

Part B Insider (Multispecialty) Coding Alert

Coverage: 'Off-Label' Cancer Drug Trials May Run Off Rails, Providers Worry

Some think that expansion will actually derail 2000 advance

A Medicare coverage decision to expand coverage for some chemotherapy drugs should seem like a good thing.

But the **Centers for Medicare and Medicaid Services'** plan to boost coverage for four colorectal cancer drugs ignited a blaze of controversy. CMS proposed to cover routine patient care costs of clinical trials involving "off-label" uses of oxaliplatin, irinotecan, bevacizumab and cetuximab.

The nine clinical trials would look into the effectiveness of these drugs in non-recurring colorectal cancer. Medicare already covers the drugs for colorectal cancer that resists other treatments.

But cancer providers worried that the expanded coverage actually represented a step backward in clinical trial coverage. In 2000, CMS said it would cover care costs of patients in all clinical trials that met certain standards.

CMS went ahead with the coverage expansion for the colorectal cancer drugs last week, but only after providing reassurance to providers that the move didn't represent a step back from the 2000 decision.

Reasoning: The main rationale behind the new coverage policy was to allow CMS to gather data on the clinical trials, including the patients enrolled in them and the outcomes. CMS wants this information as part of its new focus on "evidence-based medicine," cancer experts say.

"We are generally pleased with the outcome, and I think CMS was indeed responsive to many of the concerns," says **Deborah Walter**, senior director of policy and reimbursement with the **Association of Cancer Care Centers**. At the same time, she still questions why CMS needs to use the coverage determination process to push forward its information-gathering programs instead of using it for patient coverage.

CMS will hold an Open Door Forum on clinical trial coverage in March, and Walter hopes this new "evidence-based medicine" initiative will come up for discussion then.

PET Scans Also Covered

Separately, CMS also said the agency would cover positron emission tomography (PET) scans for evaluation of brain, cervical, ovarian, pancreatic and testicular cancers, among others. The physician ordering the scan must participate in a "high quality" clinical study or submit information to a PET database, CMS says.

Medicare coverage will become effective when CMS' working group of oncologists and others finishes putting the PET database together. CMS wants to be able to ensure physicians are using the PET data accurately and appropriately in patient management.