After years of advocating increased patient access to and participation in cancer clinical trials, the American Cancer Society recently celebrated a significant federal victory: Effective September 19, 2000, Medicare will now cover routine patient care costs for all Medicare beneficiaries with cancer or other serious or life-threatening diseases who enroll in qualifying clinical trials.

Thanks to the vigorous, consistent efforts of the ACS and other patient advocacy groups, the new benefit includes coverage for “items and services routinely provided with standard therapy, as well as those associated with the administration of the investigational item or service; clinical monitoring; items or services needed for the prevention of complications; and reasonable and necessary costs arising from the administration of the investigational item or service, including those necessary for the diagnosis or treatment of complications.” Medicare will not cover the cost of the investigational drug or device itself, or for research-related costs such as data collection and analysis.

A “qualifying trial” must meet specific criteria (outlined in the National Coverage Decision)—i.e., it must have therapeutic intent—and certain studies, such as those funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Department of Defense, the Department of Veterans Affairs, and the Health Care Financing Administration, are automatically covered.

**States Get Into the Act**

On the statewide level, momentum has been gathering to further expand access to clinical trials by private agreements or legislation that would either encourage or require managed care companies to cover costs of their members who enroll in studies. In early 1999, for instance, Rhode Island and Maryland led the way by enacting such legislation; several other states have either followed suit or have introduced similar bills. Another model is being worked out in New Jersey, where a coalition of leading health insurers is working with the state to establish an agreement regarding coverage of members’ costs when they participate in a cancer clinical trial.

The ACS applauds these and other ongoing efforts because the issue of cost has always been a sticking point when patients consider entering a cancer clinical trial. Unfortunately, while the need to increase trial enrollment is urgent, many challenges remain regarding public perceptions.
Changing Public Perceptions

Although patients and professionals often cite fears about medical coverage, other public misperceptions are as much to blame for low levels of participation in cancer clinical trials. It has been estimated that at least 10% of adult cancer patients need to enroll in clinical trials, although fewer than 3% do so now.

In surveys, both cancer patients and the general public appear to believe that opting for “standard treatment” would be better than agreeing to participate in a trial. Likewise, many fear that they will be treated with a placebo. And, even if insurance coverage is less of an obstacle, many are afraid that they would have to travel too far to obtain treatment and/or that it would be inconvenient.

Reluctance to participate in clinical trials is even more acute among minority populations and the elderly, where language barriers and mistrust of the medical community represent significant barriers.

There is a lot of misunderstanding about what a clinical trial is, and some people are frightened by the idea. Patients may think that enrolling in a trial means that their cases are hopeless or that they will have to give up control over their care. Providers should talk with patients, educating them about the realities and benefits of clinical trials, guiding and assisting them in locating appropriate trials, and encouraging them to consider participating in any that offer potential benefit.

Some cancer organizations and advocacy groups have initiated an effort to educate the public, hoping that if patients understand the benefits of participating in a clinical trial, which include highest quality care and access to new, and possibly improved, therapies, they may begin to demand information about available trials.

An Ongoing Battle

Another challenge in the uphill struggle to increase participation in cancer clinical trials is the fact that there is no central coordinating agency or site that lists all open or ongoing trials. Many pharmaceutical or biotech sponsored trials are only listed on the companies’ own Web sites. Despite the fact that government funded clinical trials are more centrally accessible, there are many interesting, potentially useful trials that are difficult to find. The ACS has begun exploring ways to consolidate such information, perhaps based on a clearinghouse model.

This is a critical time for people with cancer to participate in clinical trials. The revolution in biotechnology has left us with an enormous backlog of promising new drugs and diagnostic methods that are ready for study in humans. Everything we know so far about how to treat cancer, we learned in clinical trials, and the only way we will ever learn more—about how to prevent cancer and how to cure it—will be because of clinical trials.

—Ted Gansler, MD
—Harmon J. Eyre, MD
What is a clinical trial?
Studies of promising new treatments are known as clinical trials. Thousands of these studies are currently underway in the US. Using clinical trials, researchers try to answer certain questions about a new treatment, such as:

- Does it work better than the one we’re currently using? Is it as effective with fewer side effects?
- What side effects does it cause?
- Do the benefits outweigh the risks?
- Which people are most likely to find this treatment helpful?

Your doctor may suggest that you look into a clinical trial. This doesn’t mean that your case is hopeless. It means that your doctor believes you may benefit from the treatment being studied.

What type of care will I receive in a clinical trial?
If you agree to enroll in a trial, you will receive excellent care. In fact, instead of being treated by one or two doctors, your health and well being will be monitored by many specialists.

Will I be a “guinea pig?”
Clinical trials aren’t set up so that some people receive a less effective treatment. If the researchers see that the new treatment is more effective than the standard one, the trial is stopped and all participants receive the more successful therapy. If any evidence shows that the new treatment is inferior or toxic, the trial is stopped to protect the participants.

Could I receive a placebo?
A placebo is an inactive substance used in some scientific experiments. Clinical trials of anticancer drugs almost never include a placebo group. One patient group may receive a standard treatment for cancer while another group receives the treatment being studied. This way, researchers can compare the standard treatment with the new treatment to see whether the new treatment benefits the patients more than the other option.

Does it cost more to participate in a clinical trial?
Extra follow-up visits and regular monitoring are part of participating in a clinical trial. Check with your insurance company and health care provider to see if they pay for the costs of the treatments. Most doctors involved in clinical trials are careful to keep the number of office visits, laboratory tests, hospital stays, and other expenses to a minimum. Thanks to recent legislation, Medicare now covers routine costs for patients enrolled in clinical trials.

How can I find out about clinical trials?
Talk with your doctor. Together you can use the sources listed on the next page to research clinical trials for which you may be eligible.
### How to Find Out About Clinical Trials

| Organization                                                                 | Website/Phone          |
|------------------------------------------------------------------------------|------------------------|
| American Cancer Society                                                     | www.cancer.org         |
| 1-800-ACS-2345                                                               |                        |
| American Society of Clinical Oncology                                        | www.asco.org           |
| Cancer Care Inc.                                                             | www.cancercare.org     |
| Cancer Leadership Council                                                   | www.cancercare.org     |
| Coalition of National Cancer Cooperative Groups                             | www.ca-coalition.org   |
| CTEP                                                                         | http://ctep.info.nih.gov/relsites.htm |
| Food and Drug Administration                                                | www.fda.gov <http://www.fda.gov> |
| Memorial Sloan-Kettering Cancer Center                                      | www.mskcc.org          |
| National Cancer Institute                                                   | www.cancernet.nci.nih.gov |
| National Coalition for Cancer Survivorship                                  | www.cansearch.org      |
| NIH Cancer Trials                                                            | http://cancertrials.nci.nih.gov |
| Oncology Nursing Society                                                    | www.ons.org            |
| Oncology Tools Site (FDA)                                                   | www.fda.gov/cder/cancer |
| The University of Texas M.D. Anderson Cancer Center                         | www.mdanderson.org     |
| University of Pennsylvania                                                  | http://oncolink.upenn.edu |
| Yale-New Haven Medical Center                                               | www.info.med.yale.edu/wcc |

The FDA does not regulate or monitor cancer information on the Internet, but anyone who has questions about clinical trials advertised online can contact the FDA Cancer Liaison Program at 301-827-4460.