DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Beneficiary Choices

MEMORANDUM

TO: All Part D Plan Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

RE: Updating CY 2008 Formularies

DATE: November 28, 2007

This document outlines the operational details regarding December 2007 and January
2008 formulary enhancement windows for CY 2008 formularies and the process for
submitting formulary updates throughout the 2008 contract year.

CMS is revising the process by which Part D plan sponsors may request negative
formulary changes. Detailed user instructions regarding the HPMS negative formulary
change submission process will be provided at a later date. This memo relates to the
submission of HPMS formulary files <u>only</u>.

December 2007 and January 2008 Formulary Enhancement Windows

CMS is offering plan sponsors additional opportunities to enhance formularies prior to
the standard formulary update cycle. The December and January submission periods are
limited to formulary enhancements only. Formulary submission gates will be opened
between 12:00 AM EST on December 3, 2007 and 11:59 PM EST on December 5, 2007.
The January submission window will be from 12:00 AM EST on January 2, 2008 to
11:59 PM EST on January 4, 2008. An updated Formulary Reference File will be
available in the HPMS formulary submission module for the December and January
windows on November 26, 2007, and December 24, 2007, respectively. The formulary
enhancements that can be submitted during any of the remaining scheduled CY 2008
submission windows are outlined in Appendix A. Any file containing changes not
considered by CMS as an enhancement will be denied.

Given the additional enhancement windows and the monthly update cycle for CY 2008,
CMS will no longer be accepting formulary enhancement <u>forms</u> for CY 2008
formularies. **Any plan sponsor that has previously submitted a CY 2008 formulary
enhancement <u>form</u> must make all applicable changes to their HPMS formulary <u>files</u>
during the December 2007 submission window.** Plan sponsors are reminded that the
marketed formulary and CMS-approved HPMS formulary must be consistent. As such, it

is in the sponsor's best interest to ensure that formulary submissions contain only allowable changes so that the intended formulary enhancements may be marketed.

CY 2008 Formulary Update Process

Q1: **When are the formulary submission windows for CY 2008 formulary updates?**

A1: The CY 2008 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2008 Formulary Reference File (FRF) will be available in the CY 2008 HPMS Formulary Submission Module. The submission window begins at 12:00 AM EST on the opening date and closes at 11:59 PM EST on the closing date. Any formulary submission that is not successfully uploaded and validated prior to the submission deadline will be denied.

Please note that the last day to submit negative formulary change requests for CY 2008 formularies will be July 31, 2008.

CY 2008 FRF Release Date	Formulary Submission Window
November 26, 2007	December 3 – 5, 2007
December 24, 2007	January 2 – 4, 2008
January 25, 2008	February 1 – 5, 2008
February 25, 2008	March 3 – 5, 2008
March 25, 2008	April 1 – 3, 2008
April 24, 2008	May 1 – 5, 2008
May 23, 2008	June 2 – 4, 2008
June 24, 2008	July 1 – 3, 2008
July 25, 2008	August 1 – 5, 2008
August 25, 2008	September 1 – 3, 2008
September 24, 2008	October 1 – 3, 2008
October 27, 2008	November 3 – 5, 2008

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

A2: No. Plan 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 and approved by CMS.

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 December 2007. 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: Plan sponsors should use the "Update" option in HPMS to send their complete formulary file and attachments.

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

A5: Yes, a formulary effective date must be associated with each formulary update. A future date may be entered; otherwise this date will default to 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 2008 submission window. As noted above, the December and January windows are for enhancements only.

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 then 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) and may not be implemented or marketed.

Q7: **Are plan 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 are required to submit their prior authorization and step therapy 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. **The criteria for existing formulary drugs must not be modified.**

Q8: **Will plan sponsors be notified when their formularies are approved?**

A8: 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.

Q9: **How should plan sponsors coordinate formulary submissions and MPDPF pricing file submissions?**

A9: 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 5, 2008 will be reviewed for approval by February 19, 2008. Plan sponsors should prepare MPDPF pricing files to include pricing information reflecting these formulary changes for submission to DestinationRx on February 25, 2008 - February 26, 2008. If the submitted formulary file is not approved by 11:59 PM EST on February 19, 2008, plan sponsors should submit MPDPF pricing files reflective of the previously approved formulary.

Appendix A

Formulary 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 requirements
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)
6. Step therapy 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 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 (excluding 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 OR increasing the quantity limit days without changing the quantity limit amount)

Non-Allowable Changes
1. Change in formulary classification
2. Change in the category or class names for a formulary drug
3. Addition of proxy codes to a specialty tier that do not meet the cost criteria as outlined in the CY 2008 Call Letter
4. Additional restrictions to Step Therapy or Prior Authorization criteria in formulary attachments
5. Removal of prerequisite (e.g. Step 1 drugs) from existing step therapy protocols