

Off-Label Use of Drugs under Medicare Part D

In order for a drug to be covered under Medicare Part D, and therefore paid for by the program, it must meet the following conditions:

- It cannot be otherwise excluded by statute, e.g., benzodiazepines;
- It must be reasonable and necessary for the treatment of a medically accepted indication; and
- Its use must be supported by one or more cites in one of three designated drug compendia (American Hospital Formulary Service Drug Information, United States Pharmacopoeia–Drug Information, and DRUGDEX Information System).

A key issue that emerges from this concerns the off label use of drugs, either for a nonindicated condition or for an indicated condition at a dose greater than the FDA-labeled amount. Regarding the dosage issue, it has been ruled by CMS that support by the compendia is not required for doses greater than those recommended by the FDA as long as the drug is used for a labeled indication.

Practically speaking, this means that plans cannot deny a drug by virtue of the medically accepted indication criteria because there is no cite in the compendia specifically supporting the prescribed dosage. This does not mean, however, that plans cannot challenge the off-label dosage on the grounds that it is not reasonable and necessary.

The use of drugs off label for nonapproved indications is a different matter. The medically accepted indication criteria must be met, and there is discretion vested with the plans to determine whether there are cites to “support” the drug’s use in the manner prescribed. This is highly problematic, and such off-label prescribing is consistently challenged by the prescription drug plans (PDPs) on this basis. This issue is being reviewed, with special consideration given to the fact that the drug compendia were neither designed nor intended to be used as the basis for coverage decisions. In addition, they are notoriously out of date and inconsistent in their criteria for inclusion. Given the volume of off-label prescribing by psychiatrists (as well as other physicians), this has become a key issue in current Part D operations.