

CMS off-label drug coverage initiative may die a slow death

By Cori Vanchieri

After pushback from cancer organizations, the Centers for Medicare and Medicaid Services (CMS) may be backing off a plan that would limit off-label use of some drugs to clinical trials.

In April 2005, CMS released new draft guidance for what it called “Coverage with Evidence Development (CED).” If adopted, the guidance would require patients to take part in data collection in order to receive coverage for certain technologies and drugs. The goal, as stated by CMS Administrator Mark McClellan, MD, PhD, was to collect better evidence to improve health outcomes.

The program was announced as an expansion of coverage for off-label drugs. However, some cancer organizations, including the Association of Community Cancer Centers (ACCC) and American Society of Clinical Oncology, disagreed. “Our objection is that there is nothing new in CED and, in fact, it restricted coverage,” says Deborah Walter, ACCC’s senior director of policy and government affairs. ACCC is concerned that, if the guidance goes forward as presented last year, “patients will not get the care they should be getting because of coverage issues.”

Unfair system

In most cases, drug companies already pay for the cost of their drugs in clinical trials, according to Ms. Walter. “Now Medicare says it’ll pay for

the drugs. So what? They’re already paid for. With CMS in the process, patients have to pay a 20% co-pay for something they were going to get for free.”

In October 2005, Ms. Walter speculated that, based on criticism from

The popularity of off-label use

ONCOLOGISTS place high importance on off-label use of anticancer drugs for their patients, according to a small survey released in September 2005 by Association of Community Cancer Centers, the Biotechnology Industry Organization, and the Pharmaceutical Research and Manufacturers of America. Interviewed for the survey were 28 oncologists and 12 oncology practice managers who identified 87 oral anticancer therapies they use off label.

For some, Medicare coverage policies affect their prescribing. Fifteen of the 28 oncologists surveyed reported that concerns about the lack of Medicare coverage caused them to alter their treatment decisions frequently or very frequently. These results are similar to 1991 findings by the General Accounting Office that off-label use of anticancer therapies is widespread. According to William T. McGivney, CEO of the National Comprehensive Cancer Network, 50% to 75% of all uses of drugs and biologics in cancer care in the United States are off label.

various stakeholders, the final guidance would look very different from the April 2005 version. She credited CMS staff for their sincere desire to expand off-label coverage. But, she said, the approach they took with the CED was the wrong one. As of early March 2006, the guidance was stuck somewhere in CMS, and, Ms. Walter predicts, “I don’t think it will ever get unstuck.” She is hoping that the guidance will go away altogether. CMS originally intended to release a final CED guidance by the end of 2005, but CMS Spokesman Don McLeod confirmed the guidance is stalled.

“We’d like to see them stop CED completely,” Ms. Walter says. “It’s unfair to tell a physician or patient that if they don’t participate in a trial they won’t get access.”

What’s covered

On January 28, 2005, CMS issued a National Coverage Determination (NCD) covering off-label use of certain anticancer drugs (oxaliplatin [Eloxatin], irinotecan [Camptosar], cetuximab [Erbix], or bevacizumab [Avastin]) that are provided in nine NCI-sponsored clinical trials. The studies took a while to begin, but as of mid-March 2006, seven of the nine trials were enrolling patients. All of the drugs being studied in these nine clinical trials are listed in at least one compendium. A local Medicare carrier could approve their off-label use outside of a clinical trial. The NCD takes the decision out of local carriers’ hands when it comes to these nine clinical trials. Medicare will pay when the drugs are used in these studies.

If the CED guidance never sees the light of day, off-label coverage decisions will remain with local Medicare contractors. CMS states that 90% of Medicare's coverage policies are made at the local level. By law, Medicare Part B is required to reimburse for off-label uses of anticancer drugs if they are listed in one of three compendia. If peer-re-

viewed literature supports the off-label use, a local Medicare contractor may choose to cover it.

Medicare Part D is somewhat more stringent. Medicare contractors will generally cover all off-label uses of an anticancer drug if the drug is determined to be medically necessary and listed in specific compendia: Ameri-

can Hospital Formulary Service Drug Information, US Pharmacopeia Drug Information, DRUGDEX Information System, and the American Medical Association Drug Evaluations. However, drug plans do not have the authority to cover any use not listed. A mention in the literature is not enough for Part D coverage.

Clinical trials covered under the Medicare Anticancer Drug National Coverage Decision			
Study number	Study title	Status	Location
C80405	Cetuximab and/or bevacizumab combined with combination chemotherapy for metastatic colorectal cancer	Open	Nationwide
E2204	An intergroup randomized phase II study of bevacizumab or cetuximab in combination with gemcitabine and in combination with chemoradiation (capecitabine and radiation therapy) for completely resected pancreatic carcinoma	In review	Limited regions
E4203	Bevacizumab and oxaliplatin combined with irinotecan or leucovorin and fluorouracil for metastatic or recurrent colorectal cancer	Open	Limited regions
E5202	Oxaliplatin, leucovorin, and fluorouracil with or without bevacizumab for stage II colon cancer after surgery	Open	Nationwide
E5204	Chemotherapy with or without bevacizumab for stage II or stage III rectal cancer	Open	Nationwide
NSABP-R-04	Radiation therapy and either capecitabine or fluorouracil with or without oxaliplatin before surgery for resectable rectal cancer	Open	Nationwide
RTOG-0522	Radiation therapy and cisplatin with or without cetuximab for stage III or stage IV head and neck cancer	Open	Nationwide
S0502	Phase III randomized study of imatinib with or without bevacizumab for metastatic or unresectable gastrointestinal stromal tumors	In review	Nationwide
7325	Combination chemotherapy with or without bevacizumab for metastatic or locally advanced unresectable colorectal cancer or other solid tumors	Open	Limited regions
For details on these protocols, visit: www.cancer.gov/clinicaltrials/developments/NCD179N			