Oncology Issues

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Untying the Gordian Knot of Oral Oncology Drug Coverage

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Representatives from 14 major pharmaceutical companies and several cancer patient advocacy groups, including Cancer Care, Inc., gathered in Washington, D.C., April 26-27, for a special ACCC conference about oral oncology drug coverage, particularly for Medicare patients.

"We see oral drugs impacting our community in many ways—therapeutically, economically, and financially," said David K. King, M.D. "What does ACCC have to do with this issue? We truly believe the Association needs to be proactive and facilitate access and coverage for our patients." King is chairman of ACCC's Ad Hoc Committee on Reimbursement and a medical oncologist practicing in Phoenix, Ariz.

Although oral medications may not yet be a significant part of oncology practices or hospital formularies, more than 350 new agents will be launched in the next several years. Between 20 to 25 percent of these new agents will be oral formulations. These products are designed to attack different disease mechanisms, and can potentially be used across a broad array of tumor types. Likely benefits could include absence of drug resistance, a reduction in toxicity and side effects (such as bone marrow suppression, gastrointestinal problems, or hair loss), and the potential to provide maintenance treatment. Examples of oral anti-cancer therapies include: cytotoxic agents, anti-angiogenesis products, products that impact the cell cycle mechanism, inhibitors of signal transduction, and hormonal and hormone suppression agents.

"If you look at the future, it is broad and promising," said James L. Wade III, M.D., F.A.C.P., president of Cancer Care Specialists of Central Illinois and chair of the Clinical Practice Committee at the American Society of Clinical Oncology (ASCO). "Most of these oral agents will be additive to our practices. Some are oral versions of parenteral drugs. For example, an oral Topotecan is coming out.... At the present time, four agents are seeing the most use: capecitabine, temozolomide, etoposide, and thalidomide." Wade noted that the use of oral agents is rising within his Midwest oncology practice.

"I believe oral agents will complement rather than replace current chemotherapy," he told meeting attendees. However, he noted that management of these new agents will be very complex, particularly since there is a dearth of data regarding long-term side effects of the newer oral agents. Monitoring treatments will require development of a whole new technology to measure end points.

"In the end, the success of oral agents depends on how well they work and who will pay for them," said Wade.

He went on to urge that, for coverage, the new agents should be viewed similarly to current agents, namely access through a specialist and as an addition or replacement to current therapy (incident to a visit). Today, obtaining Medicare reimbursement for oral medications is not an easy and straightforward process. Medicare oral drug coverage is currently reimbursed in the Durable Medical Equipment Regional Carriers (DMERC) system. "Reimbursement takes about four to five weeks, just as fast as Part B," said Wade. "And reimbursement is the same. However, practices must be educated about how to work DMERC." A special supplier number is needed, and claims must be filed through regional carriers, separate from where claims are filed for injectable medicines. "Practices need outstanding billing people for this very complex billing process."

Medicare has had a limited coverage policy for oral cancer drugs. Medicare covers oral anti-cancer drugs where there is a non-self-administrable equivalent, but is precluded by law from covering oral anti-cancer drugs without an equivalent. Congressionally mandated coverage extensions for select self-administered products (such as immunosuppressive agents, erythropoietin, hemophilia clotting factors, certain oral anti-cancer drugs, and certain oral anti-emetics) do not include a number of existing oral cancer products and are too limited to ensure patient access to new novel oral cancer therapies. As a result, this policy essentially denies Medicare beneficiaries access to the majority of oral anti-cancer therapies that do not have an intravenous equivalent.

Representatives from 14 major pharmaceutical companies and several cancer patient advocacy groups gathered to hear two days of presentations about the status and future of oral cancer agents.

"We have to convince the carriers to cover oral agents in the same way they have covered parenteral therapy...that there are lives saved, improved quality of life and longevity, cost-effectiveness, and better outcomes," said Wade.

Patient advocate Patricia Spicer, C.S.W., of Cancer Care of Long Island, spoke at length about convenience and compliance issues regarding oral cancer agents. For the most part, patients find oral therapy is more convenient, takes less time away from other activities, and is more easily accepted and tolerated than IV-based therapy. "However, some patients, especially the older patient, may feel orals are not serious treatment...that orals are not as good," said Spicer.

All speakers agreed that patient advocates must take the lead in convincing Congress, and, in turn, the Health Care Financing Administration, of the need to make changes to the list of covered oral anti-cancer drugs. "Patient advocates will be key," said ASCO President Joseph S. Bailes, M.D., F.A.C.P. Throughout this year, both ASCO and ACCC will work closely with patient advocacy organizations to raise awareness of oral oncology drug issues among the public and Congress.

ASCO President Joseph S. Bailes, M.D., F.A.C.P., (left) emphasized that patient advocates will be key to raising awareness in Congress about the importance of fair reimbursement for oral oncology drugs. Speaking at ACCC's recent conference on oral oncology drug coverage, Bailes was joined by David K. King, M.D., F.A.C.P., chair of ACCC's Reimbursement Committee.

CALL FOR AMENDMENTS TO BYLAWS

Any delegate representative who would like to suggest a Bylaws change must inform the ACCC Executive Office of that intent **no later than November 15, 2000,** for consideration by the House of Delegates in March 2001. According to the ACCC Bylaws, adopted in March 1984 by the House of Delegates, "Bylaws may be amended by the vote or written assent of two-thirds of the delegate representatives voting. Written notice of proposed Bylaws amendments must be sent to voting members at least 30 days prior to the meeting at which they are to be acted on."

All suggested amendments should be sent to: ACCC, Attn: Fran Stigliano, 11600 Nebel Street, Suite 201, Rockville, MD 20852 (phone: 301-984-9496, ext. 219; fax: 301-770-1949).

CALL FOR NOMINATIONS

The ACCC Nominating Committee is soliciting nominations for the following Board positions:

- President-Elect
- Treasurer
- Five Board positions

The term of President-Elect is one year. The Treasurer and Trustee positions are two-year terms. Although nominees are not required to be the voting representative, they must represent an ACCC Active member institution or chapter.

Letters of nomination should be sent to the ACCC Executive Office, citing the nominee's name and his/her respective membership affiliation (institution/chapter), along with a copy of his/her curriculum vitae. Nominations must be received **no later than November 30, 2000.**

For more information about the nomination process, contact Fran Stigliano at the ACCC Executive Office (as noted above.)

CLINICAL RESEARCH AWARD

The Association of Community Cancer Centers (ACCC) is soliciting nominations for its annual Clinical Research Award. This award will be presented to one or more individuals, whose research has significantly and positively impacted the oncology patient, family, and/or community. A special award luncheon is held at ACCC's fall national meeting to honor the award recipient(s), who will receive a cash award and a plaque commemorating the event. Previous honorees include: Leslie G. Ford, M.D.; Betty Ferrell, R.N., Ph.D., F.A.A.N.; Henry Lynch, M.D.; Rodger Winn, M.D.; James Holland, M.D.; Jimmie Holland, M.D.; E. Donnell Thomas, M.D.; and Vincent DeVita, Jr., M.D.

To submit a nomination, please send a letter (minimum two paragraphs; maximum two pages), with your name and telephone number, stating why you believe the individual is qualified to receive this award. Please submit nominations to the ACCC Executive Office, 11600 Nebel Street, Suite 201, Rockville, MD 20852-2557, (fax: 301-770-1949) **no later than November 30, 2000.** If you need further information, please contact Fran Stigliano at the ACCC Executive Office (as noted above.)