

Why is CMS requiring “all or substantially all” of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?

CMS has a responsibility under the Medicare Modernization Act (MMA) to make sure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory. In our final formulary guidance for 2006, we noted that a majority of drugs in these categories would have to be on plan formularies and that beneficiaries should have uninterrupted access to all drugs in that class. In addition, our formulary guidance explicitly stated that we would encourage the use of formularies that have been demonstrated to be effective by their widespread use today for millions of seniors and people with disabilities. In the process of reviewing the practices of other Federal programs for comparable populations such as the Federal Employees Health Benefit Program (FEHB) and Medicaid, we learned that formulary inclusion rather than an exceptions process is an appropriate standard in certain circumstances.

In training sessions and user calls based on our formulary guidance, CMS has consistently explained that this meant that access to "all or substantially all" drugs in these specific categories needed to be addressed by plan formularies. We specified that beneficiaries should be permitted to continue utilizing a drug in these categories that is providing clinically beneficial outcomes. This is because the factors described in our formulary guidance indicated that interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe. In addition to consideration of existing formulary practices, the guidance also stated that we would consider proposed formularies in the context of the drugs prescribed within the CMS Prescription Drug Hierarchical Condition Categories (RxHCC) used to determine Medicare payment, as well as widely used treatment guidelines.

Our requirements for these six categories of drugs are consistent with our review of commonly-used formularies. For example, in the Blue Cross/Blue Shield Federal Employees Program (FEP) and other PPO formularies in FEHB, there is no prior approval or utilization management practices applied to HIV/AIDS drugs, even for new prescriptions. Also, all anti-psychotics and anti-depressant drugs are on the formulary. Such medications may be placed on different tiers.

In addition, many state Medicaid programs allow direct access to drugs within these six categories, even where the drugs are not included on the state's preferred drug list (PDL). In summary, many Americans, including millions of seniors and people with disabilities, are currently receiving drug benefits through these formularies today. Thus, there is sufficient evidence to support a benchmark of including substantially all of the drugs within the six categories, to meet the statutory requirement that all beneficiaries receive access to medically necessary treatments.

This approach is also consistent with actual prescribing patterns reflected in the drug costs observed in the RxHCC model. Diseases associated with these six categories of drugs (e.g., HIV/AIDS with antiretrovirals) have among the highest predicted drug costs

and thus predicted payments in this model. Ten of the top fifteen RxHCC diagnostic groups are treated by drugs within these six categories. The same group of diseases also has high predicted medical costs (that is, they are also included in the CMS-HCC model used for payments to MA organizations). Both the high predicted drug costs and the high predicted medical costs indicate that CMS should be concerned about selection and/or discrimination, and are consistent with the use of a broad, complex range of drugs for these diseases in actual practice.

Therefore, we expect formularies to include substantially all drugs in these six categories that are available on January 1, 2006 (including generics and older branded products). Drugs that come onto the market after January 1, 2006 will be subject to the normal Pharmacy and Therapeutic committee review process. "Substantially all" in this context means that all drugs in these categories are expected to be included in plan formularies, with the specific exceptions noted in Attachment I. We are also requiring special attention to patients already stabilized on these drugs before enrollment with a plan. In particular, for such patients, we generally expect that plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances. For beneficiaries who begin treatment with drugs in these categories other than HIV/AIDS drugs, plans may use these techniques to manage therapy. For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models (except as noted in Attachment I). Plans may, of course, conduct consultations with physicians regarding treatment options and outcomes in all cases.

This policy is in place for 2006, the first year of the Medicare drug benefit and a unique year in terms of a large number of beneficiaries transitioning to new formularies. We will reevaluate the formulary guidance for these categories for 2007, when we expect to have far fewer new transitions to Medicare coverage, and when further evidence may be available on effective formulary practices for achieving the statutory requirements of the MMA.

CMS has completed the vast majority of our work to review plan formularies, and the vast majority of formularies already meet these expectations. However, if this policy materially impacts any bid that was submitted prior to the June 6, 2005 deadline, organizations will have an opportunity to make minor adjustments to their respective bid(s) to reflect this specific policy.

- Please contact Sonia.Eaddy@cms.hhs.gov by midnight Friday, June 10 to indicate your intent to resubmit.
- All bid resubmissions must be completed by midnight, Tuesday June 14. In order to request that the gate be opened for bid re-submission, please contact Denise von Rinteln via email at denise.vonrinteln@cms.hhs.gov.

Attachment I

Exceptions to the “all or substantially all” guidance are:

- Iressa is not required on formularies, as is reflected in current formulary practices related to the pending clinical data currently under review by the Food and Drug Administration.
- Fuzeon must be listed on formularies but may have prior authorization for new users. This is considered best practice in current formularies and is widely reflected in actual formulary practice.
- Either escitalopram or citalopram may be left off formularies since escitalopram is the component of citalopram that is responsible for the antidepressant effects.
- Fosphenytoin may be left off formularies based on current, widely used best practices.
- We do not require that multi-source brands of the identical molecular structure be included, that extended release products be included, or that all dosages be included.