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CENTER FOR MEDICARE

TO: All Part D Sponsors

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SUBJECT: CY 2014 Formulary Information

DATE: January 14, 2014

This memorandum describes the process for submitting formulary updates for the 2014 contract year. Sponsors are reminded that the earliest effective date to implement approved negative formulary changes is March 1, 2014. Maintenance negative change requests may be submitted via the Health Plan Management System (HPMS) Negative Formulary Change Request (NCR) Module through July 31, 2014, and non-maintenance negative change requests may be submitted through April 30, 2014; however, only approved changes may be implemented.

CY 2014 Formulary Update Process

Q1: When are the formulary submission windows for CY 2014 formulary updates?

A1: The CY 2014 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2014 Formulary Reference File (FRF) will be available in the CY 2014 HPMS Formulary Submission Module. The submission window begins at 12:00 AM ET on the opening date and closes at 11:59 PM ET 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 in ample time to troubleshoot the problems before the deadline.

CY 2014 FRF Release Date	Formulary Submission Window
January 27, 2014	February 3 – 5, 2014
February 24, 2014	March 3 – 5, 2014
March 25, 2014	April 1 – 3, 2014
April 24, 2014	May 1 – 5, 2014
May 23, 2014	June 2 – 4, 2014
June 24, 2014	July 1 – 3, 2014
July 25, 2014	August 1 – 5, 2014
August 25, 2014	September 2 – 4, 2014
September 24, 2014	October 1 – 3, 2014

Q2: Will CMS utilize the line-level review process for CY 2014 formulary updates?

A2: Yes. Part D sponsors will continue to submit partial formulary update files and we 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. 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 denies 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.**

Line-Level Decisions Available to Plans	Plan Deadline to Accept/Deny CMS Line-Level Decisions
February 19, 2014	February 20, 2014
March 19, 2014	March 20, 2014
April 16, 2014	April 17, 2014
May 21, 2014	May 22, 2014
June 18, 2014	June 19, 2014
July 23, 2014	July 24, 2014
August 20, 2014	August 21, 2014
September 17, 2014	September 18, 2014
October 22, 2014	October 23, 2014

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 12, 2014, the P&T committee must review the drug and add it to the formulary by August 10, 2014. The drug must then be added to the HPMS formulary file during the September 2-4, 2014 submission window. **Failure to include a protected class drug or the addition of a protected class drug to the formulary with the addition of a non-allowable tier placement or utilization management (UM) during the required HPMS formulary submission window will result in denial of the formulary file and suppression of the formulary in Medicare Plan Finder (MPF).**

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

A4: Only allowable enhancements, as outlined in Appendix A, and CMS-approved negative changes may be included in updated HPMS formulary files starting with the February 2014 submission window.

CMS-approved negative changes for the current contract year submitted through the HPMS NCR Submission module should be reflected in the formulary file update submitted in the month preceding the proposed NCR effective date. For example, if the intended negative change effective date is May 1, 2014, then the proposed NCR should be sent to CMS on or before March 1, 2014. If the NCR is approved, the negative change should be reflected in the partial formulary file update uploaded during the April 1-3, 2014 formulary submission window.

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; tier increase 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; inappropriate UM type for protected classes drugs (e.g. not limited to new starts only); and missing new protected classes drug(s). We expect plan sponsors to perform internal quality assurance checks on the formulary files prior to submission in HPMS to identify unintended negative formulary changes.

Q5: Are Part D sponsors permitted to make changes to their existing prior authorization (PA) or step therapy (ST) criteria?

A5: 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)(vi), 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 Black Box warning).

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.

Q6: How do Part D sponsors submit changes to existing PA or ST criteria?

A6: For CY 2014, sponsors will utilize a new 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 new UM Criteria Change Request template for the applicable formulary IDs and ST or PA group descriptions. The group descriptions included on the template must match exactly the group descriptions from the formulary file. The reason for change field must be completed and a justification for 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 2014 Formulary ID (FID):** enter only one valid 5-digit CY 2014 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 Criteria Enhancement, Negative Change to Criteria, Addition of Drugs to Existing Criteria or Other.
    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.
    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 formulary ID and PA group description, you will enter these elements on successive rows of the template. PA criteria elements are described in the CY 2014 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.

2. Submit the completed template to the new CMS UM Criteria Requests mailbox (umcriteriarequests@cms.hhs.gov) no later than 12:00 PM ET on the last business day prior to the monthly formulary gate opening date. The subject line of the email should read "CY 2014 UM Criteria Request—Formulary ID XXXXX".
3. Upon receipt of the completed templates, we will open the applicable PA and ST group descriptions 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.

Q7: How will CMS review the revised UM criteria?

A7: After the revised criteria have been submitted via HPMS, we will review them for clinical appropriateness and to ensure that changes are limited to those that were requested in advance. Based on this review, as well as the review of new UM criteria, we may require sponsors to update their files. If sponsors make additional changes to the criteria text files, their organizations may be subjected to a compliance action by CMS.

Q8: What is the process for submitting supplemental formulary files (free first fill, partial gap or home infusion) with each formulary upload?

A8: 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) will be suppressed in the MPF until a corrected supplemental file is uploaded during the next formulary submission window. Examples of non-allowable changes to supplemental formulary files are outlined in Appendix A.

In contrast, during the Line Level Acceptance process, sponsors will not have the option to indicate whether they will be uploading new supplemental file(s) or will be using your previous version(s). By default, the system will assume that a new file will be uploaded. This means that a new supplemental file must be uploaded by 11:59 PM ET on the same day as the formulary resubmission closing date, even if the supplemental file was not affected by the line level changes and is identical to the previously submitted supplemental file**.** This applies only to Home Infusion, Partial Gap or Free First Fill supplemental files. **Failure to upload the required supplemental files will result in suppression in the MPF.**

Q9: How should Part D sponsors coordinate formulary submissions and MPF pricing file submissions?

A9: 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 3 and February 5, 2014 will be reviewed for approval by February 25, 2014. Plan sponsors should prepare MPF pricing files to include information reflecting these formulary changes for submission to DestinationRx from March 3-4, 2014. If the submitted formulary file is not approved by 11:59 PM EST on February 25, 2014, plan sponsors should submit MPF pricing files reflective of the previously approved formulary.

Appendix A

Formulary File Enhancements
1. Addition of Part D drugs, with or without UM
2. Moving drugs to a more favorable beneficiary cost-sharing tier
3. Removal of prior authorization (PA) requirements
4. 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)
5. Removal of quantity limit restrictions
6. Making existing quantity limits less restrictive (e.g. increasing the allowable quantity limit amount without changing the quantity limit days supply)
7. Step therapy (ST) enhancements: • 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) • 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) • 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) • Changing ST Type from 1 (ST applies) to 2 (ST applies to new starts only)
Negative Formulary File Changes
1. Removal of FRF RXCUIs
2. Moving drugs to a less favorable beneficiary cost-sharing tier
3. 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)
4. 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)
Non-Allowable Changes
1. Change in formulary model/classification
2. Change in the formulary file category or class names for existing formulary drugs

3. Addition of proxy codes to a specialty tier that do not meet the cost criteria as outlined in the CY 2014 Call Letter
4. Changes to existing Step Therapy or Prior Authorization criteria, whether considered to be more restrictive or an enhancement, without prior CMS approval
5. Removal of prerequisite (e.g. Step 1 drugs) from existing step therapy protocols
6. Addition of a limited access indicator to an existing formulary drug
7. Removal of a drug from a supplemental formulary file (free first fill, partial gap, or home infusion) that was not simultaneously removed from the formulary file OR the removal of a drug from a full or partial gap tier to a tier that is not covered in the gap
8. Addition of a drug to the home infusion supplemental file that was not simultaneously added to the formulary file