LEGAL CORNER

Changes to Off-Label Prescribing Practices Under Medicare Part D

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It is estimated that between 60 to 75 percent of cancer treatments are prescribed off-label. Because of the new oral anti-cancer medications that are currently on the market, or are likely to receive market approval in the near future, the off-label issue is taking on a new urgency. Why? Most of these oral anti-cancer drugs, as well as drugs that are commonly prescribed to manage some of the side effects of cancer treatment, but are not approved for such uses, are currently or will in the future be prescribed to individuals covered under Medicare Part D.

Part D vs. Part B

Compared to Medicare Part B, the approach to off-label prescribing under Medicare Part D is much narrower. Under the new Part D prescription drug benefit, oncology practitioners in particular (and physicians as a whole) must be more deliberate in documenting the underlying rationale supporting their off-label prescription decision. Under Part D, a covered drug must meet four requirements. Specifically, the drug must be:

1. Available only by prescription
2. Approved by the FDA
3. Used and sold in the United States, and
4. Used for a medically accepted indication. (A medically accepted indication includes those uses approved by the FDA, or uses that are supported by citation in one of three drug compendia: the American Hospital Formulary Service *Drug Information*, the DRUGDEX Information System, and the United States Pharmacopeia *Drug Information* Index.

In contrast, Medicare Part B permits coverage for off-label use of an approved drug if it is included in the American Hospital Formulary Service *Drug Information* or in the United States Pharmacopeia *Drug Information* (USP DI) *or* if it has been the subject of peer review in a recognized medical journal.

A Threat to Off-label Drug Use?

One purpose for the more restrictive approach for drugs covered under Part D is to help prescription drug plans (PDPs) manage drug costs and reduce unnecessary prescribing. However, the omission of the peer review standard from the Part D definition will likely change physician prescribing habits. At a minimum, oncologists will need to be more precise when prescribing off-label under the Part D program.

That said, off-label prescribing is not prohibited under Part D. Oncologists remain free to prescribe off-label for medically accepted indications. Keep in mind, however, that CMS does not have the authority to require PDPs to list off-label drugs on plan formularies. PDPs are permitted to develop their own procedures for handling off-label prescribing provided that the FDA has not made a determination that the drug is unsafe for that particular use. Some PDPs may permit their network pharmacists to fill the off-label prescription in the same manner as any other prescription. Other PDPs may require physicians to obtain prior authorization, or even pursue the exception process, before filling the prescription. A worse case scenario: physicians and patients may need to resort to the elaborate Part D appeals process to seek coverage for a non-formulary drug.

So Now What?

There are steps that practitioners can take to mitigate the effect of these limitations.

First, during the patient intake process, physicians should ask whether a patient is enrolled in a Part D program, and, if so, determine the formulary boundaries of the patient's particular PDP. Each PDP will have its own formulary of approved drugs. Certain plans may even list drugs that will be covered for certain off-label uses. Each PDP also will have its own utilization management tools, such as prior authorization. Knowing this information at this early juncture may save practitioners time when seeking coverage for certain medications.

Second, as a "best practice" of off-label prescribing, physicians should maintain precise documentation to clearly justify the rationale for prescribing a particular drug for off-label use. To justify off-label prescribing for medically necessary and medically accepted use, practitioners must determine that the drugs included on the patient's PDP formulary for treatment of the same indication would not be as effective as the off-label drugs, and/or that the patient would encounter adverse side effects from the formulary drug. Including a clear statement in the patient's medical record regarding medical necessity, benefits versus risks, and consideration of alternatives can help reduce the likelihood that the PDP's pharmacy and therapeutics (P&T) committee, or other decision-maker, will overturn the off-label prescription.

The good news is that off-label prescribing remains a viable option for oncologists under Medicare Part D. The bad news is that oncologists must be ready to justify that decision through a drawn out, and time-consuming utilization review or appeals process.

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