

Part B Insider (Multispecialty) Coding Alert

Off-Label Drugs: Medicare May Slash Coverage For Off-Label Chemotherapy Drug Uses

Your claims for high-price and off-label drugs may come under scrutiny

According to recent articles in the New York Times and the Boston Globe, the **Centers of Medicare & Medicaid Services** is conducting a review of coverage for off-label uses of high-priced drugs. And CMS may revoke coverage for some of the most commonly prescribed off-label uses if the review turns out negative.

The Globe story, dated Feb. 10, says that CMS is becoming bolder in venturing into the **Food & Drug Administration's** territory. In the past, Medicare approved off-label uses based on the physician's judgment, but marketing abuses by drug companies have driven CMS to demand more evidence of the benefits of treatments.

Certain cancer drugs are in the agency's crosshairs, including Zevalin, a non-Hodgkins Lymphoma treatment that many physicians prescribe for other cancers. One CMS official said he supports using "head-to-head trials" pitting drugs within the same class against each other. Medicare would peg its reimbursement for those drugs to the least expensive of the effective drugs, he explained.

CMS officials also pointed out that they added Medicare coverage for an off-label use of **Novartis'** drug Visudyne for age-related macular degeneration.

CMS could become even more powerful when it starts administering a Medicare drug benefit in 2006, former administrator **Tom Scully** told the Globe.

"I'm not surprised they would consider it given the expense," says attorney **Chris Crosswhite** with **Duane Morris** in Washington.