DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

TO: All Part D Sponsors

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

RE: Miscellaneous 2008 Part D Formulary Issues

DATE: February 1, 2008

This letter provides an update on several issues related to 2008 Part D sponsor formularies. Recently, CMS received questions addressing updates to prior authorization criteria, the impact on formularies when Part D drugs become eligible for over-the-counter (OTC) status during the contract year and clarification with respect to situations in which Part D sponsors determine retrospectively that beneficiaries are receiving drugs for a "non-medically-accepted indication." The following attachments contain a series of formulary-related questions and answers related to these inquiries.

The clarification that we provide on these issues will also be incorporated in a forthcoming update to Chapter 6 of the prescription drug benefit manual.

Thank you for your attention to these matters.

For questions related to submission and revision of prior authorization criteria please contact:

- Robert Dombrowski (robert.dombrowski@cms.hhs.gov) or (410) 786-5450,
- Kady Flannery (kathleen.flannery@cms.hhs.gov) or (410) 786-6722,
- Lorelei Piantedosi (lorelei.piantedosi@cms.hhs.gov) or (410) 786-8651.

For operational questions related to legend drugs that become OTC during the sponsor year please contact:

- Kady Flannery (kathleen.flannery@cms.hhs.gov) or (410) 786-6722.

For policy questions on these topics please contact:

- LCDR Greg Dill (gregory.dill@cms.hhs.gov) or (312) 353-1754.

Attachments

Attachment I	*Prior Authorization Criteria*
Attachment II	*Conversion of formulary product from legend to OTC status*
Attachment III	*Retrospective Review and Discovery of Non-Medically Necessary Indications*

Attachment I

Prior Authorization Criteria

The following questions and answers address common inquires related to sponsor submitted HPMS prior authorization (PA) criteria.

Question 1

Can a Part D sponsor make its HPMS PA criteria more restrictive during a formulary update submission?

Answer 1

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 2008 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 Pharmacy and Therapeutics Committee has completed a thorough review of proposed PA criteria prior to submission of the formulary to CMS. Additionally, during the annual enrollment period, beneficiaries may request and receive information related to prior authorization criteria to make informed decisions. 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).

Question 2

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

Answer 2

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 "PA Criteria Change Request – Formulary ID XXXX". A Microsoft Word document containing the proposed changes must be attached and be consistent with the following format:

> *PA Group Description (from formulary flat file):*
>
> *Affected Drugs (from formulary flat file with the PA group description(s) identified above)*:
>
> *Revised PA Criteria:* Note – this should be a tracked version of the existing criteria, modified to show the proposed criteria.

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

Question 3
When may a Part D sponsor submit the CMS-approved PA criteria modifications to HPMS?

Answer 3
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 in the format specified in Answer 5 below. The revised PA criteria cannot be implemented prior to the effective date of that formulary submission.

Question 4
Are Part D sponsors required to receive CMS approval in order to make their existing PA criteria less restrictive?

Answer 4
No. When sponsors are modifying their criteria to indicate coverage for new medically-accepted indications or making existing criteria less restrictive, they are not required to notify CMS of such mid-year changes. However, they should make the applicable enhancements in their PA criteria document, as described in Answer 5, during the next available HPMS formulary upload window.

Question 5
Should Part D sponsors continue to submit a comprehensive PA criteria document similar to what was uploaded with the initial formulary submissions?

Answer 5
No. Beginning with the March 3-5, 2008 formulary submission window, CMS will require Part D sponsors to submit a PA criteria document containing only criteria changes. These changes may include CMS-approved negative (more restrictive) changes, PA criteria enhancements (less restrictive), and the addition of PA criteria for new formulary drugs requiring PA. The HPMS PA attachments submitted as of March 3, 2008 should have the following title:

PA Criteria Update – Formulary ID XXXX
(Revision date: MM/DD/YYYY)

If there are no modifications to the PA criteria compared to the approved formulary as of March 3, 2008, sponsors should simply submit a 1 page Microsoft Word document containing the statement: "*No PA Criteria Changes"* underneath the aforementioned title. Sponsors will continue to submit this document with the "no changes" statement until PA criteria changes are included, at which time sponsors should follow the instructions below.

If there are PA criteria modifications, then the HPMS PA attachment should be submitted in the following format:

PA Criteria Update – Formulary ID XXXX
(Revision date: MM/DD/YYYY)

CMS-approved PA Criteria Revisions: This section should include the more restrictive PA criteria changes as approved by CMS (as a tracked version of the original criteria), including the PA group description(s), affected drug(s), and revised criteria.

PA Enhancements (less restrictive): The PA group description(s), affected drug(s), and revised criteria (also as a tracked version of the original criteria) should be included in this section for any drugs for which the PA criteria has been enhanced.

New Formulary Drug(s) PA Criteria: This section should include the PA group description for new formulary drug(s) requiring prior authorization, the affected drug(s), and the applicable PA criteria.

The PA Criteria Update document should be appended, as applicable, with each HPMS formulary submission. For example, a formulary approved as of February 22, 2008 would contain the comprehensive PA criteria to that point. The PA criteria attachment submitted with the formulary update on March 3, 2008 would contain only the PA Criteria Update document (following the above format) with changes in existing criteria and/or criteria for new formulary drugs, as applicable. Each subsequent formulary submission would include all changes contained in the March 3-5, 2008 PA criteria submission, as well as any additional changes that occur thereafter. The revision date should be updated each time new or revised criteria are appended to the PA Criteria Update document. For months when no new or revised criteria are applicable, sponsors should upload the previous month's version of the PA Criteria Update document.

Attachment II

Conversion of formulary product from legend to OTC status

The following questions and answers address common inquires related to the conversion of formulary products from legend to over-the-counter (OTC) status.

Question 1
When a legend drug changes to an OTC drug (e.g., New Drug Application (NDA) to OTC NDA), what satisfies the definition of a Part D drug?

Answer 1
Existing inventory of the previous legend product (which maintains the NDA FDA label and corresponding NDC number) is still considered a Part D drug.

The newly approved OTC version of the drug (which maintains the OTC label and NDC number) is an excluded drug.

Question 2
When can sponsors remove recently converted legend products from their formulary?

Answer 2
Sponsors will not be required to submit a change request to remove recently converted OTC products. CMS will remove the legend FRF proxy at the next available FRF update following market availability of the OTC product. For example, if the OTC version was to become available on March 15, 2008, then the FRF proxy would be removed on the March 26, 2008 FRF update. Consequently sponsors would need to remove the legend FRF proxy from their formulary for submission of their April 1, 2008 formulary file upload.

Question 3
When the legend FRF proxy is dropped, will sponsors have to add additional drugs to satisfy CMS formulary requirements?

Answer 3
Sponsors will still be accountable for CMS formulary requirements (i.e., two drugs per category and class) and should evaluate their formulary relative to the removal of a newly converted OTC drug. For example, any sponsor that does not continue to satisfy the two drugs per category and class requirement because of the removal of a recently converted OTC drug at the next formulary submission window will have their formulary file rejected in HPMS. Including the newly converted OTC product as part of the sponsor's utilization management program will not satisfy CMS formulary requirements.

Question 4
If there is remaining inventory of the legend product, even after OTC availability, may sponsors continue to permit adjudication of the residual inventory for those currently taking the product under Part D?

Answer 4
Yes. Sponsors are not required to remove the legend version of the OTC product from their adjudication file as long as the market holds residual inventory.

Question 5
Are sponsors required to provide beneficiaries with notice prior to removal of the legend product?

Answer 5
Given the market may not hold 60 days of legend product after FDA OTC approval, CMS strongly recommends prospective beneficiary notice of the drug's removal containing the same notice information used for other types of formulary changes (see section 30.3.4 of Chapter 6 of the Prescription Drug Benefit Manual) as soon as the OTC conversion is announced by FDA.

Question 6
Can sponsors implement new step therapy protocols with the transitioned OTCs mid-year?

Answer 6
No. Sponsors cannot add or modify step therapy protocols mid-year. However, as part of administrative costs, sponsors could make newly transitioned OTC products available through their broader utilization management program at no cost to their enrollees.

Attachment III

Retrospective Review and Discovery of Non-Medically Necessary Indications

The following question and answer addresses common sponsor inquires related to retrospective discovery of "non-medically-accepted indications."

Question

What should Part D sponsors do when they retrospectively determine that they have been covering drugs that were prescribed for other than a medically-accepted indication?

Answer

As we stated in the preamble to our January 2005 Part D final regulations, Part D sponsors have flexibility to decide how to monitor whether a particular drug is prescribed for a medically-accepted indication, as defined in section 1927(k)(6) of the Act, for a particular individual. We understand that it would not be feasible for sponsors to prospectively evaluate every prescription for the presence of a diagnosis supporting a medically-accepted indication. Therefore, we expect that in most cases, sponsors will operate under the assumption that dispensed drugs have been prescribed by physicians in line with widely accepted guidelines and for a medically-accepted indication, absent any indication to the contrary.

Nonetheless, Part D sponsors may retrospectively identify and confirm – either as part of their retrospective review programs required under 42 CFR 423.153, or incident to another utilization management review – that a dispensed drug was not prescribed for a medically-accepted indication for a particular individual (see the example below, in which this occurred because a dosage issue resulted in the case being flagged).

> Example: An individual receives a prescription and takes a drug within a common dosing regimen (i.e., one tablet daily). Several months later, that individual's physician writes a new prescription for an increased dosage of that drug. The second prescription triggers a quantity limit (for example, based on safety limits) and, as a result, the individual's physician submits evidence to support an exception to the quantity limit. Based on that evidence, the sponsor makes a determination that the drug was not prescribed for a medically-accepted indication.

When it was not reasonable to expect a sponsor to require prior authorization to ensure a drug is being used for an accepted medical indication, we would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees. However, Part D sponsors must send notice of coverage determination decisions to affected enrollees (i.e., those for whom a coverage determination is made based on lack of evidence of a medically-accepted indication) in accordance with the rules provided in 42 CFR §423.566 through 423.576. Such notification must include the following information:

- The name of the affected covered Part D drug,
- The reason why the sponsor is no longer covering the drug for the member,
- Alternative drugs on the sponsor formulary, and expected cost-sharing for those drugs, and
- The enrollee's right to a redetermination.

We expect a Part D sponsor to consider the enrollee's health situation, and continue to cover the drug to the extent it determines that doing so is necessary to avoid risk to the enrollee's health while providing for a transition to another form of treatment.

We also remind sponsors that this clarification does not affect our expectation that claims for drugs that could be covered under either Part B or Part D are evaluated to ensure appropriate coverage and payment. As provided in section 20.2.2 of Chapter 6 of the Prescription Drug Benefit Manual, sponsors are expected to meet the appropriate due diligence standards with regard to making coverage determinations about Part B versus Part D coverage. A sponsor would be expected to reverse claims in line with their contracts, and/or obtain payment from enrollees, for drugs retrospectively found to have been prescribed for a use that would be covered under Part B.