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

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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
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SUBJECT: CY 2023 Formulary Information

This memorandum addresses key technical questions regarding the process for submitting formulary updates for contract year (CY) 2023, including formulary submission windows, information on Formulary Reference File (FRF) updates, line-level decision dates, and plan deadlines to accept or reject CMS line-level decisions. The current CY 2023 FRF, FRF Change Report (CR), Negative Change Request (NCR) Module, and PA/ST Criteria Change Requests are now available.

CY 2023 Formulary Update Process

Q1: When are the formulary submission windows for CY 2023 formulary updates?

A1: The CY 2023 formulary submission windows are listed below. The submission window begins at 12:00 a.m. ET on the opening date and closes 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 not be accepted. As a reminder, the current CY 2023 FRF and FRF Change Report (CR) are available to download at any time. While these files may be updated throughout the month as new drugs become available, we anticipate that the majority of FRF changes will be reflected on the FRF within five business days prior to the monthly formulary submission window.

CY 2023 Formulary Submission Windows:

- January 3-5, 2023
- February 1-3, 2023
- March 1-3, 2023
- April 3-5, 2023
- May 1-3, 2023

- June 1-5, 2023
- July 3-6, 2023
- August 1-3, 2023
- September 1-6, 2023
- October 2-4, 2023
- November 1-3, 2023

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.

Q2: Will CMS utilize the line-level review process for CY 2023 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. We will review changes at the individual RXCUI level, as opposed to the file as a whole. We expect that sponsors will perform quality assurance checks to ensure their initial monthly formulary submission is accurate and they will not need to request resubmissions to correct any errors. 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 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 table 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 18, 2023	January 19, 2023
February 15, 2023	February 16, 2023
March 15, 2023	March 16, 2023
April 12, 2023	April 13, 2023
May 10, 2023	May 11, 2023
June 14, 2023	June 15, 2023
July 19, 2023	July 20, 2023

Line-Level Decisions Available to Plans	Plan Deadline to Accept/Reject CMS Line-Level Decisions
August 16, 2023	August 17, 2023
September 13, 2023	September 14, 2023
October 18, 2023	October 19, 2023
November 15, 2023	November 16, 2023

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

A3: New 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 9, 2023, the P&T committee must review the drug and add it to the formulary for adjudication by August 7, 2023. The drug must then be added to the HPMS formulary file during the September 1-6, 2023 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 may result in a compliance action.

New for CY 2023, plans that fail to add a protected class drug or add a protected class drug with non-allowable tier placement or UM will have a one-time opportunity to resubmit their formulary to add or update the drug to an allowable tier or UM prior to formulary approval. CMS will still notify plans of any other non-allowable changes via the Line-Level Accept/Reject page in HPMS and will send email notifications with instructions if protected class drugs are missing or if they are added to the formulary with a non-allowable tier placement or UM. In order to prevent plans from receiving a compliance action for failing to add a protected class drug or for adding a protected class drug to the formulary with a non-allowable tier placement or UM, we encourage sponsors to check the 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, expedited brand-generic substitution consistent with 42 C.F.R § 423.120(b)(5)(iv), and CMS-approved negative changes (beginning with the February 2023 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, 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, such as new generics, an earlier conversion could lead to better value for the beneficiary and reduced program costs.

With the exception of brand-generic substitution maintenance changes permitted under 42 C.F.R. § 423.120(b)(5)(iv), negative Formulary Change Requests (NCRs) must be submitted through the HPMS NCR Submission Module at least 30 days prior to the effective date. 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. NCRs can be submitted via the HPMS NCR Module now through October 1, 2023. We remind sponsors that the earliest effective date to implement approved negative formulary changes is March 1, 2023. Only approved negative changes may be marketed and implemented.

Additional negative changes submitted that did not receive prior approval will be denied by CMS via the line-level review process. Non-allowable changes may not be implemented or marketed. The most common reasons that would result in 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; 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). Sponsors may also receive line levels related to immediate brand generic substitutions. Six issue types may appear in the Non-Allowable Change Report for line levels generated when a generic offset is added at a less favorable formulary position than that of the brand drug on the previously approved formulary.

Q5: How will formulary changes involving interchangeable biosimilars be considered?

A5: Part D sponsors continue to have the flexibility to promote the appropriate use of biosimilar and interchangeable products through their formulary and drug UM strategies when designing their Part D benefits. Consistent with the March 30, 2015 HPMS memorandum titled "Part D Requirements for Biosimilar Follow-On Biological Products," biosimilars and interchangeable products may be added to plan formularies at any time as a formulary enhancement.

In the March 30, 2015 memorandum, we stated that formulary changes involving the addition of the biosimilar and the removal of the reference biological product will generally be considered a non-maintenance change. We also stated additional guidance may be issued for "interchangeable" biological products at a later date. The FDA recognizes biosimilars to be interchangeable when they produce the same clinical result as the reference biological product and when there is no greater safety risk or reduced efficacy presented if a patient were to alternate between use of the reference product and

the biosimilar product. We have aligned our formulary change policy with FDA guidance; therefore, the formulary addition of an interchangeable product and the removal of the reference biological product will be considered a maintenance change, and notice and refill requirements at 42 C.F.R. § 423.120(b)(5)(i) will apply.

Q6: Are Part D sponsors permitted to make changes to their existing prior authorization (PA) or step therapy (ST) criteria?

A6: 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 C.F.R. § 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.

Q7: How do Part D sponsors submit changes to existing Prior Authorization (PA) or Step (ST) criteria?

A7: When there is a need to change existing PA or ST criteria, sponsors will submit the gate opening request via HPMS. The file layout mirrors the UM Criteria Change Request template used in prior contract years, but will be uploaded into HPMS as a tab-delimited (.txt) file. The process is described in the CY 2023 HPMS Formulary Submission Module and Reports Technical Manual, page 151 "Submit or Withdraw PA/ST Criteria Change Request File Submission." The upload file layout is described on page 176 of the technical manual and is comprised of the following required fields:

a) **CY 2023 Formulary ID (FID).** Requests for multiple formularies may be uploaded simultaneously using the same file.

b) **Reason Code for UM Change.** Use codes 1 through 6 to indicate the reason for the UM change request. 1 - Removal of a restriction, 2 - Addition of drug(s) to existing criteria, 3 - Addition of a new indication, 4 - Restriction based on a new Boxed Warning/FDA Safety Communication, 5 - Other extraordinary circumstance, or 6 - Revision of existing criteria to include a Part B drug (MAPDs only) when a Part B drug is requested to be used before a Part D drug. Only one code can be selected for each gate opening request.

c) **Current UM Type.** Valid field entries are PA or ST.

d) **Current UM Group Description (UMGD).** Indicate the PA Group Description (PAGD) or ST Group Description (STGD) from the last approved formulary and PA or ST text files. The group descriptions included on the request file must exactly match the group descriptions from the formulary file, including spacing, commas, hyphens, and other characters, or the file will not validate.

You may begin to submit your requests the first business day after the monthly formulary submission window closes. Please ensure that all requests are submitted no later than three business days prior to the monthly formulary gate opening date to ensure PA and ST gates are opened. Once your request is submitted, the Formulary Contacts will receive an email from HPMS to notify you if your submission was successfully validated or rejected by validation. If the file is rejected by validation, the email will contain information regarding the validation error. Sponsors should work to fix the validation issue and resubmit an updated file. Once the file is successfully validated, 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.

Q8: How do sponsors withdraw or check the status of their PA/ST criteria change requests?

A8: New for CY 2023, sponsors can now withdraw PA/ST criteria change requests submitted during the latest request window via HPMS. Sponsors will no longer need to send emails to the Part D Formulary mailbox. The process is described in the CY 2023 HPMS Formulary Submission Module and Reports Technical Manual, page 153 "Withdraw PA/ST Criteria Change Request."

Sponsors can check the status of the PA/ST Criteria Change Request file in HPMS via the Formulary PA/ST Criteria Change Request Status History Report. Instructions for accessing this report can be found in the 2023 HPMS Formulary Submission Module and Reports Technical Manual, page 155. This report indicates which PA/ST gates have been requested for opening at the next formulary update window, along with any requests which failed to validate.

Q9: How do sponsors check the review status at the group description or criteria element level for PA and ST?

A9: The HPMS UMGD Status Report should be used to determine the status of each PA and ST group description. Instructions for accessing this report can be found in the 2023 HPMS Formulary Submission Module and Reports Technical Manual, page 161. This report indicates the status (denied, in progress, not started, and approved) of each PA or ST group description.

The HPMS UMGD Review Detail Report should be used to determine criteria level status information. Instructions for accessing this report can be found in the 2023 HPMS

Formulary Submission Module and Reports Technical Manual, page 159. This report indicates the review status (not started, in progress, denied, approved, response requested, and response received) of each criteria element contained in a PA/ST group description.

Plans will not receive email notifications confirming criteria approvals during the annual PA and ST review cycle since the information is available in the UMGD detail report.

Q10: How will CMS review revised and newly submitted UM criteria?

A10: 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 2023; 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 to the previously approved criteria or be removed, absent extraordinary circumstances.

Q11: What is the process for submitting supplemental formulary files (Free First Fill, Partial Gap, Home Infusion, Value-Based Insurance Design Model) with each formulary upload?

A11: 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.

For those formularies that are associated with Partial Gap, Free First Fill, Home Infusion, and Value-Based Insurance Design Model, plan sponsors have the option to indicate whether changes are required to the Supplemental File(s) 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. Please note that if a drug is removed from the formulary file that is also on a supplemental file, HPMS will expect a new supplemental file submission. If a plan sponsor indicates that changes are required, the user will be prompted via email to upload new files. Once you indicate that you plan to upload a new file, the system is unable to use a previously uploaded version. Once you upload a new file, please verify in the HPMS system that the new supplemental file goes into desk review, indicating that the file has been accepted. 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.

Guidance regarding the Part D Senior Savings Model supplemental file, the Model drug coverage templates submission process, and deadlines will be available at a later date.

Q12: Can sponsors implementing Indication-Based Formulary Design (IBFD) for CY 2023 update their Indication-Based Coverage (IBC) file during the plan year?

A12: We do not expect to see changes to the IBC files except in the case of a drug that receives a new indication or a newly approved drug being added to your formulary. If you need to add additional indications to your IBC file for one of the reasons previously listed, you should request the IBC file gate to be opened. You can then add the additional covered indications to your IBC file during the next monthly formulary update window. If PA criteria also need to be revised to accommodate the additional formulary indications, sponsors should request the PA gate opening as described in Q7. CMS does not expect formulary indications to be removed from the IBC file midyear, as this would be considered a negative change. To request the IBC file gate opening, sponsors should email PartDformularies@cms.hhs.gov. Please note, the Indication Reference File (IRF) may be updated periodically as needed for new indications that do not already exist on this file. Please check in HPMS for the most recent version of the IRF.

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 changing from PA Type 1 or 2 to Type 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)
   h) Brand-generic substitution maintenance changes permitted under 42 C.F.R. § 423.120(b)(5)(iv)

2) **Negative Formulary File Changes**
   a) Removal of FRF RXCUIs
   b) Moving drugs to a less favorable beneficiary cost-sharing tier, such that the out-of-pocket costs for some or all beneficiaries would be increased
   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 Contract Year (CY) 2023 Final Part D Bidding Instructions
   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
   g) Change in PA indication indicator from "1- All FDA-approved indications" to "2 - Some FDA-approved indications"
   h) Removing indications from the Indication-Based Coverage (IBC) file

i) Submitting brand-generic substitution maintenance changes that do not meet the requirements outlined in 42 C.F.R. § 423.120(b)(5)(iv)