



CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

Date: October 3, 2007

To: All Part D Sponsors

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

Subject: Addition of Part D Drugs to Conditionally Approved CY 2008 Formularies

Since the release of the March 21, 2007, CY 2008 Formulary Reference File (FRF) certain drugs have come on the market that plans may need to include on their formularies and CMS is providing a one time exception window to accommodate adding these drugs to CY 2008 formularies. The following memo documents the instructions for plans to add only these specific medications to their formularies.

After the release of the March 2007 Formulary Reference File a new antineoplastic medication (lapatinib) became available. Since this medication was available on the market prior to April 16, 2007, and is within one of the six classes of clinical concern, it must be added to all sponsors' CY 2008 formularies. CMS is offering Part D plan sponsors a one time limited opportunity to add this medication to their CY 2008 formularies to be in compliance with CMS requirements. In addition, CMS is offering Part D plan sponsors an opportunity to add several new drugs, including some first-time generics that have become available on the market since the most recent FRF update.

The currently approved HPMS formulary data will be displayed in the Medicare Prescription Drug Plan Finder (MPDPF) on October 11, 2007, therefore **plan sponsors cannot make any negative changes to their conditionally approved formulary files.** CMS is offering this limited addition window due to extraordinary circumstances. Due to the limited submission and review timeframe, the only changes that can be made to previously approved HPMS files is formulary additions. **Formulary submissions that contain negative or non-allowable changes will be denied.** Formularies that are submitted and conditionally approved during this limited formulary addition window will be displayed in the MPDPF on November 19, 2007. Please refer to the following operational questions and answers regarding this formulary addition window.

CY 2008 Limited Formulary Addition Window

Q: When can the formulary updates be submitted?

A: Formularies must be submitted to HPMS between 12:00 AM EDT on October 11, 2007 and 11:59 PM EDT on October 15, 2007.

Q: How can plan sponsors obtain the updated version of the CY 2008 FRF?

A: The updated CY 2008 FRF and change report will be available for download in the HPMS formulary submission module on October 5, 2007. Please note that the proxy NDC code has changed for two products: Ortho-Novum® 1/35-28 and Ortho Tri-Cyclen®. If these products are on your conditionally approved formulary, please replace the existing proxy codes with the newly added proxy codes.

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

A: As opposed to the limited August submission window, the October 2007 submission window is for **formulary additions only**. The formulary status of drugs on the currently approved formulary can not be modified. This includes, for example, changes to the therapeutic category or class fields, tier level value, prior authorization (PA), step therapy (ST), or quantity limits (QL) edits or criteria, or specialty pharmacy indicators. In addition, plan sponsors must ensure that formulary additions are made in accordance with existing CMS formulary policy. As such, PA and ST edits for new formulary drugs within the six classes of clinical concern must be limited to new starts only, and are not permitted on antiretroviral drugs. Further, plan sponsors must ensure that only new formulary drugs with a plan-negotiated price in excess of \$600 per month are included in a specialty tier. **Formulary submissions that contain non-allowable changes will be denied.**

Q: How will this formulary submission affect our Medicare Prescription Drug Plan Finder (MPDPF) Price File (PF) submissions?

A: The formulary approvals and denials will be entered into HPMS on October 30, 2007. As such, the pricing data submission due on November 5-6, 2007 should reflect the most recently approved HPMS formulary data as of October 31, 2007. The updated approved formulary data will be displayed in the MPDPF on November 19, 2007.

If you have any questions regarding this formulary additions window, please contact Lorelei Piantedosi at 410-786-8651 or Robert Dombrowski at 410-786-5450.