



CMA Weekly Alert – June 16, 2005

## **WILL MY PRESCRIPTION DRUGS BE COVERED? (PART 2)**

The Centers for Medicare & Medicaid Services (CMS) has issued yet another Q & A to clarify the prescriptions that must be included on a Part D plan's formulary. The latest Q&A, made available on June 13, 2005, explains the requirement in the formulary guidance that drug plans must cover "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories.

CMS originally stated that a "majority" of drugs in the six categories would have to be on the plan's formulary. CMS now clarifies that "substantially all" means that all drugs in these categories that are available on January 1, 2006, including generic drugs and older brand-name drugs, must be included, with specific exceptions. If a new drug in one of these categories becomes available after January 1, 2006, the drug must go through the standard Pharmacy and Therapeutic committee review and approval process.

CMS further expects that plans will not use prior authorization or step therapy for patients already stabilized on these drugs, unless the plan can prove extraordinary circumstances. Plans may utilize management techniques for beneficiaries who begin treatment with drugs in all of these categories except for HIV/AIDS drugs. Plans may not use prior authorization or step therapy for HIV/AIDS drugs as utilization management tools are generally not used by other insurance programs.

The exceptions to the "all or substantially all" requirement are:

- Iressa does not have to be included on formularies because pending clinical data are currently under review by the Food and Drug Administration
- Fuzeon must be included on formularies but may require prior authorization for new users.
- Either escitalopram or citalopram may be omitted.
- Fosphenytoin may be omitted.
- Multi-source brands of the identical molecular structure may be omitted.
- Plans are not required to include extended release products or all dosages.

CMS bases its policy on its review of the Federal Employees Health Benefit Program and state Medicaid programs. The Q&A states, "In the process of reviewing the practices of other Federal programs for comparable populations... we learned that formulary inclusion rather than an exceptions process is an appropriate standard in certain circumstances." CMS further notes that, where all drugs in a category are on the formulary they may be placed in different cost-sharing tiers.

CMS expressed concern that (1) beneficiaries could experience significant negative outcomes if treatment with drugs in these categories is interrupted, even briefly; and (2) the high costs of these drugs may cause adverse selection and/or discrimination.

The policy requiring that all of the drugs in the six categories (except as noted) be included on formulary is in effect for 2006 because of the large number of beneficiaries who will be transitioning to new formularies. CMS will reevaluate the formulary guidance for 2007 after the agency has more evidence “on effective formulary practices for achieving the statutory requirements of the [Medicare prescription drug law.]”

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