Medicare Demonstration Projects Acknowledge Evidence-Based Medicine in Cancer Care

Evidenced-based cancer care took a giant step forward in two new demonstration projects proposed by the Centers for Medicare and Medicaid Services (CMS) in November.

Both projects are designed to provide additional care for cancer patients and, at the same time, collect data to show whether such treatment is actually effective.

One project, which has the added benefit of providing more money to private practices that were expecting sharply reduced government reimbursements next year, will give oncologists $130 each time they ask their patients about their level of pain, nausea, vomiting, and fatigue. CMS will use data generated from these responses—and from responses during subsequent treatment for patients who need it—to trace outcomes from such care. The year-long project is expected to cost $300 million and will start January 1.

The second project provides a way for CMS to help collect patient data on a high-cost diagnostic test, positron emission tomography (PET), and on the “off-label” use of a handful of new and expensive colorectal cancer agents. Such drugs are sometimes used to treat conditions for which they have not been approved or for which no evidence of their efficacy exists, and CMS currently pays for this use only if subcontractors who administer Medicare allow it.

But the catch to such expanded coverage is that patients must be enrolled in one of nine National Cancer Institute-sponsored clinical trials to receive drugs for off-label uses, and some worry that this requirement will eventually lead to no off-label use of any drug outside of clinical trials. While he enthusiastically endorses the new project, Joseph Bailes, M.D., co-chairman of the American Society of Clinical Oncology (ASCO) government relations committee, has some qualms in that regard. “This is a good expansion of coverage for drugs—as long as it does not have a downside in which carriers begin to restrict coverage,” he said.

Helping or Hindering Care?

The decision to cover off-label uses of approved colorectal cancer drugs represents a shift in thinking at CMS, a move made by its new administrator, Mark McClellan, M.D., Ph.D., to pay only for treatments that clearly show benefit.

“We are working with the National Cancer Institute, oncologists, and the cancer community to develop better evidence to support the best possible treatment decisions for our beneficiaries,” McClellan said in a prepared statement. “There are too many unanswered questions in cancer care today for seniors and people with disabilities, and Medicare will help develop more practical evidence to improve care.”

The coverage expansions reflect new procedures that CMS is implementing to review scientific evidence for coverage decisions more rapidly, said Sean Tunis, M.D., Medicare’s chief medical officer. Although Medicare has no research budget, it wields a powerful hand because it pays for most of the treatments used by elderly Americans—the population in which cancer is most common. Requiring that these medicines and devices work before the government will pay for their use “is a new role for CMS,” said Tunis. “It’s a good thing, because the effectiveness of a lot of drugs being used off label is not known and can only be learned through systematic study.”

CMS will pay for clinical and experimental costs in nine clinical trials of four drugs—oxaliplatin (Eloxatin), irinotecan (Camptosar), bevacizumab (Avastin), and cetuximab (Erbitux)—to learn more about the benefits and risks of certain off-label uses of these treatments in Medicare patients. The trials are sponsored in part by NCI, which is collaborating with CMS in an effort both to expand participation in clinical trials and to determine the worth of the new medicines.

It is also making PET scans available to patients with certain cancers for which PET scans have not been covered, if the provider and patient participate in specific PET clinical trials or in a high-quality PET registry.

Even as CMS is asking for public comment on the project, Tunis is busy explaining why it does not force patients into clinical trials, as several newspaper articles have suggested. “Many people don’t understand this decision,” he said. “They think it is a narrowing of coverage because it said that people must participate in a clinical trial in order to be covered, but it is an actual expansion of coverage.”

Currently, several dozen contractors around the country that work on behalf of CMS make decisions on whether to cover off-label use of drugs, he said. They are guided by a 1993 statute that mandates CMS coverage for off-label uses that are listed in the drug’s compendium, which means evidence exists that the drug provides more benefit than risk. These contractors, however, have the flexibility to approve other off-label uses within their service area, as determined by the contractor’s own
clinical advisory panel. “Some contractors are more liberal, allowing CMS to pay for any off-label use, while others are conservative, paying only for uses listed in the drug compendium,” Tunis said. “On average, though, contractors are willing to pay for things with a lower standard of evidence.”

The demonstration project expands off-label uses in areas where contractors are conservative, Tunis said, because it mandates payment for specific uses if patients are willing to enter clinical trials. At the same time, CMS will continue to pay contractors who allow more liberal uses of these drugs, without requiring the patients be enrolled in the nine clinical trials, he said. “It is a more liberal policy no matter what. All the current contractors’ policies are left in place, but if a patient agrees to participate in one of the nine clinical trials in the demonstration project, payment by the contractor is mandatory.”

But Bailes and others note that CMS has started to reform the way it uses contractors by perhaps reducing their number and centralizing their operations. Tunis admits to another movement afoot, and that is “the interest in using national coverage policy to promote participation in clinical research.”

Jeffrey Kahn, Ph.D., director of the Center for Bioethics at the University of Minnesota in Minneapolis, said the new CMS initiative may ultimately represent “the age old problem of weighing individual benefit against what’s good for the group. If you think collectively, this is a good way to proceed, because it will provide proof that these drugs either work or they don’t, and that can only help patients,” he said. “But if you need the drug today and you can’t enroll in a clinical trial because maybe it isn’t offered where you live, or it hasn’t started or has stopped, then you are out of luck.”

Considering Quality of Life

While most patient organizations have not publicly weighed in on CMS’s clinical trial demonstration project, many say the other demonstration project is a clear winner.

“This is an important first step that will give oncologists an incentive to ask their patients about important quality-of-life issues,” said Bob Hall, director of government relations for the National Coalition for Cancer Survivorship, which worked with CMS to draft the project. Hall adds that now that CMS is paying for physicians to ask their patients about pain, nausea, vomiting, and fatigue, he hopes the agency will next offer to reimburse oncologists for managing those symptoms in patients.

ASCO’s Bailes says the $300 million that will be provided for this project will take the sting out of what ASCO calculated would be a $500 million drop in CMS’s 2005 reimbursements to private oncology clinics that provide chemotherapy services.

“It is a good move for CMS to recognize the need for these services and to cover them, so at the moment we are feeling a little more sanguine,” he said. Bailes added, however, that a true financial picture would not be available until mid-December—after this issue went to press—when CMS announced the final 2005 payment schedule.

—Renee Twombly

2005 Medicare Payments for Chemotherapy Will Exceed Costs

Medicare payments to oncologists for chemotherapy drugs will exceed costs by 6% in 2005, according to a new report from the Government Accounting Office (GAO). In addition, it found that fees for nearly every category of chemotherapy administration services will increase in 2005 from 2003 levels, some by more than 300%.

Following reports that Medicare payments to physicians for chemotherapy-related drugs far exceeded actual costs, Congress required the Department of Health and Human Services, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, to change the payment rates for the drugs and their administration. In response to oncologists’ claims that overpayments were needed to cover inadequate reimbursement for drug administration services, changes were made to increase these fees. However, there was still concern that, even with these changes, Medicare payments in 2004 and 2005 would not cover physicians’ total costs.

In a report prepared for the House Committee on Energy and Commerce, the GAO estimated payments and costs for 16 chemotherapy-related drugs for 2003, 2004, and 2005. These drugs represented 75% of Medicare’s payments to oncologists in 2003. Although they found that these payments will decline in 2004 and 2005 relative to 2003, they will exceed physicians’ costs for the drugs by 22% in 2004 and 6% in 2005. For example, paclitaxel, which was reimbursed at the rate of $164.08 in 2003, will be reimbursed at the rate of $26.27 in 2005, but this rate is 19% greater than its estimated acquisition cost of $22.47.

For only three of the drugs reviewed—granisetron hydrochloride, pamidronate disodium, and ondansetron hydrochloride—will the payments be less than the estimated costs for 2005, and the Centers for Medicare and Medicaid has agreed to examine the data for these drugs to ensure that the final payment rates accurately reflect the average sales prices for the drugs.

The authors of the GAO report also reviewed estimated payments for all 22 major service codes related to chemotherapy administration and found that payments for 2005 are expected to be 130% greater on average than for 2003. Only one administration code is expected to have a lower fee in 2005 than it did in 2003. The GAO report also estimated that these payments would cover nearly as much or more of physicians’ costs than will payments for services in other specialties.

—Sarah L. Zielinski