DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Drug and Health Plan Choice

MEMORANDUM

TO: All Part D Plan Sponsors

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

RE: CY 2009 Formulary Enhancement Window and Marketing Information

DATE: September 19, 2008

CMS is providing Part D sponsors an opportunity to enhance their Part D formularies prior to the Annual Coordinated Election Period. In addition to making formulary enhancements, Part D sponsors must also utilize this submission window to:

1. Modify the applicable prior authorization (PA) and/or step therapy (ST) criteria (only if you received a CMS communication on September 5, 2008 regarding your criteria), and
2. Add newly approved drugs from the six classes of clinical concerns, as outlined on page 55 of the CY 2009 Call Letter.

Formularies and PA and ST files must be submitted between 12:00 AM EDT on October 1, 2008 and 5:00 PM EDT on October 6, 2008. Any technical difficulties encountered upon upload or during validation of your formulary should be brought to the attention of the HPMS help desk (800-220-2028, hpms@cms.hhs.gov) prior to the window closing. 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.

Formulary changes must be limited to enhancements, as described in this memo, as well as modifications to PA and/or ST criteria as directed by CMS in the September 5, 2008 email notification to Part D plans with criteria review concerns. Any formulary files that contain negative changes, including the addition of a limited access indicator, or changes not otherwise described within this memo will be denied. Finally, failure to correct applicable PA and/or ST criteria review concerns with this submission will result in suppression in the Medicare Prescription Drug Plan Finder.

Please refer to the following formulary and marketing questions and answers regarding this formulary window. If you have any questions, please email the Part D Formularies mailbox at PartDformularies@cms.hhs.gov.

CY 2009 Formulary Enhancements

Q1: Will CMS provide an update to the Formulary Reference File (FRF) for this enhancement window?

A1: Yes. The October update to the FRF will be available in the HPMS CY 2009 Formulary Submission Module on September 24, 2008.

Q2: What types of formulary changes can be made during this submission window?

A2: This submission window is for formulary enhancements only. The types of formulary changes that CMS considers enhancements are outlined in Attachment 1.

Q3: What changes can be made to the PA and ST formulary attachments during the October window?

A3: If you received a notification on September 5, 2008 regarding PA and/or ST criteria that were determined to be unacceptable by CMS reviewers, you must modify the specific criteria as necessary. The changes must be limited to those elements identified by CMS reviewers. PA and ST criteria changes that were not part of the CMS communication are not permitted (except for removal of PA or ST requirements).

Q4: How does this submission window relate to the Medicare Prescription Drug Plan Finder (MPDPF)?

A4: CY 2009 formulary approvals and denials will be entered into HPMS on October 21, 2008. Pricing data submissions due during the Monday, October 27, 2008 – Tuesday, October 28, 2008 submission window should reflect the most recently approved HPMS formulary data as of October 22, 2008. If your October submission is conditionally approved, the updated formulary information will be available for display in MPDPF on November 10, 2008.

Q5: How will Part D sponsors know which drugs from the six classes of clinical concern will be required to be added to their formularies?

A5: CMS will provide an email communication to Part D sponsors before the October formulary submission window that will contain a list of missing drugs from the six

classes of clinical concern. This will be limited to those drugs that came onto the market between April 21, 2008 and the October submission window. As outlined on page 56 of the CY 2009 Call Letter, these drugs must be added to formularies within 90 days of market availability, subsequent to P&T Committee review.

Q6: If a Part D sponsor wishes to make further enhancements beyond the October submission window, can these enhancements be included in plan marketing materials and websites?

A6: Yes. If an organization has decided to enhance their formulary outside of an HPMS formulary submission window, these enhancements can be included on marketed formulary information. However, the enhancements must be limited to those listed in Attachment 1. Further, an HPMS formulary file reflective of these enhancements must be resubmitted during the next available submission window.

Q7: Regarding the posting of PA criteria on Part D plan websites, does criteria need to be posted if the PA requirement is a Part B versus Part D determination only?

A7: Yes. For drugs identified as PA Type 3 on the HPMS formulary file (Part B versus Part D PA only), the following statement must be included on Part D plan websites as the PA criteria for those drugs: “This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.”

Q8: Should the supplemental formulary files (free first fill, partial gap, and home infusion) be updated with this submission?

A8: When submitting this formulary update, you are given a choice either to use the last supplemental file(s) submitted or upload new file(s). New supplemental files should only be submitted if you are adding drugs to the HPMS formulary file, and these additional drugs will be part of your free first fill, partial gap, or bundled home infusion programs.

Attachment 1.

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. 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)
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)