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CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

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

RE: CY 2012 Formulary Information

DATE: January 17, 2012

This memorandum provides operational guidance to Part D sponsors regarding the processes that must be followed to update CY 2012 formularies. This also serves as a reminder of Part D requirements with respect to drug utilization review (DUR), and which types of restrictions or edits must be submitted to CMS for review.

Formulary Requirements and Drug Utilization Review

On October 22, 2010, CMS issued a reminder to Part D sponsors regarding the types of restrictions that must be included in the HPMS formulary submission. This reminder was necessary as CY 2010 Part D audits revealed that a number of sponsors had implemented point of sale (POS) edits that were not included on the HPMS formulary file and were not considered POS safety edits. However, as we continue work on developing guidance relating to inappropriate overutilization, it is evident that not all Part D sponsors are utilizing the formulary management and DUR tools that are available to them. We are thus providing the following clarifying questions and answers to assist sponsors in determining the types of edits and restrictions relating to the detection and prevention of inappropriate utilization that must be included in the HPMS formulary submission.

Q1: Do edits that prevent the dispensing of doses of drugs in excess of the FDA-approved maximum dose need to be included in the HPMS formulary submission?

A1: No. As per section 30.2.2.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, these types of edits would be considered a safety edit and would not be required to be submitted to CMS on the HPMS formulary file. For example, the FDA – approved labeling of a hydrocodone bitartrate and acetaminophen (APAP) 5/325 mg tablet states that the daily dose should not exceed 8 tablets. As such, an edit limiting the dispensing of the drug to no more than eight tablets a day would not require submission to CMS for approval. Part D sponsors should also consider total APAP dosing in their concurrent

DUR edits. An edit that prevents the dispensing of a drug or combination of drugs that would result in a daily APAP dose in excess of 4,000 mg is considered a safety edit and is not required to be submitted to CMS for review.

Q2: Can a Part D sponsor submit a quantity limit (QL) restriction to CMS for review for drugs that do not have a defined maximum dose in the FDA – approved labeling, or for doses that are below the FDA – labeled maximum dose?

A2: Yes. In these types of scenarios, Part D sponsors are permitted to submit QL restrictions to CMS for approval. For example, the approved labeling for an extended-release oxycodone product states that there is no defined maximum dose. However, should a Part D sponsor wish to set a QL on the drug, the QL must be submitted to CMS for review and approval.

Q3: Can QLs be added during the plan year?

A3: Yes, provided that the QL addition request was submitted to and approved by CMS in accordance with section 30.3.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual and HPMS submission requirements. As outlined in the manual chapter, the addition of QLs during the plan year is considered a non – maintenance change and thus can be applied to new starts only.

CY 2012 Formulary Update Process

Sponsors are reminded that the earliest effective date for negative formulary changes is March 1, 2012. Maintenance negative change requests may be submitted via the HPMS Negative Formulary Change Request (NCR) Module from December 30, 2011 through July 31, 2012 and non-maintenance negative change requests may be submitted from December 30, 2011 through April 30, 2012; however, only approved changes may be implemented.

Q1: When are the formulary submission windows for CY 2012 formulary updates?

A1: The CY 2012 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2012 Formulary Reference File (FRF) will be available in the CY 2012 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 2012 FRF Release Date	Formulary Submission Window
January 25, 2012	February 1 – 3, 2012
February 23, 2012	March 1 – 5, 2012
March 26, 2012	April 2 – 4, 2012
April 24, 2012	May 1 – 3, 2012
May 25, 2012	June 1 – 5, 2012
June 25, 2012	July 2 – 5, 2012
July 25, 2012	August 1 –3, 2012
August 28, 2012	September 4 – 6, 2012
September 24, 2012	October 1 – 3, 2012

Q2: Will CMS utilize the line-level review process for CY 2012 formulary updates?

A2: Yes. Part D sponsors will continue to submit partial formulary update files and CMS will perform line-level reviews on these updates. Partial formulary files must be submitted during the aforementioned formulary submission windows. CMS will review changes at the individual line level, approving or denying each individual change, as opposed to the file as a whole. Upon the Part D sponsors' acceptance of the CMS line-level decisions, a new version of the formulary containing only the allowable changes will be created. In the event that a sponsor denies CMS' line-level review decisions, 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 timelines below detail the dates in which CMS will complete the line-level review and the deadline in which Part D sponsors must accept or deny the new version. Please note that any formulary versions that are not accepted by the sponsor by the stated deadline will be denied and the formulary will revert to the last approved version in HPMS. **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 14, 2012	February 15, 2012
March 14, 2012	March 15, 2012
April 11, 2012	April 12, 2012
May 22, 2012	May 23, 2012
June 20, 2012	June 21, 2012
July 18, 2012	July 19, 2012

August 15, 2012	August 16, 2012
September 19, 2012	September 20, 2012
October 17, 2012	October 18, 2012

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, 2012, the P&T committee must review the drug and add it to the formulary by August 10, 2012. If the P&T committee takes the full 90 days, the drug must be covered at the pharmacy starting on August 10, 2012, and be added to the HPMS formulary file during the September 4-6, 2012 submission window. **Failure to include a protected class drug during the required HPMS formulary submission window will result in 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 2012 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, 2012, then the proposed NCR should be sent to CMS on or before March 2, 2012. If the NCR is approved, the negative change should be reflected in the partial formulary file update uploaded during the April 2-4, 2012 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 CMS denial of submitted 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 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.

Q5: What process should be followed when adding a new drug to the formulary file that will be included in an existing prior authorization group description (PAGD) or step therapy group description (STGD)?

A5: Depending on how a sponsor's specific utilization management criteria are written, the process for adding new drugs to a formulary file that will be included in existing criteria will vary. If, for example, the drug you are adding will be a step 1 drug in an existing STGD, and the criteria for that group does not specify the step 1 drugs by name, the plan sponsor will simply update the formulary file record to add the new drug into the existing STGD. Since no change to the actual criteria is necessary, the plan sponsor will not be required to upload a new ST file.

In contrast, if a sponsor's STGD criteria specifically lists the step 1 drugs by name, then the new step 1 drug cannot be added to the existing STGD. In order to expedite the addition of the new step 1 drugs to the formulary file, a new STGD should be created with the appropriate criteria and stepped drugs included.

Similar logic should be applied when drugs are being added to the formulary file that may fit into an existing PAGD. **CMS will not open PA or ST submission gates for criteria medication in order to accommodate the addition of drugs to existing PA or STGDs.**

Q6: Are Part D sponsors required to receive CMS approval in order to make changes to their existing PA or ST criteria?

A6**:** Yes. CMS approval is required before making changes to existing PA or ST criteria, regardless of whether the sponsor considers the change to be a restriction or an enhancement. 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 PA criteria should already have been evaluated for clinical accuracy by the P&T committee prior to submission of the formulary to CMS. It is CMS' 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., FDA release of a new Black Box warning). **All changes to existing PA and ST criteria must receive CMS approval before being implemented, including enhancements.**

Q7: What is the process Part D sponsors should follow to make changes to their existing utilization management criteria?

A7: In the event that a Part D sponsor needs to make changes to its utilization management criteria, whether it is considered more restrictive or an enhancement, 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 2012

PA (or ST) Criteria Change Request – Formulary ID XXXXX". A Microsoft Excel® CY 2012 UM Criteria Change Template must be attached to the email and should contain the following information:

1. **CY 2012 Formulary ID (FID):** enter only one valid 5-digit CY 2012 formulary ID per line item. However, you may enter more than one FID per template.
2. **Type of Change:** from a drop down menu, select Enhancement or More Restrictive.
3. **Current UM Type:** from a drop down menu, select PA type 1, 2 or 3 or ST type 1 or 2.
4. **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.
5. **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.
6. **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.**
7. **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 CY 2012 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.
8. **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.
9. **Revised/new UM Criteria:** for each UM criteria element listed on the UM Criteria Change Template, enter the new or revised clinical UM criteria.
10. **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 Template should include the FID(s) contained in the document as follows: "CY12 UM_CriteriaChangeTemplate_XXXXX"

(where XXXXX represents the 5 digit formulary ID). Multiple FIDs should be separated by an underscore.

Q8: When can a Part D sponsor submit the CMS-approved PA or ST criteria modifications to HPMS?

A8**:** 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 Revise PA/ST criteria gate will be opened in HPMS for the specific PAGD or STGD to allow for the submission of the revised criteria. The revised PA or ST criteria may be implemented upon receipt of CMS' approval.

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 and CMS-approved modifications to existing criteria. Any additional changes to the criteria text files will subject your organization to a compliance action by CMS.

Q11: Are Part D sponsors required to resubmit supplemental formulary files (free first fill, partial gap or home infusion) with each formulary upload?

A11: 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 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.

Q12: How should Part D sponsors coordinate formulary submissions and MPF pricing file submissions?

A12: 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 1 and February 3, 2012 will be reviewed for approval by February 22, 2012. Plan sponsors should prepare MPF pricing files to include pricing information reflecting these formulary changes for submission to DestinationRx from February 27-28, 2012. If the submitted formulary file is not approved by 11:59 PM EST on February 22, 2012,

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 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 2012 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.