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 2009 Formulary Updates

DATE: January 15, 2009

This document describes the process for submitting formulary updates for the 2009 contract year. Sponsors are reminded that the earliest effective date for negative formulary changes is March 1, 2009. Negative change requests may be submitted from January 1, 2009 through July 31, 2009; however, only approved changes may be implemented.

CY 2009 Formulary Update Process

Q1: When are the formulary submission windows for CY 2009 formulary updates?

A1: The CY 2009 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2009 Formulary Reference File (FRF) will be available in the CY 2009 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 2009 FRF Release Date	Formulary Submission Window
January 26, 2009	February 2 – 4, 2009
February 23, 2009	March 2 – 4, 2009
March 25, 2009	April 1 – 3, 2009
April 24, 2009	May 1 – 5, 2009
May 22, 2009	June 1 – 3, 2009
June 24, 2009	July 1 – 6, 2009
July 27, 2009	August 3 – 5, 2009
August 25, 2009	September 1 – 3, 2009
September 24, 2009	October 1 – 5, 2009

Q2: Are Part D sponsors required to submit a formulary file each month to HPMS for review and approval?

A2: No. Part D sponsors are only required to submit a file to HPMS when there are changes to the formulary, such as enhancements or negative changes that were previously submitted to and approved by CMS.

Q2: When should new drugs within the six classes of clinical concern be added to the HPMS formulary file?

A2: As outlined in the CY 2009 Call Letter, new drugs or newly approved uses for drugs within the six classes of clinical concern that come onto market after April 21, 2008 are subject to an expedited P&T committee review (90 days). The new drug(s) must be added to the formulary by the end of this 90 day 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 six classes is available on the market on May 12, 2009, the P&T committee must review the drug and add it to the formulary by August 10, 2009. If the P&T committee takes the full 90 days, the drug must be covered at the pharmacy starting on August 10, 2009, and be added to the HPMS formulary file during the September 1-3, 2009 submission window.

Q3: How often may Part D sponsors update their HPMS formulary flat files?

A3: Part D sponsors may update their HPMS formulary flat files once a month, beginning in February 2009. Updated formulary flat files should be submitted one month prior to the intended effective date and should always contain the complete formulary file, not just the formulary changes.

Q4: When uploading my monthly formulary update, what option in HPMS do I choose?

A4: Part D sponsors should use the "Update" option in HPMS to send their complete formulary file and attachments.

Q5: Do Part D sponsors need to complete the effective date field when uploading monthly formulary changes to HPMS?

A5: No. The system will default to an effective date of the first day of the following month.

Q6: What types of changes can be made to the HPMS formulary files?

A6: 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 2009 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, 2009, then the proposed NCR should be sent to CMS on or before March 2, 2009. If the NCR is approved, the negative change should be reflected in the formulary flat file update uploaded during the April 1-3, 2009 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.

Q7: Are Part D sponsors required to resubmit prior authorization and step therapy attachments with each formulary upload?

A7: No. The previously uploaded versions of these documents may be used if there are no changes in the drugs that require prior authorization or step therapy.

However, plan sponsors <u>are required</u> to submit revised prior authorization (PA) and/or step therapy (ST) attachments with each HPMS submission if there are any corresponding formulary file changes. For instance, if a newly approved drug is added to the formulary file with prior authorization requirements, the prior authorization criteria for this new drug must be included with the submission that contains the drug. Similarly, if prior authorization requirements are removed during an upload, the criteria for this drug should also be removed from the prior authorization file. **Except as outlined below, the criteria for existing formulary drugs must not be modified.**

Q8: Can Part D sponsors make HPMS prior authorization criteria more restrictive during a formulary update submission?

A8: Generally, no. Only in extraordinary circumstances may Part D sponsors make modifications to existing PA criteria. We remind sponsors that they must not change their 2009 HPMS PA 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 PA 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. Additionally, since PA criteria have already been available via sponsors' websites, beneficiaries may have made informed decisions based on this information. To permit changes after the annual enrollment period could undermine beneficiaries' enrollment decisions and anticipated drug coverage. As a result, it is CMS' expectation that Part D sponsors will not update PA 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).

Q9: What is the process Part D sponsors should follow to make their existing prior authorization criteria more restrictive?

A9: In the event that a Part D sponsor needs to make its PA 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 2009 PA Criteria Change Request – Formulary ID XXXX". A Microsoft Excel® CY09 PA Criteria Change Template must be attached to the email and should contain the following information:

1. **Affected CY 2009 Formulary ID (FID):** enter only one valid 4-digit CY2009 formulary ID per line item. However, you may enter more than one FID per template.
2. **Current PA Type:** from a drop down menu, select the PA type from the last approved formulary in HPMS; the PA type must be an integer of 1, 2 or 3.
3. **New PA Type:** this field is only applicable when adding clinical criteria to a drug with a current PA type of 3. Enter a new PA type integer of 1 or 2. This field will be pre-populated with an "NA" if the current PA type is 1 or 2 and should not be modified.
4. **Current PA Group Description**: enter the PA Group Description from the last approved formulary and PA 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 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 CY2009 HPMS Formulary Submission Module and Reports Technical Manual (June 8, 2008 release, pg 81-82 Prior Authorization File Instructions and Record Layout). 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.

- **Current PA Criteria:** for each PA criteria element listed on the PA Criteria Change Template, enter the current PA criteria from the last approved PA text file in HPMS. If your existing PA text file has no PA criteria for the selected element, please enter "NONE". The Current PA Criteria field will be pre-populated with an "NA" if the current PA type is 3 and should not be modified.
- **Revised/new PA Criteria:** for each PA criteria element listed on the PA Criteria Change Template, enter the new or revised clinical PA criteria.
- **Justification for PA Criteria Change:** enter the justification for the proposed PA criteria change(s). Please include pertinent references such as new safety warnings to support these proposed changes.

The name of each submitted PA Criteria Change Templates should include the FID(s) contained in the document as follows: "CY09PA_CriteriaChangeTemplate_XXXX" (where XXXX represents the 4 digit formulary ID). Multiple FIDs should be separated by an underscore.

CMS will address each request in order of receipt and will only permit PA criteria changes to incorporate <u>new</u> safety information.

Q10: When may a Part D sponsor submit the CMS-approved PA criteria modifications to HPMS?

A10**:** 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 criteria may be submitted during the subsequent HPMS formulary submission. The revised PA criteria cannot be implemented prior to the effective date of that formulary submission.

Q11: Are Part D sponsors required to receive CMS approval in order to make their existing PA criteria less restrictive?

A11**:** No. If existing PA criteria is made less restrictive, advanced CMS approval is not required prior to implementing the change. However, the applicable enhancements must be reflected in the HPMS PA text file during the next available HPMS formulary submission window.

Q12: Can any additional changes be included in the HPMS PA text files?

A12**:** No. CMS will scrutinize the PA criteria files to ensure that changes are limited to new criteria for new formulary drugs, CMS-approved modifications to existing PA criteria, and enhancements. Any additional changes to the PA text file will result in the denial of your entire submission and also subject your organization to a compliance action by CMS.

Q13: Will Part D sponsors be notified when their formularies are approved?

A13: The current HPMS formulary contact and the user who submitted the formulary should receive an HPMS-generated email upon conditional approval or denial of a formulary version. Additionally, plan sponsors should utilize the HPMS Formulary Status History Report to view the status of each version of the submitted formulary.

Q14: How should Part D sponsors coordinate formulary submissions and MPDPF pricing file submissions?

A14: 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 2 and February 4, 2009 will be reviewed for approval by February 24, 2009. Plan sponsors should prepare MPDPF pricing files to include pricing information reflecting these formulary changes for submission to DestinationRx on March 2, 2009 – March 3, 2009. If the submitted formulary file is not approved by 11:59 PM EST on February 24, 2009, 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. Prior authorization (PA) enhancements • Removal of prior authorization requirements for a drug (i.e. changing PA type to 0) • Changing to a less restrictive PA type (e.g. changing from PA type 1 to PA type 2 OR changing from PA type 2 to PA type 3 when appropriate)
4. Removal of quantity limit restrictions
5. Making existing quantity limits less restrictive (e.g. increasing the allowable quantity limit amount without changing the quantity limit days supply)
6. Step therapy (ST) enhancements • Removal of entire step therapy 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 step therapy 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 step therapy protocols
Negative Formulary File Changes
1. Removal of FRF proxy codes
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)
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 2009 Call Letter
4. Inclusion of additional restrictions to Step Therapy or Prior Authorization criteria in formulary attachments 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