DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

**Date:** December 17, 2018

**To:** All Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) Sponsors, Medicare-Medicaid Plans, and 1833 & 1876 Cost Plans

**From:** Amy Larrick Chavez-Valdez, Director
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**Subject:** CY 2019 Formulary Information

This memorandum addresses key technical questions regarding the process for submitting formulary updates for the contract year (CY) 2019, including dates for the Formulary Reference File (FRF) release, formulary submission windows, line-level decision dates, and plan deadline to accept or reject CMS line-level decisions. Please note the following updates:

- For CY 2019, negative formulary change requests (NCRs) are able to be submitted via the Health Plan Management System (HPMS) NCR Module from today through September 1, 2019.

- In addition to the optional CY 2019 January formulary submission window that was announced in the CY 2019 Final Call Letter, CMS will also offer an additional update window in the month of November for a December effective date. This November window will enable CMS to capture late-year formulary updates made by Part D sponsors.

- Sponsors are reminded that the earliest effective date to implement approved negative formulary changes is March 1, 2019. Only approved negative changes may be marketed and implemented. For exceptions to the above, including those applicable to Part D sponsors meeting the requirements permitting the immediate substitution of generic drugs as implemented in the April 16, 2018 final rule (83 FR 16440, 16604) ("final rule"), see §423.120(b)(5) and (6).

- CMS intends to make interim Formulary Reference File (FRF) change reports (CRs) available to Part D sponsors via the HPMS formulary submission module in between the monthly comprehensive files. These supplemental FRF CRs are planned for additions only, and will enable Part D sponsors to add new drugs to their HPMS formularies in a more expeditious manner. These CRs will thus result in an earlier display of new drugs in the Medicare Plan Finder. CMS will notify formulary contacts via an email notification upon the availability of an interim CR.

# CY 2019 Formulary Update Process

**Q1: When are the formulary submission windows for CY 2019 formulary updates?**

A1: The CY 2019 formulary submission windows are listed below, along with the dates that the corresponding updates to the comprehensive CY 2019 FRF will be available in the CY 2019 HPMS Formulary Submission Module. The submission windows begin at 12:00 a.m. ET on the opening date and close at 11:59 p.m. PT on the closing date. Any formulary submission that is not successfully uploaded and validated prior to the submission deadline will be denied.

Any difficulties encountered upon upload or validation of your formulary should be brought to the attention of CMS and/or the HPMS Help Desk prior to the window closing. For technical issues, contact the HPMS Help Desk at (800) 220-2028 or hpms@cms.hhs.gov. For other issues, please contact CMS at PartDFormularies@cms.hhs.gov. No consideration will be given for late submissions due to technical difficulties unless HPMS assistance was sought with ample time to troubleshoot issues before the deadline.

| CY 2019 FRF Release Date | Formulary Submission Window |
|---|---|
| December 21, 2018 | January 2–4, 2019 |
| January 25, 2019 | February 1–5, 2019 |
| February 22, 2019 | March 1–5, 2019 |
| March 25, 2019 | April 1–3, 2019 |
| April 24, 2019 | May 1–3, 2019 |
| May 24, 2019 | June 3–5, 2019 |
| June 24, 2019 | July 1–3, 2019 |
| July 25, 2019 | August 1–5, 2019 |
| August 26, 2019 | September 3–5, 2019 |
| September 24, 2019 | October 1–3, 2019 |
| October 25, 2019 | November 1–5, 2019 |

**Q2: Will CMS utilize the line-level review process for CY 2019 formulary updates?**

A2: Yes. Part D sponsors will continue to submit partial formulary update files and CMS will perform line-level reviews on these updates. Partial files must be submitted during the aforementioned formulary submission windows. We will review changes at the individual RXCUI level, as opposed to the file as a whole. If a sponsor submits a partial formulary update file that is fully acceptable, there is no need for the line-level resubmission process; as such, the sponsor will not receive a communication notifying

them of the need to complete this process. Plan sponsors will need to access the Line-Level Accept/Reject page in HPMS for partial formulary update file submissions that are considered only partially acceptable. Upon Part D sponsors' acceptance of our line-level decisions, HPMS will create a new version of the formulary containing only the allowable changes. In the event that a sponsor fails to accept the CMS line-level review decisions, the entire formulary will be denied and the formulary will revert back to the most recently approved version in HPMS (i.e., it will not contain any of the CMS-approved line-level changes submitted). The following chart details the dates for CMS' review of line-level changes and the corresponding dates that Part D sponsors must take action on the review. **Formulary files that contain a significant number of non-allowable changes will be denied and your organization may receive a compliance action.**

| Line-Level Decisions Available to Plans | Plan Deadline to Accept/Reject CMS Line-Level Decisions |
|---|---|
| January 16, 2019 | January 17, 2019 |
| February 13, 2019 | February 14, 2019 |
| March 13, 2019 | March 14, 2019 |
| April 17, 2019 | April 18, 2019 |
| May 15, 2019 | May 16, 2019 |
| June 12, 2019 | June 13, 2019 |
| July 17, 2019 | July 18, 2019 |
| August 14, 2019 | August 15, 2019 |
| September 18, 2019 | September 19, 2019 |
| October 16, 2019 | October 17, 2019 |
| November 13, 2019 | November 14, 2019 |

**Q3: When should new drugs within the protected classes be added to the HPMS formulary file?**

A3: New drugs, or newly approved uses for drugs, within the protected classes must be added to the formulary by the end of the 90-day expedited review period. If this time period does not exactly coincide with an HPMS formulary submission, the drug must be included on the HPMS formulary file during the next available submission window. For example, if a new drug within the protected classes is available on the market on May 8, 2019, the P&T committee must review the drug and add it to the formulary for adjudication by August 6, 2019. The drug must then be added to the HPMS formulary file during the September 3-5, 2019, submission window. **Failure to add a protected class drug, or the addition of a protected class drug to the formulary with a non-allowable tier placement or utilization management (UM), during the required**

**HPMS formulary submission window will result in denial of the formulary file, suppression of the formulary in Medicare Plan Finder (MPF), and may result in a compliance action. In order to prevent plans from being suppressed and/or receiving compliance for missing a protected class drug, we encourage sponsors to check the monthly FRF change report for deletions of protected class drugs that could necessitate addition of an equivalent product.**

**Q4: What types of changes can be made to the HPMS formulary files?**

A4: Only allowable enhancements, as outlined in Appendix A of this memo, and CMS-approved negative changes (beginning with the February 2019 submission) may be included in updated HPMS formulary files.

Formulary enhancements, such as adding a Part D drug to the formulary, may be implemented at any time. Consistent with Formulary and Formulary Change Notice Requirements (formerly section 60.4 of the Medicare Marketing Guidelines, see November 1, 2018 HPMS memo, Part D Communication Materials), the enhancements must be included in the Part D sponsor's communication materials. The posted formulary enhancements must then be reflected in the next HPMS formulary submission. In addition, sponsors are encouraged to directly notify beneficiaries of formulary additions in a timely manner since in some cases, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

Revisions to §423.120(b)(5)(i) implemented in the final rule reduced CMS notice requirements for specified midyear formulary changes from 60 days to 30 days. NCRs, therefore, must be submitted through the HPMS NCR Submission Module at least 30 days prior to the effective date, with the exception of, for example, the brand-generic substitution maintenance changes permitted under §423.120(b)(5)(iv). CMS-approved negative changes for the current contract year should be reflected in the formulary file update submitted in the month preceding the proposed NCR effective date. Once an NCR is approved, the negative change should be reflected in the next available partial formulary file update.

**Additional negative changes submitted that did not receive prior approval will be denied by CMS via the line-level review process.** Any non-allowable changes may not be implemented or marketed. The most common reasons that would result in our denial of submitted formulary changes are: changes in the therapeutic category and/or pharmacological class name; moving a drug to a less favorable beneficiary cost-sharing tier or deletion of a drug without an approved NCR; addition of a drug to the specialty tier that does not meet the specialty tier cost threshold; addition of UM to an existing drug without an approved NCR; inappropriate UM type for protected class drug(s) (e.g., not limited to new starts only); and missing new protected class drug(s). We expect plan sponsors to perform internal quality assurance checks on the formulary files to identify unintended negative formulary changes prior to submission in HPMS.

**Q5: How does CMS evaluate negative formulary change requests?**

A5: Negative formulary change requests are reviewed in accordance with the midyear formulary change policy outlined in section 30.3.3 of chapter 6 of the Medicare Prescription Drug Benefit Manual. The vast majority of change requests that have been submitted for review have been maintenance changes typically involving negative changes to a brand name drug with the corresponding addition of an equivalent generic. Non-maintenance changes (e.g., changing preferred or non-preferred formulary drugs, adding utilization management, increasing cost sharing on drugs, removing dosage forms, or exchanging therapeutic alternatives), have been submitted much less frequently and can only be applied to those enrollees not currently taking the affected drug. When sponsors submit non-maintenance requests for review, a corresponding clinical justification that supports the change must also be submitted. In order for CMS to approve a non-maintenance change, the formulary must continue to satisfy the minimum formulary requirements established by CMS, and the proposed change must not substantially discourage enrollment by certain beneficiary groups.

**Q6: How do revisions to §423.120(b)(5)(iv), implemented in the final rule regarding immediate substitutions of certain generics, affect the submission of NCRs and the monthly formulary submissions?**

A6: A Part D sponsor that meets all requirements of §423.120(b)(5)(iv), as revised by the final rule, may immediately remove or change the tier/cost sharing of a brand name drug on its formulary when substituting a therapeutically equivalent generic drug that could not have been included in the initial formulary submission because it was not yet available on the market.

While permitted brand-generic substitutions may be implemented immediately by Part D sponsors meeting all requirements, it is expected that sponsors will still submit a NCR notifying CMS of the change as soon as the decision to implement this change is made. The HPMS formulary file should be updated once the generic is available on the FRF. The effective date of the NCR submission for expedited substitutions that are implemented immediately should reflect the date of implementation even if the date is prior to the NCR submission date.

Plan sponsors are reminded that brand-generic substitutions that do not meet all of the requirements of §423.120(b)(5)(iv) require 30 days' notice to CMS and an approved NCR prior to formulary update submissions.

**Q7: Are Part D sponsors permitted to make changes to their existing prior authorization (PA) or step therapy (ST) criteria?**

A7: Yes, but only in limited circumstances. Generally, a sponsor should not need to make significant revisions to its approved criteria during the contract year. As per 42 CFR §423.120(b)(1)(x), submitted UM criteria should already have been evaluated for clinical accuracy by the P&T committee prior to submission of the formulary to CMS. It is our expectation that Part D sponsors will not need to update criteria except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., a new Boxed warning). Revisions should be

limited in scope as opposed to a significant rewrite of existing criteria. Part D sponsors are expected to perform all necessary quality assurance checks on formulary files prior to HPMS submission. As a result, criteria changes to correct spelling or grammatical errors, for example, will not be accepted.

As detailed below, plan sponsors are required to submit a request to CMS before making changes to existing PA or ST criteria, regardless of whether the sponsor considers the change to be a restriction or an enhancement.

**Q8: How do Part D sponsors submit changes to existing Prior Authorization (PA) or Step (ST) criteria?**

A8: For CY 2019, the UM template submission deadline will continue to be to two days prior to the monthly gate opening. Sponsors will continue to utilize the UM Criteria Change Request template (attached) when there is a need to change existing PA or ST criteria. We must receive an accurately completed template by the stated deadline to ensure that criteria gates are opened for submission. The following steps detail the submission process:

1. Complete the UM Criteria Change Request template for the applicable formulary IDs and ST or PA group descriptions. The group descriptions included on the template must exactly match the group descriptions from the formulary file, including spacing, commas, hyphens, and other characters. **If the group descriptions do not exactly match, the PA and/or ST gates will not open in HPMS and the request will need to be submitted correctly the following month**. The "Reason for UM Change" field must be completed by selecting a specific reason for the change from the drop-down options. Do not modify the drop-down options listed in the UM Criteria Change Request template. A justification describing the rationale for the change is also required. Please note that multiple formularies may be listed on a single worksheet. The template must be completed as follows:

    a) **CY 2019 Formulary ID (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) **Reason for UM Change:** from a drop-down menu, select Removal of a restriction, Addition of drug(s) to existing criteria, Addition of a new indication, Restriction based on a new Boxed Warning/FDA Safety Communication, Other extraordinary circumstance, or Revision of existing criteria to include a Part B drug (MAPDs only).

    c) **Current UM Type:** from a drop-down menu, select PA type 1, 2, or 3, or ST type 1 or 2.

    d) **Current UM Group Description:** enter the Group Description from the last approved formulary and PA or ST text files. This field will be pre-populated with an "NA" if the current PA type is 3 and should not be modified. The group descriptions on the template must exactly match the group descriptions from the formulary file, including all characters and spacing.

e) **PA Criteria Element (N/A for ST Criteria):** from a drop-down menu, select the PA criteria element for which you will be adding revised or new PA criteria. Only one PA element may be selected for each line item. If you will be modifying multiple PA criteria elements for the same FID and PA group description, you will enter these elements on successive rows of the template. Do not select "NA" on the template for PA criteria elements when submitting a criteria change for a PA group description. The option of NA is only appropriate for ST criteria change requests. PA criteria elements are described in the CY 2019 HPMS Formulary Submission Module and Reports Technical Manual. Please note the character limitations for each element. Any criteria that exceed authorized character limitations as noted in the record layout will be rejected.

f) **Justification for UM Change:** enter the justification for the proposed UM change(s). Please include pertinent references, such as new safety warnings to support proposed changes, as applicable. Save the completed template with the following naming convention: "CY19UMCriteria RequestFIDXXXXX". Note that any modifications to the template, such as a change to the file layout, or a change to the tab name, will result in a rejected submission.

2. Submit the completed template to the CMS UM Criteria Requests mailbox (umcriteriarequests@cms.hhs.gov) no later than two business days prior to the monthly formulary gate opening date. The subject line of the email should read "CY 2019 UM Criteria Request—Formulary ID XXXXX".
3. Upon receipt of the completed templates, we will open the applicable PA and ST group description gates so that criteria revisions may be submitted by plan sponsors.
4. Sponsors will submit the monthly formulary update partial file during the regularly scheduled formulary submission window, along with the updated ST and/or PA criteria partial files.

**Q9: How will CMS review revised and newly submitted UM criteria?**

A9: After criteria have been submitted via HPMS, we will review them for clinical appropriateness. Based on this review, we may require sponsors to update their files. This process has not changed for CY 2019; however, we are providing additional clarification as CMS has observed instances where sponsors have required multiple resubmissions to achieve compliance with Part D program requirements. Due to short review timeframes, and because beneficiaries need access to accurate information, sponsors will be allotted a limited number of opportunities to revise their criteria based on CMS feedback. Criteria elements that remain unacceptable will revert back to the previously approved criteria or be removed, absent extraordinary circumstances.

We will also review revised criteria to ensure that changes are limited to those that were requested in advance and that extraordinary circumstances exist which would warrant the change. If extraordinary circumstances do not exist, criteria will not be reviewed and must revert back to the previously approved criteria. If sponsors make additional changes

to the criteria text files, their organizations may be subjected to a compliance action by CMS.

**Q10: What is the process for submitting supplemental formulary files (free first fill, partial gap, or home infusion) with each formulary upload?**

A10: During the monthly update windows, sponsors must indicate in HPMS whether they will be using the previously uploaded versions of these documents or if they will be uploading a new file(s). Sponsors must submit a new version of the file(s) only if there are changes in the list of drugs that have supplemental coverage. If there are no changes, sponsors must indicate that they are using their previous file(s). Please note that if a new supplemental file is uploaded and the file contains non-allowable changes, the affected plan(s) may be suppressed in the MPF until a corrected supplemental file is uploaded. Examples of non-allowable changes to supplemental formulary files are outlined in Appendix A.

For those formularies that are associated with a Partial Gap, Free First Fill, or Home Infusion Supplemental Files, plan sponsors have the option to indicate whether changes are required to the Supplemental Files when they accept CMS review decisions via the line-level process. If a plan sponsor indicates that no changes are required, the system will continue to use the previously uploaded supplemental file. If a plan sponsor indicates that changes are required, the user will be prompted via email to upload new files. New supplemental files must be uploaded by 11:59 p.m. PT on the same day as the formulary resubmission line-level closing date. **Failure to upload the required supplemental files may result in a compliance action.**

**Q11: How should Part D sponsors coordinate formulary submissions and MPF pricing file submissions?**

A11: Plan sponsors are reminded that MPF pricing files must contain pricing for all drugs included in their current CMS-approved formulary. Since formulary submission dates and MPF pricing file submission dates differ, it is imperative that plan sponsors continuously refer to the MPF operational calendar to ensure the coordination of formulary and pricing updates. For example, formulary updates submitted between February 1 and February 5, 2019, will be reviewed for approval by February 20, 2019. Plan sponsors should prepare MPF pricing files to include information reflecting these formulary changes for submission from March 4–March 5, 2019. If the submitted formulary file is not approved by 11:59 p.m. ET on February 20, 2019, plan sponsors should submit MPF pricing files reflective of the previously approved formulary.

## Appendix A

1) **Formulary File Enhancements**
   a) Addition of Part D drugs, with or without UM
   b) Moving drugs to a more favorable beneficiary cost-sharing tier
   c) Removal of prior authorization (PA) requirements
   d) Changing PA Type from 1 (PA applies) to 2 (PA applies to new starts only) or 3 (Part B versus Part D PA only, if a Part B versus Part D PA is appropriate)
   e) Removal of quantity limit (QL) restrictions
   f) Making existing quantity limits less restrictive (e.g., increasing the allowable quantity limit amount without changing the quantity limit days supply)
   g) Step therapy (ST) enhancements:
      i) Removal of entire ST protocol (e.g., removal of step therapy requirements for the stepped drug(s) and the corresponding removal of step edits from all prerequisite drugs)
      ii) Removal of ST requirements for a drug(s) within the highest step level of a protocol (e.g., removal of step requirements for one step 2 drug within a step therapy protocol containing two step levels and more than one step 2 drug)
      iii) Addition of prerequisite step 1 drugs to existing ST protocols (i.e., the new step 1 drug *or* the existing step 1 drugs would qualify the member for the step 2 drug)
      iv) Changing ST Type from 1 (ST applies) to 2 (ST applies to new starts only)

2) **Negative Formulary File Changes**
   a) Removal of FRF RXCUIs
   b) Moving drugs to a less favorable beneficiary cost-sharing tier
   c) Addition of any UM edits to existing formulary drugs (except for the addition of step 1 edits to prerequisite drugs in existing or new step therapy protocols, as outlined above)
   d) Making existing quantity limits more restrictive (e.g., decreasing the allowable quantity limit amount without changing the quantity limit days supply OR increasing the quantity limit days supply without changing the quantity limit amount)

3) **Non-Allowable Changes**
   a) Change in formulary model/classification
   b) Change in the formulary file category or class names for existing formulary drugs
   c) Addition of RXCUIs to a specialty tier that do not meet the cost criteria as outlined in the CY 2019 Call Letter
   d) Removal of prerequisite (e.g., Step 1 drugs) from existing step therapy protocols
   e) Addition of a limited access indicator to an existing formulary drug
   f) Change from a QL type 1 to a QL Type 2 or from a QL Type 2 to a QL Type 1