

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



## CENTER FOR BENEFICIARY CHOICES

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### MEMORANDUM

**DATE:** July 21, 2006

**Memorandum to:** All Part D Plan Sponsors

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

**Subject:** Expedited Review of New Drugs or New Indications for Drugs  
In the Six Classes of Clinical Concern Reminder

Recently, several new drugs or new indications for drugs within the six classes of clinical concern have been approved by the Food and Drug Administration. In the 2007 formulary guidance, we indicated an expectation that any new drug or new indication for a drug within the six classes of clinical concern, that was approved after April 17, 2006, will be subject to an expedited Pharmacy and Therapeutics (P&T) committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. Therefore, these new drugs or new indications for drugs now within the six classes of clinical concern need to be reviewed and acted upon by P&T committees within 90 days of release onto the market. Plans may add new drugs to their 2007 formularies at any time to accommodate P&T decisions.

Again, thank you for your participation in the Medicare prescription drug benefit. While we have had many successes, it is important that we continue to improve. If you have any questions or comments about formulary requirements, please contact Denise Von Rintel ([denise.vonrinteln@cms.hhs.gov](mailto:denise.vonrinteln@cms.hhs.gov)) or Brian Martin ([brian.martin@cms.hhs.gov](mailto:brian.martin@cms.hhs.gov)).