Summary of 2007 Medicare Part D Formulary Guidelines

The Centers for Medicare & Medicaid Services (CMS) has issued its final guidelines for 2007 regarding Medicare Part D formularies. The guidelines for 2007 are largely the same as the guidelines that CMS applied in 2006, although there are some changes relevant to oncology, summarized below.

Antineoplastics

The 2006 guidance required formularies to include substantially all antineoplastics, as well as substantially all drugs in five other classes, to ensure that patients taking a particular drug before the start of the Part D program could continue to obtain it under Part D.[1] The 2007 guidance extends this requirement and no longer links the requirement to maintaining access to drugs that a patient is currently taking. Part D plan formularies for 2007 are required to include all antineoplastic drugs, including unique dosage forms, that are available on April 17, 2006, with certain minor exceptions.

Within the class of antineoplastic drugs, Part D plans may identify preferred drugs and impose utilization controls, such as requirements for prior authorization or for failure on one drug before a non-preferred drug can be used. If a Part D enrollee is currently on a particular antineoplastic, however, such utilization controls are not permitted with respect to that enrollee and drug..

New Antineoplastics and New Indications for Antineoplastics

Ordinarily, Part D plans are required to review new drugs and new indications for approved drugs and decide whether to add the new drugs or indications to their formularies within 180 days after the product is first marketed. In the case of antineoplastics and the five other classes of drugs subject to universal formulary coverage, however, CMS has shortened that period to 90 days for 2007. Prior to the time that a new drug is on a plan's formulary, an enrollee can seek coverage of the drug through the exceptions process.

Specialty Tiers

Part D plans are permitted to use a tiered copayment structure in which enrollees pay lower copayments for preferred drugs than for non-preferred drugs. Ordinarily, a plan must have an exceptions process by which an enrollee can seek to have a drug in a high copayment tier treated as being in a lower copayment tier if the drug is medically necessary for the enrollee. Plans, however, are entitled to establish a "specialty tier" for high cost drugs that the exceptions process does not apply to.

Under the guidance for 2007, use of the specialty tier is limited to drugs that cost more than $500 per month, and coinsurance for drugs in the specialty tier is limited to 25 percent.

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[1] The other classes are immunosuppressants, antidepressants, antipsychotics, anticonvulsants, and antiretrovirals.