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Proposed Legislation To Cover Cancer Clinical Trials for Medicare Recipients

by Jamie Young

United States Senator Jay Rockefeller (D-W.V.) and Connie Mack (R-Fla.) introduced the "Medicare Cancer Clinical Trial Coverage Act of 1996" on July 17. The bill (S. 1963) establishes a demonstration project requiring Medicare coverage for patient care costs for people with cancer enrolled in approved clinical trials.

The legislation has generated broad support from the cancer community, including not only ACCC but also many patient advocacy organizations, most notably the National Coalition for Cancer Survivorship, which has spearheaded this effort.

Specifically, the legislation mandates that beginning no later than January 1, 1997, the Secretary of Health and Human Services shall establish a demonstration project to study the impact on the Medicare program of covering routine patient care costs for beneficiaries enrolled in approved clinical research. Medicare beneficiaries with a diagnosis of cancer shall be automatically eligible for coverage of routine patient care costs provided in the context of an approved clinical trial, defined to include any clinical trial approved by one of the National Institutes of Health (NIH), an NIH cooperative group or an NIH center, the Food and Drug Administration in the form of an investigational new drug or device exemption, the Department of Veterans Affairs, the Department of Defense, or a qualified non-governmental research entity identified in guidelines issued by the NIH for center support grants.

"Routine patient care" is defined to include items and services that would otherwise be covered outside the scope of a trial and are furnished according to the design of an approved clinical trial or to treat conditions resulting from an approved clinical trial. It does not include an investigational drug or device (unless the Secretary of HHS has authorized the manufacturer to charge for such drug or device) or any item or service supplied without charge by the sponsor of the approved clinical trial.

The Secretary of HHS is to report back to Congress no later than January 1, 2001, regarding any incremental cost to the Medicare program resulting from the demonstration project. The report is also to include projections for Medicare expenditures should coverage of patient care costs in clinical trials be extended to diagnoses other than cancer. Unless changed, the provisions of the proposed law would not apply after June 30, 2001.

The legislation follows the recent release of a U.S. General Accounting Office report regarding coverage of autologous bone marrow transplantation for Breast Cancer (GAO/HEHS-96-83). This column described the initiation of this GAO project in the November/December 1995 *Oncology Issues*. At the request of the GAO, ACCC agreed to provide names of some of our members who might be willing to take part in the study.

The report was requested by U.S. Senator Ron Wyden of Oregon. The GAO was asked to address 1) the factors that have influenced insurers in deciding whether to cover the treatment, 2) the status of the research on ABMT for breast cancer and consensus on what is known about its effectiveness, and 3) the consequences of the increased use and insurance coverage of the treatment while it is still being evaluated in clinical trials.

According to its report, the GAO surveyed 12 health insurance companies, which included a mix of indemnity and managed care plans. They also obtained information from researchers and oncologists at major research centers, large urban hospitals, and community hospitals.

The GAO concluded that although ABMT is widely considered an experimental therapy, many health insurers are covering ABMT following high-dose chemotherapy for breast cancer. The twelve insurers responded that they based their decision to cover the treatment on the preliminary clinical evidence, but also on factors such as fear of lawsuits and adverse public relations.

The GAO provided statistics that show the use of ABMT for breast cancer has increased rapidly in just a few years, from an estimated 522 patients in 1989 to an estimated 4,000 in 1994. At least seven states have passed laws that require insurers to pay for the procedure. In addition, Medicaid covers the treatment in some states, and the Office of Personnel Management has required that all beneficiaries of the Federal Employees Health Benefits Program be covered.

The report found that NCI-sponsored randomized clinical trials have been slow to accrue patients in part due to the wide availability of ABMT (see related article on page 24). The GAO said that many experts expressed concern that a substantial portion of patients receiving ABMT are outside of a research setting which will further slow down the effort to learn whether the treatment is effective.

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