ACCC Survey Reveals Need for Medicare Payment Adjustment to Adequately Capture Pharmacy Service Costs

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An ACCC survey of hospital oncology pharmacists reveals that pharmacy handling and overhead costs may account for approximately 30 percent of total drug costs. In stark contrast, CMS is proposing to pay hospitals only 2 percent to cover these costs in 2006.

ACCC’s survey findings are similar to those included in the June 2005 Medicare Payment Advisory Commission (MedPAC) report, which suggested pharmacy service overhead costs make up 26 to 28 percent of total pharmacy costs. MedPAC is an independent advisory council that reports to Congress.

“To reach a reasonable compromise, ACCC is proposing that CMS implement a pharmacy service and handling add-on of at least 8 percent of average sales price (ASP),” said Deborah Walter, ACCC Senior Director of Policy and Government Affairs. “Based upon our extensive data analysis, increasing the add-on percentage from 2 percent to 8 percent would protect beneficiary access to drug therapy in the hospital setting while increasing projected total Medicare payments to hospitals by less than 1 percent (0.33 percent).”

ACCC and members of its OPEN (Oncology Pharmacy Education Network) Advisory Board have shared these findings with Congressional Hill staff and CMS officials. Discussions have focused on the importance—and need—of an add-on adjustment that will ensure hospital pharmacies can continue to provide high-quality care to patients. ACCC has also been working very closely with other pharmacy associations and hospital groups to develop a more unified message on the necessary reforms.

“I am deeply concerned that the effect of this proposed reimbursement policy—coupled with CMS’s proposal to reduce payments by 50 percent to hospitals for select multiple diagnostic imaging procedures and cut reimbursement for administering drug therapies—could slowly dismantle multidisciplinary cancer care, which is certainly not CMS’s intent,” said Jeanne Musgrove, member of ACCC’s Governmental Affairs Committee. “Hospitals cannot continue to sustain these hits. It is critical to establish reimbursement rates that ensure hospitals are appropriately reimbursed for the services they provide,” she added. Musgrove is cancer services director at Piedmont Medical Center in Rock Hill, S.C. The survey results are available on ACCC’s website at: www.accc-cancer.org.
ACCC Submits Comments to CMS on 2006 Proposed HOPPS Rule
On September 16, 2005, ACCC submitted its comments to CMS regarding proposed changes to the hospital outpatient prospective payment system (HOPPS) and calendar year 2006 payment rates. The comments are a culmination of issues that have been discussed with Congress, CMS, and others. ACCC urged CMS to protect cancer patients’ access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under HOPPS. Toward that end, ACCC urged CMS to increase the add-on payment for pharmacy handling costs to at least 8 percent of ASP (see above) and make an appropriate fixed-rate add-on payment to reimburse pharmacy service costs for packaged drugs. In addition, ACCC urged CMS to:

- Revise the coding and payment policies for drug administration services to make separate payment for additional hours of infusion services and to allow hospitals to bill for more than one initial service code in a single day
- Develop and implement a quality improvement demonstration project for cancer care provided in hospital outpatient departments, similar to the demonstration project implemented in physician offices in 2005
- Rethink the proposal with respect to multiple diagnostic imaging services in the same family performed during the same session
- Continue to study the economies of providing multiple diagnostic imaging services and implement a reduction of no more than 25 percent for these services in the meantime
- Begin working with stakeholders to develop a future rate-setting methodology that accounts for all the costs of providing radiopharmaceuticals
- Postpone implementation of the proposed C-codes for pharmacy overhead charges and study the issue in greater depth
- Issue proposed coding guidelines for evaluation and management services to help hospitals bill appropriately for cancer therapy support services
- Reconsider the proposed rates for the brachytherapy APCs.

Medicare Part B Monthly Premium Increases in 2006
CMS Administrator Mark B. McClellan, MD, PhD, announced that the Medicare Part B monthly premium will be $88.50 in 2006, an increase of $10.30 from the current $78.20 premium. The 2006 premium is roughly the same amount that CMS actuaries have been projecting since early this year. Though premiums are rising, most Medicare beneficiaries will see significantly lower out-of-pocket health care costs in 2006 because of the savings in drug costs from the new Medicare prescription drug benefit. In addition, about one-fourth of beneficiaries can receive assistance that pays for their entire Part B premium, and about one-third of beneficiaries can receive assistance for their Part D premium.

Update on NCI/CMS Oncology Pilot Project: Progress Is Slow, Patient Accrual Not Completed
On September 20-21, the National Cancer Advisory Board convened in Bethesda, Md. to discuss a number of issues, including the status of the Centers for Medicare & Medicaid Services (CMS) and National Cancer Institute (NCI) Oncology Pilot Project.

The pilot project originated in a national coverage decision (NCD) issued on January 28, 2005. As outlined in the NCD, CMS is covering the “clinical and experimental” costs of four anti-cancer drugs: oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™) in nine NCI-sponsored clinical trials. All nine trials evaluate the drugs’ use in off-label indications, and the pilot project will collect and validate clinical evidence to improve the use of these new therapies.

According to Mark Clanton, MD, MPH, NCI Deputy Director for Cancer Care Delivery Systems, the six colorectal and three non-colorectal NCI/CMS collaborative clinical trials selected for launch were chosen based on each treatment’s high level of off-label usage and perplexing irregularities for researchers.
Dr. Clanton indicated that the NCI/CMS partnership is intended to explore how the two agencies can align their resources and agency-specific goals to accelerate development of evidence for emerging cancer treatment regimens. He further suggested, “This can be done by having CMS collect data to make reasonable and necessary determinations for off-label cancer treatments, while NCI sponsors trials as part of a research agenda to evaluate use of new agents in off-label indications to determine safety and efficacy.”

In addition, as CMS lacks the statutory authority to conduct research, the agency views the Oncology Pilot Project as an opportunity to reach its goal of becoming more evidence based. By contrast, NCI views these clinical trials as an opportunity to advance the knowledge for these drugs, as well as to serve as a potential model for additional coverage expansions in clinical trials for other anti-cancer agents by both CMS and other insurance carriers.

Almost ten months after the NCD was announced, the nine trials have yet to begin.

**Physician Offices Face another Round of Steep Payment Cuts in 2006**

Medicare beneficiaries’ access to quality cancer care could suffer immensely from payment cuts proposed in the 2006 Medicare Physician Fee Schedule, according to ACCC’s official comments submitted to CMS on September 30, 2005. The proposed cuts—combined with ongoing payment reforms spurred by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)—could create significant obstacles for cancer patients and their physicians in 2006.

For 2006, CMS forecasts a 5.6 percent reduction in Medicare payments for hematology and oncology services provided in physician offices. Payment cuts for drug administration services are even deeper, ranging from 6 to 7 percent. “These cuts alone could create access problems, but when combined with proposed cuts in reimbursement for drugs and their administration services at hospitals, the effects could be disastrous,” according to Edward Braud, MD, chair of ACCC’s Governmental Affairs Committee and a practicing physician in Springfield, Ill.

With hospitals possibly reducing or eliminating their cancer programs in the face of similar levels of payment cuts, the proposed reductions in the proposed 2006 physician fee schedule come at a time when physicians may be confronted with increased volumes of patients and greater challenges to providing quality patient care.

“We are now aware of hospitals that have reduced or eliminated their outpatient services, leaving some patients to seek care in physician offices and other patients, who need treatments that are available only in hospitals, with nowhere to turn,” Dr. Braud added.

Deborah Walter, ACCC senior director of Policy and Government Affairs expressed concerns for patients battling cancer. “Many of our members simply cannot absorb the significant cuts in payment rates for cancer services without substantial ramifications for patient care,” she said. Walter hopes that CMS will carefully consider a number of recommendations that could mitigate this problem.

ACCC recommends that CMS revise the sustainable growth rate formula as needed to prevent the expected 4.3 percent cut in the conversion factor and review the practice expense relative value units (RVUs) for drug administration services as soon as the necessary data are available to ensure that these RVUs accurately reflect all of the costs associated with administration of advanced drug therapies. ACCC also looks forward to working with CMS to identify appropriate quality measures and payment incentives that will promote the delivery of high quality, patient-centered cancer care.

**Caution! Invalid Chemo Codes**

As of October 1, 2005, the diagnosis code V58.1, encounter for chemotherapy, and is no longer a valid code. The ICD-9-CM now requires you to use a fifth digit with this code. The new codes are:

- V58.11, encounter for antineoplastic chemotherapy
- V58.12, encounter for immunotherapy for neoplastic condition.

The FDA defines immunotherapies as Bacille Caimette-Guerin (BCG), interferon-alfa, interleukin-2, and the monoclonal antibodies. Use code V58.12 with these agents. V58.11 should be used with cytotoxic chemotherapy treatments. This is an initial interpretation of the ICD-9-CM committee, look for a more complete list of the immunotherapy agents on your carrier/intermediary website.
Approved Drugs

- The U.S. Food and Drug Administration (FDA) has approved GlaxoSmithKline’s (Philadelphia, Pa.) Arranon® (nelarabine) Injection, a chemotherapy agent, for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted. Arranon also received Orphan Drug Designation from the FDA.
- OSI Pharmaceuticals, Inc., and Genentech, Inc. (Melville, N.Y., and South San Francisco, Calif.) have received FDA approval for Tarceva® (erlotinib) in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. Tarceva is the first drug in a Phase III trial to have shown significant improvement in overall survival when added to gemcitabine chemotherapy as initial treatment for pancreatic cancer. Tarceva is a once-daily oral tablet already approved for use in patients with non-small cell lung cancer whose disease has progressed after one or more courses of chemotherapy.

Drugs in the News

- ABRAXANE, THE NEXT-GENERATION TAXANE, has been issued a unique HCPCS code, J9264, 1mg (Injection, Paclitaxel Protein-Bound Particles). J9264 is effective for dates of service on or after January 1, 2006.
- ZymoGenetics, Inc. (Seattle, Wash.) announced that the FDA has granted orphan drug designation to Interleukin 21 (IL-21) for the treatment of melanoma patients with advanced or aggressive disease. ZymoGenetics is testing IL-21 in an ongoing Phase Ib clinical trial in melanoma and renal cell carcinoma with a dosing regimen administered in an outpatient setting. IL-21 is a novel cytokine with potent effects on a number of immune effector cells such as cytotoxic T cells and natural killer cells.

Upcoming Event

Spring Meeting
in conjunction with the
South Carolina Cancer Alliance
Date & Time: TBD