DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: All Part D Plan Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

RE: CY 2010 Formulary Updates

DATE: January 7, 2010

This document describes the process for submitting formulary updates for the 2010 contract year. Sponsors are reminded that the earliest effective date for negative formulary changes is March 1, 2010. Maintenance negative change requests may be submitted via the HPMS Negative Formulary Change Request (NCR) Module from January 1, 2010 through July 31, 2010 and non-maintenance negative change requests may be submitted from January 1, 2010 through April 30, 2010; however, only approved changes may be implemented.

CY 2010 Formulary Update Process

Q1: When are the formulary submission windows for CY 2010 formulary updates?

A1: The CY 2010 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2010 Formulary Reference File (FRF) will be available in the CY 2010 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 2010 FRF Release Date	Formulary Submission Window
January 25, 2010	February 1 – 3, 2010
February 22, 2010	March 1 – 3, 2010
March 25, 2010	April 1 – 5, 2010
April 26, 2010	May 3 – 5, 2010
May 25, 2010	June 1 – 3, 2010
June 24, 2010	July 1 – 6, 2010
July 26, 2010	August 2 – 4, 2010
August 25, 2010	September 1 – 3, 2010
September 24, 2010	October 1 – 5, 2010

Q2: When should new drugs within the protected classes be added to the HPMS formulary file?

A2: 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, 2010, the P&T committee must review the drug and add it to the formulary by August 10, 2010. If the P&T committee takes the full 90 days, the drug must be covered at the pharmacy starting on August 10, 2010, and be added to the HPMS formulary file during the September 1-3, 2010 submission window.

Q3: What types of changes can be made to the HPMS formulary files?

A3: 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 2010 submission window.

CMS-approved negative changes for the current contract year submitted through the HPMS Negative Formulary Change Request (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, 2010, then the proposed NCR should be sent to CMS on or before March 2, 2010. If the NCR is approved, the negative change should be reflected in the formulary flat file update uploaded during the April 1-5, 2010 formulary submission window.

If there are additional negative changes submitted that did not receive prior approval, the entire HPMS formulary file will be denied. The formulary may not be resubmitted until the following month's open submission period. Any formulary changes contained within the denied file will not be reflected in the Medicare Prescription Drug Plan Finder (MPDPF). In addition, any unauthorized negative changes included in the denied file may not be implemented or marketed.

The most common reasons for a monthly formulary file being denied by CMS are: changes in the therapeutic category and/or pharmacological class name; tier increase or deletion of a drug without approved NCR; addition of a drug to the specialty tier that does not meet the specialty tier cost threshold; inappropriate utilization management type for protected classes drugs (e.g. not limited to new starts only); and missing new protected classes drug(s). CMS expects plan sponsors to perform internal quality assurance checks on the formulary files prior to submission in HPMS to identify unintended negative formulary changes.

Q4: Are Part D sponsors required to resubmit prior authorization (PA) and step therapy (ST) criteria files with each formulary upload?

A4: No. The previously uploaded versions of these documents must be used provided that there are no criteria changes or differences in the list of drugs that require PA or ST. **Except as outlined below, the criteria for existing formulary drugs must not be modified.**

Q5: Can Part D sponsors make HPMS prior authorization or step therapy criteria more restrictive during a formulary update submission?

A5: Generally, no. Only in extraordinary circumstances may Part D sponsors make modifications to existing criteria. We remind sponsors that they must not change their CY 2010 HPMS criteria to make them more restrictive or limiting without direct CMS approval. During the contract year, a sponsor should not need significant revision of its approved criteria. For instance, submitted PA criteria should already have been evaluated for clinical accuracy, since in accordance with §423.120(b)(vi), the sponsor's P&T committee has completed a thorough review of proposed PA criteria prior to submission of the formulary to CMS. It is CMS' expectation that Part D sponsors will not update criteria except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., FDA release of a new Black Box warning).

Q6: What is the process Part D sponsors should follow to make their existing utilization management criteria more restrictive?

A6: In the event that a Part D sponsor needs to make its utilization management criteria more restrictive, the sponsor must first submit an email to the CMS Part D Formularies mailbox (partDformularies@cms.hhs.gov). The subject line of the email should read "CY 2010 PA (or ST) Criteria Change Request – Formulary ID XXXXX". A Microsoft Excel® CY10 UM Criteria Change Template must be attached to the email and should contain the following information:

1. **Affected CY 2010 Formulary ID (FID):** enter only one valid 5-digit CY2010 formulary ID per line item. However, you may enter more than one FID per template.
2. **Current UM Type:** from a drop down menu, select PA type 1, 2 or 3 or ST type 1 or 2.

3. **New PA Type:** from a drop down menu, select PA type 1 or 2. This field is only applicable when adding clinical criteria to a drug with a current PA type of 3. This field will be pre-populated with an "NA" if the current PA type is 1 or 2 or if the Utilization Management chosen is ST and must not be modified.
4. **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.
5. **New PA Group Description**: this field is only applicable when adding clinical criteria to a drug with a current PA type of 3. Enter a new PA group description which is no more than 100 characters in length. The group name may represent a drug category or class or may be the name of the drug if no other group structure applies. **This field will be pre-populated with an "NA" if the current PA type is 1 or 2 or if the Utilization Management chosen is ST and must not be modified.**
6. **PA Criteria Element:** 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 CY2010 HPMS Formulary Submission Module and Reports Technical Manual. Please note the character limits for each element. Any criteria that exceeds authorized character limits as noted in the record layout the will be rejected. This field will be pre-populated with an "NA" if the Utilization Management chosen is ST and should not be modified.
7. **Current UM Criteria:** for each criteria element listed on the UM Criteria Change Template, enter the current UM criteria from the last approved PA or ST text file in HPMS. If your existing PA text file has no PA criteria for the selected element, please enter "NONE". The Current UM Criteria field will be pre-populated with an "NA" if the Utilization Management chosen is PA and the current PA type is 3 and should not be modified.
8. **Revised/new UM Criteria:** for each UM criteria element listed on the UM Criteria Change Template, enter the new or revised clinical UM criteria.
9. **Justification for UM Criteria Change:** enter the justification for the proposed UM criteria change(s). Please include pertinent references such as new safety warnings to support these proposed changes.

The name of each submitted UM Criteria Change Templates should include the FID(s) contained in the document as follows: "CY10 UM_CriteriaChangeTemplate_XXXXX" (where XXXXX represents the 5 digit formulary ID). Multiple FIDs should be separated by an underscore.

CMS will address each request in order of receipt and will only permit UM criteria changes to incorporate new safety information.

Q7: When can a Part D sponsor submit the CMS-approved PA or ST criteria modifications to HPMS?

A7**:** Upon CMS review of the proposed change, an email reply will be sent that contains CMS' decision regarding the requested change. If the change request is approved, the revised PA or ST criteria may be submitted during the subsequent HPMS formulary submission. The revised PA or ST criteria cannot be implemented prior to the effective date of that formulary submission.

Q8: Are Part D sponsors required to receive CMS approval in order to make their existing PA or ST criteria less restrictive?

A8**:** No. If existing PA or ST criteria is made less restrictive, advanced CMS approval is not required prior to implementing the change. However, the enhancements must be reflected in the applicable HPMS PA or ST criteria text file during the next available HPMS formulary submission window.

Q9: Can any additional changes be included in the HPMS PA or ST criteria text files?

A9**:** No. CMS will scrutinize the PA and ST criteria files to ensure that changes are limited to new criteria for new formulary drugs, CMS-approved modifications to existing criteria, and enhancements. Any additional changes to the criteria text files will result in the denial of your entire submission and also subject your organization to a compliance action by CMS.

Q10: Are Part D sponsors required to resubmit supplemental formulary files (free first fill, partial gap or home infusion) with each formulary upload?

A10: No. The previously uploaded versions of these documents must be used provided that there are no differences in the list of drugs that have supplemental coverage. If a new supplemental file is uploaded and the file contains non-allowable changes, the plan(s) will be suppressed in the Medicare Prescription Drug Plan Finder 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.

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

A11: Plan sponsors are reminded that MPDPF pricing files must contain pricing for all drugs included in their current CMS – approved formulary. Since formulary submission dates and MPDPF pricing file submission dates differ, it is imperative that plan sponsors continuously refer to the MPDPF operational calendar to ensure the coordination of formulary and pricing updates. For example, formulary updates submitted between February 1 and February 3, 2010 will be reviewed for approval by February 23, 2010. Plan sponsors should prepare MPDPF pricing files to include pricing information reflecting these formulary changes for submission to DestinationRx on March 1, 2010 –

March 2, 2010. If the submitted formulary file is not approved by 11:59 PM EST on February 23, 2010, plan sponsors should submit MPDPF pricing files reflective of the previously approved formulary.

Appendix A

Formulary File Enhancements
1. Addition of Part D drugs, with or without utilization management
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 utilization management 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 2010 Call Letter
4. Inclusion of additional restrictions to Step Therapy or Prior Authorization criteria 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 drug from a supplemental formulary file (free first fill, partial gap, or home infusion) that was not simultaneously removed from the formulary file
8. Addition of a drug to the home infusion supplemental file that was not simultaneously added to the formulary file.