY 2021 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 1, 2020 submission deadline.

Important dates related to the CY 2021 Formulary Submission:

- May 11, 2020 – CY 2021 HPMS Formulary Submission Module released
- June 1, 2020 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 3, 2020 – Supplemental formulary and Additional Demonstration Drug

- (ADD) file submission window opens
- June 5, 2020 11:59 a.m. EDT – Supplemental formulary and ADD file submission deadline
- On or about June 8, 2020 – Stage 1 review concerns communicated
- On or about June 23, 2020 – Stage 2 review concerns communicated
- On or about July 20, 2020 – Stage 3 review concerns communicated
- Late July – Early August 2020 – Summer limited update window
- September 2020 – Formulary update window for limited enhancements and generic substitutions only

## **Specialty Tier**

Additional information related to the specialty tier is forthcoming.

## **Indication-Based Coverage File Submission**

Sponsors implementing Indication-Based Formulary Design (IBFD) for CY 2021 are reminded to answer “Yes” to the questions in both the HPMS formulary submission module and the PBP submission asking if IBFD is being implemented. Please note, the answers for these questions must be consistent across the two systems.

For CY 2021, the process to submit Indication-Based Coverage (IBC) files for sponsors that choose to apply IBFD to their formulary has been updated. Sponsors will no longer need to wait until their bid is in “desk review” status to submit the IBC file. Now, 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.

Beginning in CY 2021, 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.

## **Indication-Based Formulary Design Best Practices**

Indication-based formulary design was a new option for the CY 2020 plan year. After receiving feedback from sponsors implementing IBFD for CY 2020, we wanted to share best practices for sponsors considering implementing IBFD in CY 2021.

Sponsors that were able to determine diagnoses at point-of-sale, through coordination with dispensing pharmacists, appear to have had the most success in implementing IBFD. In this process, when a pharmacy submits a claim for a drug that is subject to indication-based coverage, the claim rejects with additional messaging to the pharmacist instructing her/him to enter a diagnosis code to confirm that the drug is being used for a formulary indication. This information can then be utilized by the sponsor in reprocessing the claim to determine whether the drug is non-formulary or requires a prior authorization.

## **Line Levels**

A new field has been added to the Plan Line Level Decisions Accept/Reject page in the CY 2021 HPMS module: Comment To Plan. This field may contain a comment from CMS reviewers regarding decisions related to the formulary submission. This will provide sponsors with more detail as to why specific updates to their monthly formulary submission are being denied by CMS. The Comment To Plan field may also contain a comment to refer to the Non-allowable change report, where the plan user can view the comment to plan from CMS related line level decisions.

## **Prior Authorization and Step Therapy (PA/ST) Updates**

The PA/ST criteria change request file layout has been updated for CY 2021. The PA criteria element and justification for UM Change fields have been removed from this file upload. The following fields are required in the PA/ST criteria change request file:

- Formulary ID
- Current UM type. We will now only require sponsors to submit PA for Prior Authorization or ST for Step Therapy. Previously this field required the submitter to include the PA or ST type as well.
- Reason for UM Change. This field remains the same. The submitter should submit one of the reason codes provided in the file layout.
- Current UM group description. This field remains the same from the previous file layout.

Starting in CY 2021, the PA/ST criteria review status will now be available in HPMS. A review status will be assigned to each utilization management (UM) group description and it will be communicated to sponsors via HPMS. This process is being updated in order to improve communication and efficiency of this review. We anticipate that this system upgrade will be released in HPMS in June 2020. We will provide more detailed information at a later date.

## **Expedited Generic Substitution**

Part D sponsors that plan to implement immediate brand-generic substitutions in CY 2021 should answer “Yes” to the question “Will this formulary be subject to expedited generic substitution, as outlined in §423.120(b)(5)(iv)?” during initial formulary submission in the HPMS formulary submission module.

Sponsors implementing generic substitution without advance notice must meet the requirements of §423.120(b)(5)(iv). Part D sponsors implementing these immediate brand-generic substitutions consistent with this regulation, do not need to submit a Negative Change Request to CMS. Rather, we consider notice to CMS of these formulary changes to occur when the HPMS formulary file is updated once the new generic is available on the FRF.

Per §423.120(b)(5)(iv), Part D sponsors are required to provide general notice to all current and prospective enrollees that brand-generic substitutions may occur at any time without

advance direct notice to affected enrollees. This notice should also inform current and prospective enrollees that if a brand-generic substitution occurs, affected enrollees will receive direct notice with information on the affected drug and steps they may take to request a coverage determination or exception. Part D sponsors should utilize the model documents, including the formulary model document, to guide communication to current and prospective enrollees regarding expedited generic substitution.

## **Tier Model Changes**

CMS is consolidating the supplemental drug tier options from four (including Supplemental Drugs, Supplemental Brand Drugs, Supplemental Generic Drugs, and Supplemental Brand and Generic Drugs) to one (supplemental drugs) to simplify the available options. Sponsors will no longer have to consider the tier composition of an excluded drug-only tier when selecting the tier label model options.

## **Part D Supplemental Files**

When creating HPMS formulary submissions for the 2021 plan year, sponsors should be mindful that all supplemental Part D files are linked at the formulary ID level. This is unchanged from CY 2020 and applies to most plans, including Medicare-Medicaid Plans (MMPs).

With the exception of value-based insurance design (VBID) plans, all plans tied to a single formulary ID must use the same versions of the supplemental file types. 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. In other words, this means that the content of supplemental files shared by plans with the same formulary ID must be identical. Please note 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.

The HPMS Formulary Submission Module & Reports Technical Manual has been updated to provide additional details on the specific scenarios that would result in a plan being unable to share a formulary ID. Details have been provided for how this impacts each type of supplemental file. Also 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.

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.

## **Additional Information**

### **Formulary Training Video**

CMS created a training video for plan users that provides a high-level overview of the HPMS formulary submission process. 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 2021, it may still be a useful resource, especially for new users.

**If you have questions regarding the CY 2021 formulary submission process, please email [PartDFormularies@cms.hhs.gov](mailto:PartDFormularies@cms.hhs.gov).**