Oncology Issues

Oncology Issues

ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

Progress Report: Assuring Access to Clinical Trials

Jamie Young

To cite this article: Jamie Young (1997) Progress Report: Assuring Access to Clinical Trials, Oncology Issues, 12:1, 6-40, DOI: 10.1080/10463356.1997.11904654

To link to this article: https://doi.org/10.1080/10463356.1997.11904654

Published online: 18 Oct 2017.

Progress Report: Assuring Access to Clinical Trials

by Jamie Young

Progress recently made at both the state and national levels continues to chip away the barriers to clinical trials faced by those with cancer. In late October, the National Cancer Institute (NCI) and the Department of Veterans Affairs (VA) signed an interagency agreement for a clinical trials partnership for cancer. One month prior to that, California became the only state in the nation to guarantee terminal patients who are denied experimental treatment an independent review by medical experts. Their decision is binding on the plan or insurer. Finally, after repeated attempts, legislation in Illinois requiring coverage of patient care costs of clinical trials passed the state House of Representatives, setting up the possibility that a law could be passed in early January 1997.

The VA operates an extensive health care delivery system that includes 173 medical centers and more than 400 clinics. VA outpatient services register 30 million visits a year. According to the interagency agreement, "the VA medical system has substantial expertise in the diagnosis and management of cancer and has currently designated or proposed fifty-six institutions as comprehensive cancer centers." The VA's Cooperative Studies Program has sponsored a clinical research program, including cancer research, for decades. Many of these institutions are already affiliated with the NCI's cooperative group program.

The interagency agreement builds upon NCI/VA's existing relationship by creating a more formal structure to cover the full range of NCI-sponsored studies in diagnosis, treatment, and prevention. NCI sponsorship includes trials reviewed and approved by NCI staff, NCI cooperative group studies, studies conducted in clinical and comprehensive cancer centers under an NCI-approved protocol review and surveillance mechanism, and protocols performed under the direct support of an NCI peer-reviewed grant.

The fundamental features of the NCI/VA partnership are to 1) increase the access of eligible veterans to NCI-sponsored trials of new approaches to the diagnosis, treatment, and prevention of cancer and 2) provide VA clinical investigators with expanded opportunities to participate in clinical cancer research.

The VA will be responsible for all medical care, including tests, treatment, follow-up, management of complications, and costs of commercially available drugs, for eligible veterans participating in trials at VA sites. The agreement states, "the NCI will provide funding for the research costs of participation in NCI-sponsored studies. These may include costs considered allowable by PHS policy as well as the provision of any investigational agents used in the protocols. These research costs will not be the responsibility of the eligible veteran participating in the trial." The joint demonstration project began on January 1, 1997, and will be conducted for three years.

LEGISLATIVE PROGRESS

Assembly Bill 1663, sponsored by Assemblywoman Barbara Friedman and Assemblyman David Knowles, was signed by California Governor Pete Wilson on September 27, 1996. Numerous cancer-related organizations were instrumental in the bill's passage, including the Medical Oncology Association of Southern California (MOASC) and the Association of Northern California Oncologists (ANCO).

Under this new law, any patient whose doctor has certified that he or she has a terminal condition with a high probability of causing death within two years is eligible for an independent review process. The expert review is triggered when a health plan denies treatment recommended by a doctor who has determined that standard therapies would not be appropriate or effective. Health plans would be bound by the decision of the independent experts. As a result, "terminal patients can be assured that their treatment decisions will be made on the basis of medical science, not corporate profits," said Friedman.

The ACCC Governmental Affairs Committee reviewed the bill in September and chose not to actively seek introduction and passage of similar legislation in other states until the implementation of the law is further along. However, ACCC has pledged to assist MOASC by participating in the process of developing the regulations that are necessary to implement the law.

House Bill 3168, the Illinois clinical trials legislation sponsored by Rep. Anne Zickus and Rep. Judy Erwin, and backed by ACCC, the Illinois Medical Oncology Society, and the Illinois Division of the American Cancer Society, has begun to move rapidly after months of being bottled up in the House Rules Committee. A hearing was held September 10, 1996, in Chicago by the House Health Care and Human Services Committee. Committee members present for the hearing were generally favorable toward the bill.

The Health Care and Human Services Committee held another hearing on the bill on December 4, hearing testimony from ACCC Board of Trustees member Dr. Edward Braud, and promptly

continued on page 40

Jamie Young is ACCC director for state societies and government relations.

Medicare Coding and Billing: Practical Survival Tips

continued from page 33

have taken for granted that in a managed care world coding does not count for much. The key to maintaining income levels is to track utilization. Whoever has the best data wins. In addition, most cancer practices are not capitated, and thus, payment is directly related to coding. Approval for drugs is directly linked to ICD-9 coding, so do not neglect it.

Many practices do not appeal denials nor go after money that is owed to them. Physicians should be aggressive about payment regardless of source. Pharmaceutical companies can often assist you. Also remember that patients may have sources of payment that they don't even know about. With managed care, patients are responsible for their coverage choices—even Medicare patients. This means that beneficiaries and employers should be involved in denials, plan choices, pre-existing conditions, and poor chemotherapy coverage.

Make sure billing operations are in gear. If more than 10 percent of your receivables are more than 120 days, you are not in good financial shape. The following are check points to ensure that your office stays on track.

- Percentage of collections are 70 to 80 percent for medical oncologists.
- Substantial denials are reviewed by a physician in the practice.
- Coding books—ICD-9, CPT, and HCPCS—are from 1997.
- Medicare bulletins are up to date.
- All pertinent personnel understand existing contracts and their terms.
- Drugs are appropriately paid by carriers.
- Providers understand their EM utilization.

To survive in today's competitive, complex world, become an active participant. Attend meetings of your local oncology society. Exchange ideas on how to manage the unmanageable. Don't allow yourself the luxury of being outdated. You own your destiny!

CAPITOL COMMENTS

continued from page 6

approved the bill unanimously. The following day the bill was approved by the full House of Representatives by a 111-0 margin. The legislature does not end its current session until the first full week of January, at which time any bills that have not been approved by both chambers must be reintroduced to be considered in the new General Assembly that convenes January 7, 1997. IMOS, ACCC, and others are hopeful that the overwhelming support of the House and the well-placed support in the Senate may lead to a happy new year indeed.

WELCOMING NEW STATE CHAPTERS

Two state oncology societies have joined the ranks of ACCC state chapters. The Nevada Oncology Society, led by Dr. Mary Ann Allison, and the Hawaii Society of Clinical Oncology, led by Dr. Carl Higuchi, became the thirteenth and fourteenth state chapter members, respectively. The ACCC Board of Trustees proudly welcomes the members of these societies to our association. Complete listings of members for both chapters are listed on the ACCC website **(http://www.assoc-cancer-ctrs.org)**.

SCORECARD, CONTINUED

In the November/December 1996 *Oncology Issues*, Arkansas was left off the legislative "scorecard." Arkansas became the eighteenth state to pass off-label drug legislation into law when Governor Jim Guy Tucker signed Senate Bill 816 on April 12, 1995. Effective July 28, 1995, the law requires coverage of off-label uses of FDA-approved cancer drugs when the off-label use is recognized as safe and effective for treatment of that specific type of cancer in any of the three compendia or two articles from major peer-reviewed professional medical journals.

PROFESSIONAL OPPORTUNITIES