NCI Shares Details on Goals of CMS Collaboration

On May 23, 2005, key officials from the National Cancer Institute (NCI) met with the Association of Community Cancer Centers (ACCC) to discuss a common goal—how best to expand cancer research and improve care to cancer patients. In attendance were ACCC policy staff and members of ACCC's ad hoc New Technology Committee and Clinical Expert Panel. Of particular interest was NCI's role in its current collaboration with the Centers for Medicare & Medicaid Services (CMS) on the national coverage determination (NCD) for anticancer chemotherapy for colorectal cancer. CMS released a final decision memorandum on the NCD for anticancer chemotherapy for colorectal cancer on Jan. 28, 2005.

The memorandum announced that CMS will cover the non-compendia off-label use of oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™), in nine clinical trials identified by CMS and sponsored by NCI.

Although details of the selected trials have not yet been released, ACCC has learned that all nine trials are slated to be active by Fall 2005, after protocols are developed and reviewed—with several trials likely beginning this month. Two-thirds will be Phase III trials and will be offered by participating entities across the nation. Among the remaining three trials, one is limited to a "single-institution" and two others will be offered in "limited regions." With few exceptions, the trials are slated to accrue from 160 to 2,289 patients, not all Medicare beneficiaries. One Phase III trial will also screen an additional 3,438 patients.

The trials covered under the NCI-CMS Pilot Project focus on the use of the new monoclonal antibodies (bevacizumab and cetuximab) in combination with standard, aggressive chemotherapy in areas such as the adjuvant treatment of colorectal cancer, the treatment of advanced pancreatic and head and neck cancers, and in refractory gastrointestinal stromal tumors. Yet, questions remain about what will and will not be covered as part of these trials and about the study questions. NCI is currently working through many of these details and will provide information to ACCC as soon as it becomes available.

Through partnership in these clinical trials, both CMS and NCI hope to define more precisely the role of these new therapies. Although NCI has indicated that it will not be involved in any coverage decisions made by CMS, NCI staff hopes that data collected from the trials will "improve the evidence that actually flows into the coverage process." A tangential goal of this effort also may be to encourage private payers to also generate data that could improve physician practice efficiencies.

Is CCOP Funding in Jeopardy?

Squelching recent rumors, NCI staff has confirmed with ACCC that Community Clinical Oncology Program (CCOP) funding could be impacted by the upcoming projected NCI budget deficits.

NCI has decided not to release the Request for Applications (RFAs) in 2005. This means that those CCOPs and CCOP Research Bases whose multi-year grants will expire June 2006 will not have an RFA to respond to. (Note: a CCOP or Research Base grant application can currently only be accepted in response to the RFA.)

PHOTOGRAPH/PICTUREQUEST

However, according to Dr. Lori Minasian, Program Director for the CCOP, "This does not apply to those CCOPs or Research Bases that have grants that will expire in years beyond 2006. Those CCOPs and Research Bases who are affected will receive a one year funding extension commensurate with performance." Of note, the NCI Executive Committee anticipates releasing the CCOP RFA in 2006.

According to top officials, "NCI remains committed to the CCOP program and NCI will go forward under any concept." However, future reductions in grant amounts may be necessary.

Physicians "Just Say No" to CAP

Big changes are on the horizon. Beginning Jan. 1, 2005, physicians must choose between purchasing their drugs and being reimbursed under average sales price (ASP) *or* obtaining drugs through Medicare's Competitive Acquisition Program (CAP). CMS released its interim final rule regarding CAP on June 27. The

continued on page 12

new program will apply to physician-injectable drugs covered under Medicare Part B that are commonly provided incident to the physician's service. Of about 440 drugs that are billed incident to a physician service and paid under Part B, 181 will be included in the CAP. CMS anticipates receiving bids from vendors later this summer and awarding contracts in early fall in anticipation of starting the program in 2006.

In late spring, ACCC surveyed its physician practice members about their level of interest in CAP, as well as their perceptions of potential advantages and disadvantages of the program. The results were surprising.

Overall, the majority of survey respondents appear unwilling to participate in CAP. Not surprisingly, respondents are more likely to consider obtaining drugs through CAP vendors if favorable pricing could be obtained. Overwhelmingly—and regardless of specific practice demographics—physicians viewed CAP as administratively burdensome and resource intensive. Also problematic is the perception of the need to maintain separate inventories, which most practices do not find feasible given facility and space limitations. Taken together, these shortcomings seem to outweigh any benefits that CAP offers. When asked outright about CAP participation, here's how the votes tallied:

- 52 percent indicated they were "definitely not" likely to participate
- 26 percent were "undecided"
- 20 percent "needed more information" before making a decision
- Only 3 percent indicated that their likelihood of participation was a definite "yes."

Why the cold reception? As stated above, the physicians surveyed offered these potential "deal-breakers":

- 76 percent did not like having to keep separate inventories
- 75 percent did not like the added administrative work
- 74 percent were turned off by the thought of expending additional staff resources to operate under CAP
- 63 percent thought CAP posed "unrealistic" emergency requirements.

On the other side of the equation, physicians offered these reasons in support of CAP participation:

- 26 percent saw a potential for reducing or eliminating bad debt on patient co-pays or the need to collect co-pays
- 24 percent saw a potential for reducing or eliminating patient billing
- 23 percent thought CAP could reduce or eliminate potential losses on drugs
- 21 percent saw CAP as potentially reducing or eliminating large drug inventories.

In the end, many physician respondents are generally *not* interested in participating in CAP—regardless of its ability to provide favorable drug pricing. More than one in three would not consider obtaining drugs through a CAP vendor regardless of the level of ASP +6 percent. Nearly half (43 percent) would consider obtaining drugs through a CAP vendor *only if* ASP +6 percent went below the price at which their practice was able to acquire the drug. About 12 percent said they might consider CAP if ASP +6 percent was at the same level as what the practice paid to acquire the drug. Only 16 percent of physician respondents said they would consider CAP participation if ASP +6 percent stayed higher than their cost of acquiring drugs.

Information on specific practice demographics included three categories: location (large urban vs. rural practice), total annual revenue, and patient mix. The full results of this survey are available to ACCC members at the members-only web site, *www.accc-cancer.org/membersonly*.

Stakeholders Share Perspectives on CMS Coverage Guidance Document

On May 23, 2005, ACCC Executive Director Christian Downs, JD, MHA, and Senior Director of Policy and Government Affairs Deborah Walter, MPA, welcomed close to 50 oncology organizations to a meeting on "Medicare Coverage and the Future of Patient Care Delivery" at a stakeholders' forum in Washington, D.C. They joined a distinguished panel of clinicians, patient advocates, clinical researchers, and policy experts to listen and share perspectives about the CMS new guidance on Coverage with Evidence Development, or CED.

Stakeholders represented a wide constituency, including the Asian Pacific Island American Health Forum, the American Red Cross, the Alliance for Prostate Cancer Prevention, and the International Myeloma Foundation.

CMS has issued a draft document on when a coverage decision will be linked to a requirement for additional data collections—such as through a clinical trial or national registry. CMS may require such linkage when it is faced with a coverage decision in which there is insufficient evidence of benefit for the Medicare population. According to Downs, ACCC agrees with CMS that clinical evidence is essential for helping patients and physicians make treatment decisions, and the Association strongly supports efforts to expand research. Still, he notes, ACCC finds the draft guidance document to be vague, and Walter has indicated that it seems to be inconsistent with oral descriptions of CED made by agency staff, as well as CMS' recent application of CED in a national coverage determination (NCD) for anticancer chemotherapy for colorectal cancer.

In comments submitted to CMS on June 3, 2005, ACCC recommends that CMS include

Among the speakers were (from left) Robert L. Comis, MD; Joseph S. Bailes, MD; John E. Feldmann, MD, FACP; Al B. Benson III, MD, FACP; and Christian Downs, JD, MHA.

the following points in its next draft of the guidance document:

- CED will be used very rarely and never will be used for on-label uses of drugs or off-label, compendia-listed uses of drugs used in an anticancer chemotherapeutic regimen
- CED will be used only to expand access to care and will not be used to curtail access to therapies currently covered through the local coverage process
- CED will not be used to force patients or providers to enroll in clinical trials
- CMS will apply CED in a manner that minimizes increased costs for beneficiaries and providers
- When CMS uses CED, it must use data collection methods that fully acknowledge the heterogeneity of the Medicare population
- The decision to use CED will be made after consultation with stakeholders, including providers, and will be made only at the request of trial sponsors who believe Medicare coverage could help a trial move forward.

At the May 23 meeting, many overlapping stakeholder concerns emerged. "We are all in favor of evidenced-based medicine. We are all committed to help CMS in this effort, but there are significant cautionary aspects we must continue to provide as this moves forward," one participant commented.

Shown here are patient advocates and panel members Virginia T. Vaitones, MSW, OSW-C, from the Association of Oncology Social Work (at left) and Gail McGrath from the National Patient Advocate Foundation.

Generally, stakeholder concerns fell into the following areas, patient access to care, data collection and dissemination, impact on clinical research enterprise, impact on cancer and rare disease treatment, unclear or ambiguous language in the draft guidance, and the complexity of cancer care.

While the new CMS approach could potentially expand coverage and access to care, participants questioned whether an unintended consequence might actually be to limit coverage. And despite the draft guidance acknowledgment that local carrier discretion should be preserved, some asked if this new approach might actually erode local carrier discretion. Patients might be adversely affected as physicians lose both the ability to treat patients on a case-by-case basis and the flexibility to present new data in a local and personal fashion. Panelists also envisioned a scenario in which CMS would require more evidence for a given treatment—implying the current evidence is insufficient—which may in turn influence local carrier coverage decisions.

Many stakeholders expressed a need for more information. While many at the meeting expressed respect and support for Dr. McClellan's vision, common threads were an overriding concern for continued patient access to care; a need to look to existing resources for data collection and research; and finally, the importance of recognizing the changing nature of cancer research and treatment.