

Part B Insider (Multispecialty) Coding Alert

Off-Label Drugs: Medicare May Cover Unlisted Uses, But Expect to Back Them Up

Drug compendia, studies and documentation all may help gain payment

If your physician is prescribing drugs for uses that aren't approved by the Food & Drug Administration, you could be filling a prescription for hassles.

The most common off-label prescriptions are for oncology drugs. A chemotherapy drug "might be tested for lung cancer, but you try it on a prostate cancer," says attorney **David Glaser** with Fredrickson & Byron in Minneapolis.

"If it's an off-label use, one question that comes up is the extent to which it can be covered under programs like Medicare," says attorney **Chris Crosswhite** with Duane Morris in Washington. Even if the physician uses her best judgment that the drug will help this patient, the carriers may not include that use of the drug in their local medical review policies or other policies.

There's no guarantee of coverage with off-label drugs, but the carriers will apply their usual test: "Is it reasonable and necessary?" Glaser says. "It's no higher risk in my mind."

The Medicare Carriers Manual, section 2049.4, says Medicare will cover drugs for an unlabeled use on an incident-to basis if they've been determined to be effective, Glaser says. The carrier will look at sources including the three major drug compendia issued by cancer societies and others to figure out whether the drug should be covered for that use. And the "treating physician rule" says that if a treatment could be reasonable, the carriers should defer to the physician's judgment.

Glaser and Crosswhite offer these tips:

1. You'll have an easier time if the drug is commonly prescribed for that use. Glaser says that Viagra and Rogaine were both prescribed off-label for their most common uses at one point.
2. Make sure the patient knows you're prescribing the drug for an off-label use. This is a potential malpractice issue, Glaser says, because if the patient is unaware the drug is off-label, he may not understand the risks of taking it. "Certainly there's the risk the patient ultimately says, 'I didn't know it wasn't approved for this particular use.'"
3. Try other drugs first. Glaser has handled appeals of denials for oncology doctors. It frequently sways the carrier if the oncologist says, "Look, this was a tumor that was resisting other treatments, and this was our last line of use," Glaser says.
4. Use an advance beneficiary notice so you can bill the patient if Medicare denies the claim, Crosswhite says.