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Medicare Widens Drugs It Accepts for Cancer

By REED ABELSON and ANDREW POLLACK

Medicare, with little public debate, has expanded its coverage of drugs for cancer treatments not approved by the Food and Drug Administration.

Cancer doctors had clamored for the changes, saying that some of these treatments, known as off-label uses, were essential if patients were to receive the most up-to-date care. But for many such uses there is scant clinical evidence that the drugs are effective, despite costing as much as $10,000 a month. Because the drugs may represent a patient's last hope, though, doctors are often willing to try them.

The new Medicare rules are the latest twist in a protracted debate over federal spending on off-label drugs — drugs prescribed for uses other than those for which they have been specifically approved.

Proponents of the changes say such spending not only helps patients, but can also enhance medical understanding of which treatments work against various forms of cancer.

But opponents argue that the new approach may waste money and needlessly expose patients to the side effects of drugs that may not help them. They also raise the possibility of conflicts of interest, because the rules rely on reference guides that in some cases are linked to drug makers.

The new policy, which took effect in November, makes it much easier to get even questionable treatments paid for, critics of the changes say. Medicare is providing "carte blanche in treatment for cancers," said Steven Findlay, a health policy analyst for Consumers Union. He said overly expansive coverage encourages doctors to use patients as guinea pigs for unproved therapies.

Because Medicare officials canceled a cost analysis of the changes, it is hard to predict how much spending will increase beyond the $2.4 billion Medicare paid in 2007 for cancer drugs. But cancer doctors and other experts say the new policies, adopted in the final months of the Bush administration, seem almost certain to raise the federal drug bill, while making it more difficult for the new administration to rein in spending on unproven medical treatments.

Although President Obama has made a goal of controlling health care costs, a spokesman for the Obama administration declined to comment on the Medicare changes.

One of the many drugs whose use is likely to expand is the Eli Lilly product Gemzar, which costs $2,500 to $5,000 a month. The F.D.A. has approved it to treat only four types of cancer. But the new rules will virtually guarantee that Medicare will pay for its use for about a dozen other cancers, including advanced cervical cancer — even though the evidence supporting Gemzar for that use is "inconclusive," according to one of the reference guides Medicare will now be consulting.

In the case of Genentech's Avastin, one of the world's most expensive and widely used cancer drugs, Medicare

rejected in 2007 nearly all of the estimated $16 million in requests from doctors' offices to cover its off-label use for ovarian cancer, according to claims specialists who work with Medicare data but declined to be identified because of the controversy over the topic. Under the new rules, Avastin will be routinely covered for ovarian cancer — as will at least some other off-label uses, including for brain and kidney cancer.

It is unclear how much precedent Medicare's new rules might have on private insurers, which often follow the agency's lead on paying for drugs.

Medicare officials defend the new policies, saying they respond to cancer doctors' concerns that the agency has been too slow to recognize promising new off-label treatments. Dr. Steve Phurrough, who has overseen coverage for the agency since 2003, noted that a 1993 federal law gave Medicare specific authorization to cover some unapproved uses of cancer drugs.

"Congress wanted a lesser level of evidence," Dr. Phurrough said. The question of what is adequate evidence is "not a line in the sand," he said. "It's a broad stripe in the sand."

The American Society of Clinical Oncology, which represents cancer doctors, has hailed the new rules, saying they will ensure that the appropriate off-label uses are covered.

But some specialists say that being able to offer off-label drugs can also let physicians avoid hard discussions with patients about a grim prognosis.

"It makes it easier to give drug after drug," said Dr. Andrew Berchuck, director of gynecologic oncology at Duke University, "and keep the fantasy alive."

The new rules expand the number of reference guides — or compendiums — that Medicare relies on for determining which off-label uses of cancer drugs to cover. The writers and editors of these compendiums, who work completely outside the federal government, scan the medical literature and evaluate the evidence in making their recommendations.

In 1993, Congress had authorized three compendiums for Medicare, all published by not-for-profit organizations. But by 2007 two had stopped publishing, leaving Medicare with a single compendium. Having selected three additional guides last year, the agency plans to review its choice of guides every year.

Under the old rules, Medicare representatives were supposed to consult the compendiums but also use their own discretion in interpreting the guides' recommendations. The new rules essentially delegate the decision to guides Medicare has selected, even when there is little clinical evidence behind a particular recommendation. As long as at least one of them recommends a cancer treatment, Medicare is essentially obliged to pay for it — unless one of the other guides specifically advises against it.

And some of these new compendiums have close financial ties to the drug industry, according to the draft of a report Medicare commissioned last year after Congress raised questions about possible conflicts of interest. The draft was completed in October, with a final version to be released soon.

The draft criticizes the new rules for essentially taking most decisions about off-label cancer drugs out of Medicare's hands, even when the agency is aware of potential conflicts. The guide's recommendation, the report says, "becomes the final word."

For some experts, the bigger concern about using some cancer drugs off-label without adequate evidence is that they may not only be useless — they may cause dangerous side effects.

"We have very little faith that those indications that make it into the compendia are safe, let alone effective," said Dr. Allan M. Korn, the chief medical officer for the Blue Cross and Blue Shield Association, who added that Medicare should cover off-label drugs only if the results of their use are carefully tracked afterward. There is no such requirement in the new Medicare guidelines.

There have been three different top Medicare administrators since the off-label rule changes were set in motion a few years ago. The second of them, Leslie V. Norwalk, chose to select the compendiums through a streamlined and internal administrative process, instead of the more elaborate and public process that Medicare often uses for broad coverage decisions.

"I did not see it as a significant step in coverage," said Ms. Norwalk, who left Medicare in 2007.

Drug makers say they welcome the Medicare changes. A spokesman for the Pharmaceutical Research and Manufacturers of America, the industry's main trade group, said the new rules ensured "that cancer patients have access to the treatments they need."

Many oncologists say they needed greater flexibility in using cancer drugs because it can take months or years for a new use to be approved by the F.D.A. They cite the example of Celgene's drug thalidomide, now a mainstay treatment for multiple myeloma, which was prescribed only off-label for years before the F.D.A. formally approved it for that use.

And in the case of rare types of cancer, there may be so few potential patients that companies have little financial incentive to undergo the formal F.D.A. process for approving a drug for expanded use. Only two drugs have been approved by the F.D.A. for brain cancer, for example, and cancer doctors say they need the ability to try other drugs or other combinations of treatments.

"To arbitrarily stop after two drugs to me is ludicrous," especially for younger patients, said Dr. Virginia Stark-Vance, a solo practitioner in Dallas and Fort Worth. She said one of her brain cancer patients had been kept alive for 10 years by off-label use of irinotecan, a colon cancer drug that was the ninth drug the patient tried.

Medicare seems to have ignored some concerns raised by a group of outside researchers whom the agency had asked to survey a half-dozen compendiums, including the four that Medicare has now adopted. That report, completed in 2007, found that the six guides "cited very little of the available evidence," said Dr. Amy P. Abernethy, a Duke oncologist who led the study.

The study also found great variability among the guides, in terms of what uses were recommended — or discussed at all.

Despite her study's findings, Dr. Abernethy says she does not oppose Medicare's new rules.

"I think the addition of the new compendia this year is an important increase in the bandwidth," she said.

Critics say the agency also seems to have played down the potential financial conflicts of interests between the drug industry and the producers of the compendiums. The draft study that was completed in October notes that one of the new guides is published by the National Comprehensive Cancer Network, a group of 21 leading

cancer centers that routinely employs experts who have financial ties to the drug industry.

William T. McGivney, the network's chief executive, said each committee of reviewers had 20 to 30 members, which "diminishes the opportunity for dominance of one person's opinion," regardless of any ties to drug makers.

Then there is the American Hospital Formulary compendium, the one that Medicare was using before the November changes and will continue to consult. It has long been published by the nonprofit American Society of Health-System Pharmacists. But last year the society forged a financial relationship with a foundation linked to drug companies and some cancer doctors' private practices.

A drug company can apply to that foundation, the Foundation for Evidence-Based Medicine, and pay a $50,000 fee to have new uses of its drug reviewed by the compendium within 90 days. The foundation was started in 2007 by the Association of Community Cancer Centers, which represents oncology practices, and says it received about $200,000 in initial funding from drug makers.

Gerald K. McEvoy, the guide's editor in chief, said the application fee was meant to raise money to pay for additional researchers, to address previous criticism that the publication was too slow to vet new evidence. The foundation insulates the guide's staff from industry pressure, he said, and fewer than one-third of the reviews under the new arrangement have resulted in a positive recommendation in the compendium.

Medicare officials acknowledge that some of the potential conflicts need to be addressed. But they say they have confidence in the guides they have chosen. "We had significant conversations with all the companies," Dr. Phurrough said.

Coverage of Routine Patient Care Costs in Clinical Trials
Position Statement

Approved by the ASCO Board of Directors, March 2005

For people with serious or life-threatening illness, like cancer, completely satisfactory or curative treatment often is not available. Those patients are nevertheless able to receive state-of-the-art therapy through high-quality clinical trials, offering not only an important treatment option but an opportunity to advance medical knowledge.

Cancer patients face a number of obstacles to clinical trials enrollment. One of the barriers is the potential denial of third party payment for the routine patient care costs for those enrolled in clinical trials. Historically, payers have denied coverage for care provided in a clinical trial, arguing that such care is "experimental" and therefore not a covered benefit.

Current Clinical Trials Coverage

The American Society of Clinical Oncology (ASCO) and its partners in the patient advocacy community have sought, over the course of more than a decade, to reform clinical trials payment policy in public and private health plans. These efforts have resulted in reforms in Medicare payment policy and in enactment of legislation to ensure clinical trials coverage in more than 20 states.

In 2000, in response to Congressional pressure and cancer community advocacy, the Clinton Administration issued an Executive Memorandum setting a policy for coverage of the routine patient care costs for Medicare beneficiaries enrolled in clinical trials for all diseases.

In addition to action by Medicare, a number of states have enacted legislation that would ensure coverage of routine patient care costs in clinical trials (coverage ranges from cancer clinical trials only to trials for all diseases) by those health plans that are regulated by the state. Some of those states have adopted, either in statute or in implementing regulations, the coverage standards of the Medicare program. In several states without clinical trials coverage mandates, third party payers have entered into voluntary agreements to cover routine costs in clinical trials. States continue to engage in efforts to improve coverage in state plans.

ASCO Position

These federal, state, and private sector initiatives reflect widespread recognition of clinical trials coverage as a critical element of quality cancer care. However, not all of the initiatives meet the standards for coverage endorsed by ASCO, and a significant number of cancer patients remain beyond the reach of these reimbursement reforms. ASCO recommends that every cancer patient should have access to clinical trials under the criteria defined below.

Standards for Clinical Trials Coverage

The following ASCO standards should remain the standard for Medicare coverage and should serve as the model for state legislative initiatives, including provisions governing coverage under state-funded programs like Medicaid, as well as mandates for private insurance and managed care plans.

The cost of medical care provided when a patient with serious or life-threatening disease is entered on a Phase I, II, III, or IV (post-marketing) clinical trial – including hospital, physician, and other health care items and services as well as the cost of approved drugs for labeled or unlabeled uses which might be part of the regimen[1] – should not be denied coverage when all of the following are demonstrated:

- Treatment is provided with a therapeutic intent[2];
- Treatment is being provided pursuant to a 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 (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption; the Department of Defense; the Department of Veterans Affairs; or a qualified non-governmental research entity as identified in National Cancer Institute guidelines or center support grants;
- The trial is conducted according to a written protocol, which includes the following elements: trial design and scientific justification, criteria for inclusion and exclusion, outcome measures, statistical analysis plan, conflicts and other ethical controls, and publication policy;
- The protocol has undergone scientific review by a group of independent and qualified experts;
- The clinical trial has been reviewed and approved by a qualified institutional review board (IRB);
- The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training;
- There is no non-investigational therapy that is clearly superior to the protocol treatment; and
- The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.[3]

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As amended June 1994 and March 2005

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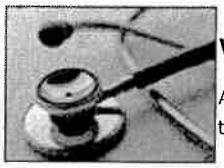
[1] Items and services required by the design of the trial should be covered, except those items or services normally paid for by other funding sources such as the cost of certain investigational drugs, the costs of any non-health services that might be required for a person to receive the treatment, and the costs of managing the research.

[2] Treatment with therapeutic intent may be aimed at improving patient outcome relative to either survival or quality of life.

[3] While these standards refer to clinical trials involving "treatment" or "therapy", the same principles would apply equally to trials of interventions to prevent, rather than treat, diseases.

Clinical Trials: What are States Doing?
February 2009 Update



What is a Clinical Trial?

A clinical trial is a research study on human patients to test the safety and effectiveness of new treatments. These trials offer patients access to new and potentially life saving drugs and cures.

The dramatic progress made in treating childhood cancers in recent years, is attributable, in part, to clinical trials, because 60 percent of all children with cancer are enrolled in some kind of trial. A ten percent drop in breast cancer mortality for women under the age of 50 is said to be the result of clinical trials research conducted in the 1970's.

Who Enrolls in Clinical Trials?

Only two to three percent of eligible adult patients enroll in clinical trials. For cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment.
Only a small percentage (approximately 20%) of cancer patients are eligible to participate in a clinical trial and very few (approximately 3% of cancer patients and less than 0.5% of Medicare patients) currently enroll. Even if enrollment was increased to the full 20 percent, it is unlikely that these numbers will significantly impact overall costs to health plans;[1]

Insurance Coverage for Clinical Trials

Typically, when a patient enrolls in a clinical trial, the cost of tests, procedures, drugs and any research activity directly associated with the investigation, are covered by the group sponsoring the trial, such as a pharmaceutical company or the National Cancer Institute. However, because some health plans define clinical trials as "experimental" or "investigational," health insurance coverage may or may not include some or all of the costs of "routine patient care," such as the doctor visits, hospital stays, tests and x-rays, that a patient would normally receive whether or not they were enrolled in a trial.

A growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of the routine medical care a patient receives as a participant in a clinical trial.

Advantages:

For cancer patients, properly designed and conducted clinical trials represent an important therapeutic option, as well as a critical means of advancing medical knowledge. Lack of insurance coverage is a barrier to patients who might otherwise participate. Sixty percent of patients in one survey cited fear of insurance denial as a major reason for not participating in clinical trials. And finally, a recent study found only a slight increase in treatment costs for adult clinical trial patients compared to nonparticipants--$35,418 versus $33,248.[2]

Some large HMOs have computed costs associated with patients in clinical trials. Kaiser Permanente discovered the cost of medical care for enrollees in clinical trials that haven't had bone marrow transplant were no higher than for patients who were not enrolled in a trial. The Kaiser report further states, "Kaiser has been participating in cancer clinical trials without substantial increases in the direct costs of medical care."[3]

Researchers at the Mayo Clinic found that patient care costs for those enrolled in clinical trials is only slightly more than for patients who received standard therapy protocols.[4]

The Institutes of Medicine has also found the following:
-The reimbursement costs are limited to the cost of "standard care" which would be covered if the patient were not enrolled in the trial;[1]

-Only a small percentage (approximately 20%) of cancer patients are eligible to participate in a clinical trial and very few (approximately 3% of cancer patients and less than 0.5% of Medicare patients) currently enroll. Even if enrollment was increased to the full 20 percent, it is unlikely that these numbers will significantly impact overall costs to health plans;[1]

-Through clinical trials, we will be able to identify ineffective treatments, which could save health plans money and will benefit the nation as a whole.[1]

Disadvantages:

Even though the same recent study found only a slight increase in treatment costs, the 6.5 percent increase between participants and

nonparticipants in clinical trials translated into an additional $16 million in 1999 spent on treatment costs for the 19,000 adult patients enrolled in National Cancer Institute-sponsored clinical trials.[2] These additional insurance costs, like other mandated benefits and services, may result in higher insurance premium rates, which are often cost-shifted onto workers in the form of higher deductibles and copayments.

For states without insurance mandates, it is possible that some physicians may enroll patients in clinical trials but not inform the patients' insurance companies, bypassing the reimbursement issue for the patient and potentially the physician.[5]

It may also be possible to encourage participation in clinical trials by working within networks of health care providers and industry, research facilities, patient groups, as well as major media outlets, without enacting a state wide insurance mandate.

Sources:

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2. Goldman DP, Berry SH, McCabe M, et al. Incremental Treatment Costs in National Cancer Institute–Sponsored Clinical Trials. JAMA. 2003;289(22):2970-2977 (doi:10.1001/jama.289.22.2970) http://jama.ama-assn.org/cgi/reprint/289/22/2970.pdf

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4. Wagner JL, Alberts SR, Sloan JA, *et al.* Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *J Natl Cancer Inst* 1999;91:847-53.

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Definitions of Phases:

A clinical trial study is conducted in four phases.

Phase I: Research is conducted on a small group of volunteers (20 to 80 people) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.

Phase II: The experimental drug or treatment is given to or a procedure is performed on a larger group of people (100 to 300 individuals) to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, monitor the side effects, compare commonly used treatments and collect information on safe use. Phase III trials are typically conducted on 1,000 to 3,000 individuals.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and whether there are side effects associated with long-term use.

Summary of State Laws as of December 2008

Table One provides a summary of the **23 states and District of Columbia** that have enacted laws regarding mandated coverage of clinical trials.

Table One
Clinical Trials Laws

State Year of Enactment Bill Number and/or Citation	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Arizona (2000) Senate Bill 1213 20-2328	Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans	Patient costs associated with participation in Phase I through IV cancer clinical trials.	Trail must be reviewed by an Institutions Review Board in AZ. Health professional must agree to accept reimbursement from insurer as payment in full. Only covers trial when no clearly superior nonivestigational treatment exists. Trail must be in AZ.

California (2000) Senate Bill 37	All California insurers, including Medicaid and other medical assistance programs	Routine patient care costs associated with Phase I through IV cancer clinical trials.	May restrict coverage to services in CA.
Connecticut (2001) Senate Bill 325 Public Act 01-171	Private insurers, individual and group health plans	Routine patient care costs associated with cancer clinical trials.	Prevention trials are covered only in Phase III and only if involve therapeutic intervention. Insurer may require documentation of the likelihood of therapeutic benefit, informed consent, protocol information and/or summary of costs.
Delaware (2001) Senate Bill 181	Every group of blanket policy, including policies or contracts issued by health service corporations	Routine patient care costs for covered persons engaging in clinical trials for the treatment of life threatening diseases under specified conditions.	Trial must have therapeutic intent and enroll individuals diagnosed with the disease. Trial must not be designed exclusively to test toxicity or disease pathophysiology.
District of Columbia (2008) Bill 17-469 (D.C. Law 17-166)	All insurers in the District	Routine patient care costs for people in clinical trials undertaken for prevention, early detection, treatment, or monitoring of cancer and approved or funded in full or in part by one of the following: National Institutes of Health or one of its cooperative groups or centers, Centers for Disease Control and Prevention, Agency for Health Care Research and Quality, Centers for Medicare and Medicaid Services, U.S. Food and Drug Administration (FDA), U.S. Department of Defense, U.S. Department of Veterans Affairs, U.S. Department of Energy, nongovernmental research entity that has been awarded a National Cancer Institute support grant.	Routine patient care costs shall not include tests or measurements conducted primarily for the purpose of the clinical trial involved. services or products provided solely for data collection and analysis purposes. services or products customarily provided free of charge to trial participants by the research sponsors.
Georgia* (1998) 33-24-59.1	Insurers and the state health plan	Routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's cancer.	For the treatment of cancer that generally first manifests itself in children under the age of 19.
Illinois (1999) House Bill 1622 (amended 2004) Senate Bill 2339 Public Act No. 93-1000 20 ILCS 1405/56.3**	HMOs and individual/group insurance policies to offer coverage to the applicant or policyholder (2004 amendment: Plans may not be canceled or non renewed based on an individual's participation in a qualified clinical trial)	Routine patient care if the individual participates in an approved Phase II through IV cancer research trial.	Coverage benefit can have annual limit of $10,000. Trial must be conducted at multiple sites in state. Primary care MD must be involved in coordination of care. Researchers must submit results of trial for publication in nationally recognized scientific literature.
Louisiana (1999) RS 22:230.4	HMOs, PPOs, State Employee Benefits Program and other specified insurers	Patient costs incurred in Phase II through IV cancer clinical trials.	Only covers costs when no clearly superior, noninvestigational approach exists. Available data must support reasonable expectation that the treatment will be as effective as the noninvestigational alternative. Patient must sign an Institutional Review Board-approved consent form.
Maine (2000) 24-A-4310	Managed care organizations and private insurers	Routine patient care costs associated with clinical trial.	Participation must offer meaningful potential for significant clinical benefit. Referring physician must conclude that trial participation is appropriate.

Maryland*** (1998) Chap 146-15-827	Private insurers and other specified managed care organizations.	Patient costs for Phase I through IV cancer treatment, supportive care, early detection, and prevention trials. Phase II through IV for other life-threatening conditions, with Phase I considered on a case-by-case basis.	There is no clearly superior, nonivestigational alternative. The data provide a reasonable expectation that the treatment will be as least as effective as the alternative.
Massachusetts (2002) Chap 176A Sec 8X	All health plans issued or renewed after Jan. 1, 2003	Patient care services associated with all phases of qualified cancer clinical trials.	Insurers must provide payment for services that are consistent with the usual and customary standard of care provided under the trial's protocol and that would be covered if the patient did not participate in the trial.
Missouri (2002) 376.429 (2006)- Phase II SB 567 & 792	All health benefit plans operating in the state	Routine patient care costs as the result of Phase II, III or IV clinical trials for the prevention, early detection, or treatment of cancer.	There must be identical or superior nonivestigational treatment alternatives available before providing clinical trial treatment, and there must be a reasonable expectation that the trial will be superior to the alternatives. Requires coverage of FDA-approved drugs and devices even if they have not be approved for use in treatment of patient's particular condition.
New Hampshire (2000) 415:18	Private insurers and specified managed care plans	Medically necessary routine patient care costs incurred as a result of a treatment for Phase I through IV cancer clinical trial or trial for a life-threatening disease.	Coverage for Phases I or II decided on case-by-case basis. Coverage is required for services needed to administer drug or device under evaluation. Coverage is required for routine patient care associated with drugs or devices which are not subject of trial, as long as they have been approved by FDA.
Nevada (2003) (amended 2005) SB 29 NRS 695G.173	All health insurance insurers, medical service corporations, HMOs and managed care organizations	Patient costs associated with Phase I through IV cancer or chronic fatigue clinical trial	Healthcare facility and personnel must have experience and training to provide the treatment in a capable manner. There must be no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial. There must be a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment. Amendment revises type of medical treatment covered.
New Mexico (2002) (amended 2004 to delay repeal until July 1, 2009) 59A-22-43	A health insurer; a nonprofit health service provider; a HMO; a managed care organization; a provider service organization; or the state's medical assistance program.	Routine patient care costs incurred as a result of the patient's participation in a phase II, III or IV cancer clinical trial.	Must be undertaken for the purposes of the prevention of reoccurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists. Must not be designed exclusively to test toxicity or disease pathophysiology and it has a therapeutic intent. Must be provided as part of a scientific study of a new therapy or intervention and is for the prevention of reoccurrence, early detection, treatment or palliation of cancer in humans and in which includes specific provisions of scientific study.
New Mexico	Private insurers,	Routine patient care costs incurred as result of	Effective through July 1, 2004.

(2001) 59A-22-43	specified managed care plans, and Medicaid and other state medical assistance programs	Phase I through IV cancer clinical trial.	Trial must have therapeutic intent. Reasonable expectation that investigational treatment will be at least as effective as standard treatment.
North Carolina (2001) ? 58-3-255	All health insurance plans and teachers' and state employees' comprehensive major medical plan.	Medically necessary costs of health care services associated with Phase II through IV of covered clinical trials.	Patients suffering from a life-threatening disease or chronic condition may designate a specialist who is capable of coordinating their health care needs.
Ohio (2008) ORC Ann. 1751.01 (2008)	All health benefit plans including those for public employees.	Medically necessary costs of health care services associated with any stage of clinical trial.	Trial must be approved by NIH or another group under HHS, FDA, DOD or VA. May exclude coverage for service or product that is part of the investigative trial, item or procedure used only for data collection for the trial, item not approved by FDA, and transportation, lodging and food related to travel for participation in the trial.
Rhode Island (1994, 1997) 94-S 2623B 97-S 1A am	Private insurers and specified managed care plans	Coverage for new cancer therapies if treatment is provided under Phase II through IV cancer clinical trial.	
Tennessee (2005) HB 837	All health benefit plans	Routine patient care costs related to Phase I through IV cancer clinical trial.	Treatment must involve drug that is exempt under federal regulations from a new drug application, or approved by: NIH, FDA in form of new drug application, DOD, or VA.
Vermont (2001) (amended 2005 to remove March 1, 2005 sunset provision) Chap 107 ? 4088b HB 6	All health insurance policies and health benefit plans, including Medicaid	Routine patient care costs incurred during the participation in a cancer clinical trial.	Providers and insurers required to participate in a cost analysis to determine impact of the program on health insurance premiums. Amended law allows for participation in trial outside of Vermont if patient notifies health benefit plan prior to participation, and no clinical trial is available at Vermont or New Hampshire cancer care providers.
Virginia (1999) ? 38.2-3418.8	Private insurers, specified managed care plans, and public employee health plans	Patient costs incurred during the participation in Phase II through IV cancer clinical trials. Coverage provided on a case-by-case basis for Phase I.	There must be no clearly superior, nonivestigational alternative. Data must provide a reasonable expectation that the treatment will be at least as effective as the alternative.
West Virginia (2003) ?9-2-12	Individual and group insurers, health service corporations, health care corporations, HMOs, public employees insurance agency, Medicaid and the children's health insurance program	Patient costs associated with the participation in Phase II through IV clinical trial for treatment of life-threatening condition or the prevention, early detection and treatment of cancer.	Facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise. There must be no clearly superior, noninvestigational treatment alternative. Data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative.
Wisconsin AB 617 (2006) Act 194	Any health insurance plan offered by the state, any self-insured plans	Routine patient care costs incurred during the participation in all phases of a cancer clinical trial. No policy, plan, or contract may exclude coverage for the cost of any routine patient care that is administered to an insured in a cancer	Trial must meet all criteria: 1. The purpose is to test whether the intervention potentially improves the trial participant's health outcomes. 2. The treatment provided as part of the trial is given with the intention of

		clinical trial satisfying the criteria under par. (c) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.	improving the trial participant's health outcomes. 3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology. 4. The trial does one of the following: a. Tests how to administer a health care service, item, or drug for the treatment of cancer. b. Tests responses to a health care service, item, or drug for the treatment of cancer. c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer. d. Studies new uses of health care services, items, or drugs for the treatment of cancer. 5. The trial is approved by one of the following: a. A National Institute of Health, or one of its cooperative groups or centers, under the federal department of health and human services; federal food and drug administration; federal department of defense; federal department of veterans affairs.
Wyoming SF 024 (2008 budget session)	All health insurance policies, contracts, and certificates providing coverage to any resident of this state.	Routine patient care for a person enrolled in a Phases II- IV clinical trial. Includes a medical service or treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or a drug provided to a patient during a cancer clinical trial, other than the drug that is the subject of the clinical trial, if the drug has been approved by the federal food and drug administration for use in treating the patient's particular condition.	Trial must also be approved by NIH, FDA, Dept. of Defense, or Dept. of Veterans Affairs. The medical treatment must be provided by a licensed health care provider operating within the scope of his/her license in a facility whose personnel has the experience and training necessary to provide the treatment in a competent manner. The clinical trial participant must have signed an informed consent document prior to starting the trial.

*In 2002, all major insurers in Georgia agreed to cover routine patient care costs associated with Phase I, II, III, or IV cancer clinical trials. Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. The agreement also provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization (see below).

**Illinois Executive Branch Administrative Code (20 ILCS 1405/1405-20) required the Department of Insurance to conduct an analysis and study of costs and benefits derived from the implementation of the coverage requirements for investigational cancer treatments. The study covered the years 2000 through 2002 and included an analysis of the effect of the coverage requirements on the cost of insurance and health care, the results of the treatments to patients, the mortality rate among cancer patients, any improvements in care of patients, and any improvements in the quality of life of patients.

***A 2003 Maryland law (S 128) repealed a reporting requirement for insurers, nonprofit health service plans, and HMOs to submit a report that described the trials covered during the previous year.

Sources: National Cancer Institute, Health Policy Tracking Service.

Summary of Other Actions

Table Two summarizes the special agreements some states have arranged with insurance companies to voluntarily provide coverage for

clinical trials.

Table Two Special Agreements			
State (Year Agreement Became Effective)	**Who is Required to Pay?**	**What Services or Benefits are Covered?**	**Other Key Criteria:**
Georgia (2002) Georgia Cancer Coalition	All major insurers	Routine patient care costs associated with Phase I through IV cancer clinical trials.	Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. Provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization.
Michigan (2002) Michigan Consensus Agreement	Private insurance plans, HMOs and Medicaid	Routine patient care costs associated with Phase II and III cancer clinical trials.	Coverage for Phase I trials is under consideration.
New Jersey (1999) New Jersey Consensus Agreement	All insurers	Routine patient care costs associated with all phases of cancer clinical trials.	
Ohio (1999) Ohio Med Plan	State employees on Ohio Med Plan	Routine patient care costs associated with Phase II and III cancer treatment clinical trials.	Preauthorization is required for clinical trial participation.

Federal Activity

In 2000, Medicare began covering beneficiaries patient care costs in clinical trials. While many state Medicaid programs have no legal requirements to cover clinical trials costs, many do cover all or some of the costs.

Additional Resources

American Cancer Society, National Government Relations memo on Clinical Trials.
http://www.indianacancer.org/documents/factsheet_ACS_clinical%20trials.pdf

National Cancer Institue, States That Require Health Plans to Cover Patient Care Costs in Clinical Trials. Information and Overview: http://www.cancer.gov/clinicaltrials/ctlaws-home

To legislators and legislative staff: For more information please contact Karmen Hanson at health-info@ncsl.org

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POSITION PAPER ON HEALTH PLAN COVERAGE FOR PATIENT CARE COSTS IN CANCER CLINICAL TRIALS

Sponsored by the Denali Oncology Group, the Alaska State Affiliate of the American Society of Clinical Oncology

February 24, 2008

BACKGROUND:

1. Clinical trials for cancer patients provide state-of-the-art treatment for patients with life-threatening diseases. Cancer patients and their physicians typically look to clinical trials as an option when the investigational treatment offers as much or more benefit than standard treatment.
2. Currently, in Alaska, health plans can exclude coverage for routine patient care costs while a patient with cancer is enrolled on a clinical trial.
3. Since 2000, Medicare has provided coverage for beneficiaries for routine costs associated with cancer clinical trial enrollment.
4. Twenty-three states in the United States have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care a patient receives while participating in a clinical trial.
5. Health plans mistakenly think that money is saved by excluding care while patients participate in clinical trials. However, if not enrolled on a clinical trial, these patients will continue to receive conventional therapy. Studies have shown that there are not differences in cost of care for patients enrolled on clinical trials compared with patients on conventional therapy.
6. Results of clinical trials lead to more rational use of cancer treatment and more successful outcomes, resulting in short-term and long-term cost savings.

PROPOSED LEGISLATION:

We propose that the Senate and House of the State of Alaska pass a bill requiring that all health care plans, including Medicaid, cover routine patient care costs for patients enrolled in all phases of clinical trials, including prevention, detection, treatment and palliation (supportive care) of cancer.

BENEFITS:

1. Passage of this bill will remove an important barrier to the participation of patients in cancer clinical trials. It will result in physicians more often recommending patient participation and in patients having greater desire to enroll in clinical trials.
2. Greater participation by Alaskans in cancer clinical trials will result in improved care of our patients in the short- and long-term, improved doctor-patient relationship, increased patient satisfaction with treatment, and increased retention of patients in Alaska for their cancer care.
3. Alaska will be in the forefront in making meaningful progress in providing care for cancer and other life threatening conditions.

REFERENCES:

1. States That Require Health Plans to Cover Patient Care Costs in Clinical Trials http://www.cancer.gov/clinicaltrials/learning/laws-about-clinical-trial-costs
2. Clinical Trials and Insurance Coverage - A Resource Guide http://www.cancer.gov/clinicaltrials/learning/insurance-coverage/page1
3. Coverage of Routine Patient Care Costs in Clinical Trials Position Statement http://www.asco.org/asco/downloads/patient_care_costs_3.05.pdf
4. American Society of Clinical Oncology Response to CMS Town Hall Meeting "The Effect of Coverage and Payment on Clinical Research Study Participation and Retention" September 10, 2007
5. Harris Interactive. *Health Care News.* Vol 1, Issue 3. January 22,200 1.
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9. Bennett CL, et al: Evaluating the financial impact of clinical trials in oncology: results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *Journal of Clinical Oncology.* 18:2805-28 10, 2000.
10. Fireman BH: Cost of care for patients in cancer clinical trials. *Journal of the National Cancer Institute.* 92: 136-142, 2000.
11. Wagner JL, et al: Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *Journal of the National Cancer Institute.* 9 1947-853, 1999.
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13. Bennett C L, et al: Evaluating the financial impact of clinical trials in oncology: Results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *Journal of Clinical Oncology.* 18:2805-10, 2000 .

CANCER CLINICAL TRIALS FAST FACTS
DENALI ONCOLOGY GROUP, October 28, 2007

Frequently Asked Questions (FAQ)

1. **What is a clinical trial?** A clinical trial is a scientific way of studying a new treatment for a specific disease that may be better and/or safer than existing treatments.
2. **Why are clinical trials necessary?** Without these studies, we can not determine whether a new treatment is safe, effective, and better than existing options.
3. **What types of cancer clinical trials exist?** Trials may be for prevention, early detection, diagnosis, or treatment of cancer. There are also trials for reducing symptoms and improving quality-of-life.
4. **Why would a cancer patient consider participating in a clinical trial?**
    a. Treatment given on the clinical trial offers the potential for better outcome (e.g. longer life or higher cure rate) than the standard treatment.
    b. Results of the trial will help improve treatment for future patients.
5. **Is it risky to be on a clinical trial?** There are risks with any type of cancer treatment. Side effects that occur in patients on a clinical trial are monitored very closely and described in paperwork that patients receive (i.e., consent form).
6. **Are clinical trials available in Alaska?** Yes, more than 50 cancer clinical trials are open in Alaska for patients to receive treatment in-state.
7. **Do doctors or patients gain financially from participating in clinical trials?** We only support the conduct of studies where there is no financial gain for patients or physicians. Support is provided by the sponsor of the study to help pay for costs associated with the trial, such as research personnel and regulatory requirements.

Myths

1. **"I may receive placebo."** Placebo is rarely used in cancer clinical trials because there is usually an acceptable standard treatment. However, if the standard is to offer no treatment, then the new treatment under investigation will be compared to no treatment (i.e., placebo). Patients will always be informed of the potential to receive placebo.
2. **"I will be a guinea pig."** Patients on clinical trials are treated with respect, receive informed consent, and have all questions answered. They have the right to withdraw from the study at any time without compromising their future care.
3. **"I'm not sick enough for a clinical trial."** Many trials are studying ways to prevent cancer in healthy people at risk for cancer. Other trials are studying ways to improve upon the most common types of treatment used when patients are first diagnosed with cancer.

State Laws Addressing Third-Party Reimbu[illegible]ement for Clinical Trials for the Treatment of Cance[illegible]
(as of September 30, 2007)

State	Statute	Coverage Requirements			Types of Insurers Covered				Clinical Trial Phases Covered			
		Mandatory Coverage	Mandatory Offer	Prohibits Exclusion of Coverage	Private Insurers	Specified Managed Care	Medicaid/Other Medical Assistance	Public Employee Health Plans	Phase I	Phase II	Phase III	Phase IV
Arizona	ARIZ. REV. STAT. ANN. §§ 20-1342.03, 20-826.01, 20-1057.07, 20-1402.01, 20-1404.01, and 20-2328	X[1]			X	X			X	X	X	X
California	CAL. HEALTH & SAFETY CODE § 1370.6; CAL. INS. CODE § 10145.4; and CAL. WELF. & INST. CODE § 14132.98	X[2]			X	X	X		X	X	X	X
Connecticut	CONN. GEN. STAT. ANN §§ 38a-504a to 38a-504g and 38a-542a to 38a-542g	X[3]			X						X	
Delaware*	DEL. CODE ANN. tit. 18, § 3567	X[4]			X							
Georgia	GA. CODE ANN. § 33-24-59.1	X[5]			X	X		X		X[6]	X[6]	
Louisiana	LA. REV. STAT. ANN. § 22:230.4	X			X	X		X		X	X	X
Maine*	ME. REV. STAT. ANN. tit. 24-A, §§ 4301-A and 4310	X			X	X						
Maryland	MD. CODE ANN., INS. § 15-827	X			X	X			X	X	X	X
Massachusetts	MASS. GEN. LAWS ANN. ch. 175, § 110L	X[4]			X	X			X	X	X	X
Missouri	MO. REV. STAT. § 376.429	X			X	X				X	X	X
Nevada	NEV. REV. STAT. §§ 689A.04033, 689B.0306, 695B.1903, 695C.1693, and 695G.173	X			X	X			X	X	X	X
New Hampshire	N.H. REV. STAT. ANN. § 415:18-l	X[7]			X	X			X	X	X	X
New Mexico	N.M. STAT. ANN. § 59A-22-43	X[4]			X	X	X			X	X	X
North Carolina*	N.C. GEN. STAT. ANN. § 58-3-255	X			X	X				X	X	X
Rhode Island	R.I. GEN. LAWS §§ 27-18-36, 27-18-36.2, 27-19-32 to 27-19-32.3, 27-20-27 to 27-20-27.3, and 27-41-41 to 27-41-41.3	X			X	X				X	X	X
Tennessee	TENN. CODE ANN. § 56-7-2365	X[4]			X	X			X	X	X	X
Vermont	VT. STAT. ANN. tit. 8, § 4088b [8]	X			X	X	X					
Virginia	VA. CODE ANN. §§ 2.2-2818 and 38.2-3418.8	X			X	X		X	X[9]	X	X	X

Source: National Cancer Institute, State Cancer Legislative Database Program, Bethesda, MD: SCLD

State Laws Addressing Third-Party Reimbu[illegible]ment for Clinical Trials for the Treatment of Cancer
(as of September 30, 2007)

State	Statute	Coverage Requirements			Types of Insurers Covered				Clinical Trial Phases Covered			
		Mandatory Coverage	Mandatory Offer	Prohibits Exclusion of Coverage	Private Insurers	Specified Managed Care	Medicaid/Other Medical Assistance	Public Employee Health Plans	Phase I	Phase II	Phase III	Phase IV
West Virginia	W. VA. CODE §§ 5-16-7d, 5-16-7e, 5-16B-6a, 5-16B-6b, 9-2-12, 9-2-12a, 33-25F-1, and 33-25F-2	X[4]			X	X	X	X		X	X	X
Wisconsin	WIS. STAT. ANN. §§ 632.87 and 40.51			X[4]	X			X	X	X	X	X

Note: Because arrangements for the reimbursement of clinical trials for several states fall outside the scope of the State Cancer Legislative Database protocols, those states are not included herein. Michigan and New Jersey, for example, instituted special non-legislative agreements whereby insurers voluntarily cover routine medical care that is part of a clinical trial. According to the state employee benefits handbook, Ohio provides coverage for cancer treatment clinical trials to state employees who are enrolled in the state employee health benefit plan. In Georgia, a non-legislative agreement among a number of private health plans and state-based plans provides coverage for adults and children.

* Laws in Delaware, Maine, and North Carolina provide coverage of clinical trials for life threatening medical conditions and not specifically for the treatment of cancer.

[1] Indicated insurers are only obligated to provide coverage for covered patient costs that are directly associated with the clinical trial.

[2] Coverage requirement applies only to routine patient care costs related to cancer clinical trials having a therapeutic purpose, upon recommendation by a treating physician.

[3] In order to be eligible for coverage, clinical trials for the *prevention of cancer* must be a Phase III trial that involves a therapeutic intervention and is conducted at multiple institutions under the auspices of an independent peer-reviewed protocol approved by a specified Federal authority.

[4] Coverage requirement applies only to clinical trials that have a therapeutic intent.

[5] Coverage requirement applies only to routine patient care costs incurred in connection with clinical trials for the treatment of children's cancer.

[6] Applies only to Phase II or III prescription drug clinical trial programs.

[7] Coverage for Phase I and Phase II clinical trials is decided on a case-by-case basis.

[8] Requires the state Department of Banking, Insurance, Securities, and Health Care Administration to issue regulations that specify the requirements for coverage of routine costs for patients who participate in approved cancer clinical trials conducted by specified providers. Coverage requirements are included in Regulation H-2001-04.

[9] Treatment in a Phase I clinical trial may be covered on a case-by-case basis.

Bob Boerner

From: "Dick Cauchi" <dick.cauchi@ncsl.org>
To: "Bob Boerner" <bob.boerner@ncsl.org>
Sent: Thursday, April 03, 2008 2:58 PM
Subject: Clinical Trials What are States Doing 2008

Although it is not possible to provide this live by phone today, the NCSL report provided below is our best information on this topic. Next week Karmen Hanson, our author and expert, may be able to provide additional information or insights.
The online version is located at: http://www.ncsl.org/programs/health/clinicaltrials.htm

NCSL Health Program

Clinical Trials: What are States Doing?
April 2008 Update

What is a Clinical Trial?

A clinical trial is a research study on human patients to test the safety and effectiveness of new treatments. These trials offer patients access to new and potentially life saving drugs and cures.

The dramatic progress made in treating childhood cancers in recent years, is attributable, in part, to clinical trials, because 60 percent of all children with cancer are enrolled in some kind of trial. A ten percent drop in breast cancer mortality for women under the age of 50 is said to be the result of clinical trials research conducted in the 1970's.

Who Enrolls in Clinical Trials?

Only two to three percent of eligible adult patients enroll in clinical trials. For cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment.

Insurance Coverage for Clinical Trials

Typically, when a patient enrolls in a clinical trial, the cost of tests, procedures, drugs and any research activity directly associated with the investigation, are covered by the group sponsoring the trial, such as a pharmaceutical company or the National Cancer Institute. However, because some health plans define clinical trials as "experimental" or "investigational," health insurance coverage may or may not include some or all of the costs of "routine patient care," such as the doctor visits, hospital stays, tests and x-rays, that a patient would normally receive whether or not they were enrolled in a trial.

Nevertheless, a growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of the routine medical care a patient receives as a participant in a clinical trial.

Advantages:

For cancer patients, properly designed and conducted clinical trials represent an important therapeutic option, as well as a critical means of advancing medical knowledge. Lack of insurance coverage is a barrier to patients who might otherwise participate. Sixty percent of patients in one survey cited fear of insurance denial as a major reason for not participating in clinical trials. And finally, a recent study found only a slight increase in treatment costs for adult clinical trial patients compared to nonparticipants--$35,418 versus $33,248.

Disadvantages:

Even though the same recent study found only a slight increase in treatment costs, the 6.5 percent increase between participants and nonparticipants in clinical trials translated into an additional $16 million in 1999 spent on treatment costs for the 19,000 adult patients enrolled in National Cancer Institute-sponsored clinical trials. These additional insurance costs, like other mandated benefits and services, may result in higher insurance premium rates, which are often cost-shifted onto workers in the form of higher deductibles and copayments.

Definitions of Phases:

A clinical trial study is conducted in four phases.

Phase I: Research is conducted on a small group of volunteers (20 to 80 people) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.

Phase II: The experimental drug or treatment is given to or a procedure is performed on a larger group of people (100 to 300 individuals) to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, monitor the side effects, compare commonly used treatments and collect information on safe use. Phase III trials are typically conducted on 1,000 to 3,000 individuals.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and whether there are side effects associated with long-term use.

Summary of State Laws

Table One provides a summary of the **20 states** that have enacted laws regarding mandated coverage of clinical trials.

Table One
Clinical Trials Laws
April 2006

State Year of Enactment Bill Number and/or Citation	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Arizona (2000) Senate Bill 1213 20-2328	Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans	Patient costs associated with participation in Phase I through IV cancer clinical trials.	Trail must be reviewed by an Institutions Review Board in AZ. Health professional must agree to accept reimbursement from insurer as payment in full. Only covers trial when no clearly superior nonivestigational treatment exists. Trail must be in AZ.
California (2000) Senate Bill 37	All California insurers, including Medicaid and other medical assistance programs	Routine patient care costs associated with Phase I through IV cancer clinical trials.	May restrict coverage to services in CA.
Connecticut (2001) Senate Bill 325	Private insurers, individual and group health plans	Routine patient care costs associated with cancer clinical trials.	Prevention trials are covered only in Phase III and only if involve therapeutic intervention.

Public Act 01-171			Insurer may require documentation of the likelihood of therapeutic benefit, informed consent, protocol information and/or summary of costs.
Delaware (2001)Senate Bill 181	Every group of blanket policy, including policies or contracts issued by health service corporations	Routine patient care costs for covered persons engaging in clinical trials for the treatment of life threatening diseases under specified conditions.	Trial must have therapeutic intent and enroll individuals diagnosed with the disease. Trial must not be designed exclusively to test toxicity or disease pathophysiology.
Georgia* (1998) 33-24-59.1	Insurers and the state health plan	Routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's cancer.	For the treatment of cancer that generally first manifests itself in children under the age of 19.
Illinois (1999) House Bill 1622 (amended 2004) Senate Bill 2339 Public Act No. 93-1000 20 ILCS 1405/56.3**	HMOs and individual/group insurance policies to offer coverage to the applicant or policyholder (2004 amendment: Plans may not be canceled or non renewed based on an individual's participation in a qualified clinical trial)	Routine patient care if the individual participates in an approved Phase II through IV cancer research trial.	Coverage benefit can have annual limit of $10,000. Trial must be conducted at multiple sites in state. Primary care MD must be involved in coordination of care. Researchers must submit results of trial for publication in nationally recognized scientific literature.
Louisiana (1999) RS 22:230.4	HMOs, PPOs, State Employee Benefits Program and other specified insurers	Patient costs incurred in Phase II through IV cancer clinical trials.	Only covers costs when no clearly superior, noninvestigational approach exists. Available data must support reasonable expectation that the treatment will be as effective as the noninvestigational alternative. Patient must sign an Institutional Review Board-approved consent form.
Maine (2000) 24-A-4310	Managed care organizations and private insurers	Routine patient care costs associated with clinical trial.	Participation must offer meaningful potential for significant clinical benefit. Referring physician must conclude that trial participation is appropriate.
Maryland*** (1998) Chap 146-15-827	Private insurers and other specified managed care organizations.	Patient costs for Phase I through IV cancer treatment, supportive care, early detection, and prevention trials. Phase II through IV for other life-threatening conditions, with Phase I considered on a case-by-case basis.	There is no clearly superior, nonivestigational alternative. The data provide a reasonable expectation that the treatment will be as least as effective as the alternative.
Massachusetts (2002)	All health plans issued or renewed after Jan. 1,	Patient care services associated with all phases of qualified cancer clinical	Insurers must provide payment for services that are consistent with the

Chap 176A Sec 8X	2003	trials.	usual and customary standard of care provided under the trial's protocol and that would be covered if the patient did not participate in the trial.
Missouri (2002) 376.429 (2006)- Phase II SB 567 & 792	All health benefit plans operating in the state	Routine patient care costs as the result of Phase II, III or IV clinical trials for the prevention, early detection, or treatment of cancer.	There must be identical or superior nonivestigational treatment alternatives available before providing clinical trial treatment, and there must be a reasonable expectation that the trial will be superior to the alternatives. Requires coverage of FDA-approved drugs and devices even if they have not be approved for use in treatment of patient's particular condition.
New Hampshire (2000) 415:18	Private insurers and specified managed care plans	Medically necessary routine patient care costs incurred as a result of a treatment for Phase I through IV cancer clinical trial or trial for a life-threatening disease.	Coverage for Phases I or II decided on case-by-case basis. Coverage is required for services needed to administer drug or device under evaluation. Coverage is required for routine patient care associated with drugs or devices which are not subject of trial, as long as they have been approved by FDA.
Nevada (2003) (amended 2005) SB 29 NRS 695G.173	All health insurance insurers, medical service corporations, HMOs and managed care organizations	Patient costs associated with Phase I through IV cancer or chronic fatigue clinical trial	Healthcare facility and personnel must have experience and training to provide the treatment in a capable manner. There must be no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial. There must be a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment. Amendment revises type of medical treatment covered.
New Mexico (2002) (amended 2004 to delay repeal until July 1, 2009) 59A-22-43	A health insurer; a nonprofit health service provider; a HMO; a managed care organization; a provider service organization; or the state's medical	Routine patient care costs incurred as a result of the patient's participation in a phase II, III or IV cancer clinical trial.	Must be undertaken for the purposes of the prevention of reoccurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists. Must not be designed exclusively to

	assistance program.		test toxicity or disease pathophysiology and it has a therapeutic intent. Must be provided as part of a scientific study of a new therapy or intervention and is for the prevention of reoccurrence, early detection, treatment or palliation of cancer in humans and in which includes specific provisions of scientific study.
New Mexico (2001) 59A-22-43	Private insurers, specified managed care plans, and Medicaid and other state medical assistance programs	Routine patient care costs incurred as result of Phase I through IV cancer clinical trial.	Effective through July 1, 2004. Trial must have therapeutic intent. Reasonable expectation that investigational treatment will be at least as effective as standard treatment.
North Carolina (2001) ? 58-3-255	All health insurance plans and teachers' and state employees' comprehensive major medical plan.	Medically necessary costs of health care services associated with Phase II through IV of covered clinical trials.	Patients suffering from a life-threatening disease or chronic condition may designate a specialist who is capable of coordinating their health care needs.
Rhode Island (1994, 1997) 94-S 2623B 97-S 1A am	Private insurers and specified managed care plans	Coverage for new cancer therapies if treatment is provided under Phase II through IV cancer clinical trial.	
Tennessee (2005) HB 837	All health benefit plans	Routine patient care costs related to Phase I through IV cancer clinical trial.	Treatment must involve drug that is exempt under federal regulations from a new drug application, or approved by: NIH, FDA in form of new drug application, DOD, or VA.
Vermont (2001) (amended 2005 to remove March 1, 2005 sunset provision) Chap 107 ? 4088b HB 6	All health insurance policies and health benefit plans, including Medicaid	Routine patient care costs incurred during the participation in a cancer clinical trial.	Providers and insurers required to participate in a cost analysis to determine impact of the program on health insurance premiums. Amended law allows for participation in trial outside of Vermont if patient notifies health benefit plan prior to participation, and no clinical trial is available at Vermont or New Hampshire cancer care providers.
Virginia (1999) ? 38.2-3418.8	Private insurers, specified managed care plans, and public employee health plans	Patient costs incurred during the participation in Phase II through IV cancer clinical trials. Coverage provided on a case-by-case basis for Phase I.	There must be no clearly superior, noninvestigational alternative. Data must provide a reasonable expectation that the treatment will be at least as effective as the alternative.
West Virginia (2003) ?9-2-12	Individual and group insurers, health service corporations, health care corporations,	Patient costs associated with the participation in Phase II through IV clinical trial for treatment of life-threatening condition or the	Facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients

	HMOs, public employees insurance agency, Medicaid and the children's health insurance program	prevention, early detection and treatment of cancer.	treated to maintain expertise. There must be no clearly superior, noninvestigational treatment alternative. Data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative.
Wisconsin AB 617 (2006) Act 194	Any health insurance plan offered by the state, any self-insured plans	Routine patient care costs incurred during the participation in all phases of a cancer clinical trial. No policy, plan, or contract may exclude coverage for the cost of any routine patient care that is administered to an insured in a cancer clinical trial satisfying the criteria under par. (c) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.	Trial must meet all criteria: 1. The purpose is to test whether the intervention potentially improves the trial participant's health outcomes. 2. The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes. 3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology. 4. The trial does one of the following: a. Tests how to administer a health care service, item, or drug for the treatment of cancer. b. Tests responses to a health care service, item, or drug for the treatment of cancer. c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer. d. Studies new uses of health care services, items, or drugs for the treatment of cancer. 5. The trial is approved by one of the following: a. A National Institute of Health, or one of its cooperative groups or centers, under the federal department of health and human services; federal food and drug administration; federal department of defense; federal department of veterans affairs.
Wyoming SF 024 (2008 budget	All health insurance policies, contracts, and certificates providing	Routine patient care for a person enrolled in a Phases II- IV clinical trial. Includes a medical service or	Trial must also be approved by NIH, FDA, Dept. of Defense, or Dept. of Veterans Affairs. The medical

session)	coverage to any resident of this state.	treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or a drug provided to a patient during a cancer clinical trial, other than the drug that is the subject of the clinical trial, if the drug has been approved by the federal food and drug administration for use in treating the patient's particular condition.	treatment must be provided by a licensed health care provider operating within the scope of his/her license in a facility whose personnel has the experience and training necessary to provide the treatment in a competent manner. The clinical trial participant must have signed an informed consent document prior to starting the trial.

*In 2002, all major insurers in Georgia agreed to cover routine patient care costs associated with Phase I, II, III, or IV cancer clinical trials. Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. The agreement also provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization (see below).

**Illinois Executive Branch Administrative Code (20 ILCS 1405/1405-20) required the Department of Insurance to conduct an analysis and study of costs and benefits derived from the implementation of the coverage requirements for investigational cancer treatments. The study covered the years 2000 through 2002 and included an analysis of the effect of the coverage requirements on the cost of insurance and health care, the results of the treatments to patients, the mortality rate among cancer patients, any improvements in care of patients, and any improvements in the quality of life of patients.

***A 2003 Maryland law (S 128) repealed a reporting requirement for insurers, nonprofit health service plans, and HMOs to submit a report that described the trials covered during the previous year.

Sources: National Cancer Institute, Health Policy Tracking Service.

Summary of Other Actions

Table Two summarizes the special agreements some states have arranged with insurance companies to voluntarily provide coverage for clinical trials.

Table Two
Special Agreements

State (Year Agreement Became Effective) Web Address of Agreement	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Georgia (2002) Georgia Cancer Coalition	All major insurers	Routine patient care costs associated with Phase I through IV cancer clinical trials.	Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. Provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established

			by any nationally recognized health care organization.
Michigan (2002) Michigan Consensus Agreement	Private insurance plans, HMOs and Medicaid	Routine patient care costs associated with Phase II and III cancer clinical trials.	Coverage for Phase I trials is under consideration.
New Jersey (1999) New Jersey Consensus Agreement	All insurers	Routine patient care costs associated with all phases of cancer clinical trials.	
Ohio (1999) Ohio Med Plan	State employees on Ohio Med Plan	Routine patient care costs associated with Phase II and III cancer treatment clinical trials.	Preauthorization is required for clinical trial participation.

Federal Activity

In 2000, Medicare began covering beneficiaries patient care costs in clinical trials. While many state Medicaid programs have no legal requirements to cover clinical trials costs, many do cover all or some of the costs.

To legislators and legislative staff: For more information please contact Karmen Hanson at health-info@ncsl.org

Denver Office: Tel: 303-364-7700 | Fax: 303-364-7800 | 7700 East First Place | Denver, CO 80230 | Map
Washington Office: Tel: 202-624-5400 | Fax: 202-737-1069 | 444 North Capitol Street, N.W., Suite 515 | Washington, D.C. 20001

Clinical Trial Information

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Clinical & Admin Support
OPS
Efficient Programs
Practice Support
ORS
Specialty Pharmacy

The greater the number of people who participate in clinical trials, the faster emerging anticancer therapies can be brought to market. US Oncology accrued more than 32,000 cancer patients to clinical trials, and is bringing the search for new therapies directly into local communities across America.

Our research team members conduct more than 50 clinical trials each year. While we have complete Phase I-IV capabilities, the majority of our research is in Phase II and III development stages.

Our extensive clinical trial program, plus our provision of care for approximately 200,000 new cancer patients each year, provides us with a unique research platform. In sharing what we learn with one another, we can more readily advance the latest developments as they relate to investigational drugs, the reduction of side effects, and new methods of care.

If you are interested in contacting a US Oncology-affiliated physician to learn more about our clinical trial program, please click here.

Frequently Asked Questions About Clinical Trials

If you are a cancer patient or someone you know is a cancer patient, you may be interested in learning more about clinical trials. The information below offers a brief overview of the clinical trial process, with a look at key questions and terms.

What are Clinical Trials?
Clinical trials, or research studies, utilize patient volunteers to help investigate different ways to treat diseases - such as cancer. Clinical trials involve the use of investigational drugs (also known as study drugs) and drug delivery methods. Each study tries to answer specific scientific questions about different ways to prevent, diagnose, and treat whatever disease it is addressing.

Why are Clinical Trials Important?
Clinical trials contribute to the overall knowledge and progress made in developing therapies for diseases, such as cancer. These research studies are conducted to determine if a study drug or delivery method is safe and effective. Patients who agree to participate may possibly benefit from the research study, while receiving the best current standard treatment as well.

How are Clinical Trials Structured?
Clinical trials are structured into four phases:

In *Phase I clinical trials*, researchers test a study drug in a small group of people (20 to 80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In *Phase II clinical trials*, the study drug is tested in a larger group of people (100 to 300) to measure its effectiveness and further evaluate its safety.

In *Phase III clinical trials*, the study drug is tested in large groups of people (1,000 to 3,000) to confirm its effectiveness, monitor side effects, compare it to approved standard treatments, and collect information that will allow the study drug to be used safely.

In *Phase IV clinical trials*, the drug is tested after it has been marketed to collect information about its effect in various populations and about any side effects associated with long-term use.

What Happens During a Clinical Trial?
In many trials, if the patient is eligible and agrees to participate through Informed Consent, the patient is randomized (by chance, like a coin toss) to either receive the current standard treatment, or the current standard treatment and the study drug regimen. If no standard treatment is available, a trial may compare the study drug to a placebo, which is similar to the study drug, but contains no active ingredient. During a trial, patients are treated and monitored by a team of health care professionals. This team will give the patient specific instructions about the trial, about more tests, and additional doctor's visits that might be required.

Throughout the clinical trial, you come first. If there is no improvement or you experience intolerable side effects, you and your physician can decide to discontinue trial participation and resume other

treatment options. Should you do so, your decision will be respected without any effect on future treatment plans.

Why Do Some Cancer Patients Choose to Participate in Clinical Trials?
Some cancer patients may participate because they are hoping for a possible cure and longer life or a way to feel better. Others find that the current standard therapies are not optimal for their cancer and wish to be among the first to participate in a research study and receive an investigational drug. Whatever the reason, participation could make a difference in a patient's future, as well as in the lives of future cancer patients.

How Do I Know If I Should Participate in a Clinical Trial?
The decision to participate in a clinical trial is one that only you can make, with the help of your physician and the people close to you. If you are interested in participating in a clinical trial, you will be informed of the clinical trial's potential benefits and drawbacks before making your decision. If the investigational drug is proven to be effective, you may be among the first to benefit. In addition, through your participation in a research study, you will also be helping future cancer patients.

Are There Risks Involved in Participating?
Because clinical trials are research studies, study drugs may not be better than current standard drugs or treatments. In addition, you may experience side effects that are worse than those of current standard drugs and treatments. Also, your health insurance company or managed care provider may not cover all of the patient care associated with a clinical trial. All of these factors should be discussed thoroughly with your physician and those close to you before deciding whether or not to participate in a clinical trial.

Where are the Trials Held?
Many clinical trials may be available right in your own community. Ask your physician for specific information or search the US Oncology clinical trial list to find a current US Oncology trial in your region.

How Do I Learn More About a Specific Clinical Trial?
Through a process called "Informed Consent," you will learn the key facts about a particular clinical trial before making a decision about participating. Your doctor will explain the purpose and requirements of the study, including any potential drawbacks and benefits. If you agree to take part in the trial, you will be asked to review and sign a form that outlines the study's details prior to participating.

How Do I Get More Information?
Consult your physician to find out whether or not there is a clinical trial that would be appropriate for your care. If you are a US Oncology patient, your physician has information on clinical trials that are being held throughout the company's national research network. Or you can search a list of all current US Oncology clinical trials for more specific information.
For more details on clinical trial research conducted by the US Oncology network, please click USON Research.
For definitions of the clinical trial terms used on this site, please click Trial Terms.

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Clinical Trials: Questions and Answers

Key Points

- Clinical trials are research studies that test how well new medical approaches work in people (see Question 1).
- Every clinical trial has a protocol, which describes what will be done in the study, how it will be conducted, and why each part of the study is necessary (see Question 4).
- Informed consent is a process by which people learn the important facts about a clinical trial to help them decide whether to participate (see Question 6).
- Payment of patient care costs in clinical trials varies by health insurance plan and by study (see Question 11).

1. What are clinical trials, and why are they important?

   Clinical trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat a disease. People who take part in cancer clinical trials have an opportunity to contribute to knowledge of, and progress against, cancer. They also receive up-to-date care from experts.

2. What are the types of clinical trials?

   There are several types of clinical trials:

   - **Prevention trials** test new approaches, such as medications, vitamins, or other supplements, that doctors believe may lower the risk of developing a certain type of cancer. Most prevention trials are conducted with healthy people who have not had cancer. Some trials are conducted with people who have had cancer and want to prevent recurrence (return of cancer), or reduce the chance of developing a new type of cancer.

   - **Screening trials** study ways to detect cancer earlier. They are often conducted to determine whether finding cancer before it causes symptoms decreases the chance of dying from the disease. These trials involve people who do not have any symptoms of cancer.

   - **Diagnostic trials** study tests or procedures that could be used to identify cancer more accurately. Diagnostic trials usually include people who have signs or symptoms of cancer.

   - **Treatment trials** are conducted with people who have cancer. They are designed to answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way of using a standard treatment. These trials test many types of treatments, such as new drugs, vaccines, new approaches to surgery or radiation therapy, or new combinations of treatments.

   - **Quality-of-life (also called supportive care) trials** explore ways to improve the comfort and quality of life of cancer patients and cancer survivors. These trials may study ways to help people who are experiencing nausea, vomiting, sleep disorders, depression, or other effects from cancer or its treatment.

   - **Genetics studies** are sometimes part of another cancer clinical trial. The genetics component of the trial may focus on how genetic makeup can affect detection, diagnosis, or response to cancer treatment.

     Population- and family-based genetic research studies differ from traditional cancer clinical trials. In these studies, researchers look at tissue or blood samples, generally from families or large groups of people, to find genetic changes that are associated with cancer. People who participate in genetics studies may or may not have cancer, depending on the study. The goal

of these studies is to help understand the role of genes in the development of cancer.

3. Who sponsors clinical trials?

Government agencies, such as the National Cancer Institute (NCI) and other parts of the National Institutes of Health (NIH), the Department of Defense, and the Department of Veterans Affairs, sponsor and conduct clinical trials. In addition, organizations or individuals, such as physicians, medical institutions, foundations, volunteer groups, and pharmaceutical companies, also sponsor clinical trials.

NCI sponsors a large number of clinical trials and has a number of programs designed to make clinical trials widely available in the United States. These programs include the following:

- The **Cancer Centers Program** provides support to research-oriented institutions, including those that have been designated as NCI Comprehensive or Clinical Cancer Centers for their scientific excellence. More information is available in the NCI fact sheet *The National Cancer Institute Cancer Centers Program*, which is available at http://www.cancer.gov/cancertopics/factsheet/NCI/cancer-centers on the Internet.

- The **Specialized Programs of Research Excellence (SPOREs)** bring together scientists and researchers to design and implement research programs that can improve prevention, detection, diagnosis, and treatment of specific types of cancer. More information about SPOREs is available at http://spores.nci.nih.gov/index.html on the Internet.

- The **Clinical Trials Cooperative Group Program** brings researchers, cancer centers, and doctors together into cooperative groups. These groups work with the NCI to identify important questions in cancer research, and design and conduct multisite clinical trials to answer these questions. Cooperative groups are located throughout the United States and in Canada and Europe. For more information, refer to the fact sheet *NCI's Clinical Trials Cooperative Group Program* at http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group on the Internet.

- The **Cancer Trials Support Unit (CTSU)** makes NCI-sponsored phase III treatment trials available to doctors and patients in the United States and Canada . Doctors who are not affiliated with an NCI-sponsored Clinical Trials Cooperative Group (see above) must complete an application process, which includes credential verification and site preparedness assessment, to become members of the CTSU's National Network of Investigators. CTSU members can enroll patients in clinical trials through the program's Web site, which is located at http://www.ctsu.org on the Internet. General information about the CTSU is also available on the program's Web site, or by calling 1–888–823–5923.

- The **Community Clinical Oncology Program (CCOP)** makes clinical trials available in a large number of communities across the United States. Local hospitals throughout the country affiliate with a cancer center or a cooperative group. This affiliation allows doctors to offer people participation in clinical trials more easily, so they do not have to travel long distances or leave their usual caregivers. The **Minority-Based Community Clinical Oncology Program** focuses on encouraging minority populations to participate in clinical trials. More information about the CCOP can be found in the NCI fact sheet *Community Clinical Oncology Program: Questions and Answers*, which is available at http://www.cancer.gov/cancertopics/factsheet/NCI/CCOP on the Internet.

- The **National Institutes of Health Clinical Center**, a research hospital located in Bethesda, Maryland, is part of the NIH. Trials at the Clinical Center are conducted by the components of the NIH, including the NCI. The NCI fact sheet *Cancer Clinical Trials at the National Institutes of Health Clinical Center: Questions and Answers* has more information about the Clinical Center. This fact sheet is available at http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-center on the Internet.

4. How are participants protected?

Research with people is conducted according to strict scientific and ethical principles. Every clinical trial has a protocol, or action plan, which acts like a "recipe" for conducting the trial. The plan describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. The same protocol is used by every doctor or research center taking part in the trial.

All clinical trials that are federally funded or that evaluate a new drug or medical device subject to Food and Drug Administration regulation must be reviewed and approved by an Institutional Review Board (IRB). Many institutions require that all clinical trials, regardless of funding, be reviewed and approved by a local IRB. The Board, which includes doctors, researchers, community leaders, and other members of the community, reviews the protocol to make sure the study is conducted fairly and participants are not likely to be harmed. The IRB also decides how often to review the trial once it has begun. Based on this information, the IRB decides whether the clinical trial should continue as initially planned and, if not, what changes should be made. An IRB can stop a clinical trial if the

researcher is not following the protocol or if the trial appears to be causing unexpected harm to the participants. An IRB can also stop a clinical trial if there is clear evidence that the new intervention is effective, in order to make it widely available.

NIH-supported clinical trials require data and safety monitoring. Some clinical trials, especially phase III clinical trials, use a Data and Safety Monitoring Board (DSMB). A DSMB is an independent committee made up of statisticians, physicians, and patient advocates. The DSMB ensures that the risks of participation are as small as possible, makes sure the data are complete, and stops a trial if safety concerns arise or when the trial's objectives have been met.

5. What are eligibility criteria, and why are they important?

Each study's protocol has guidelines for who can or cannot participate in the study. These guidelines, called eligibility criteria, describe characteristics that must be shared by all participants. The criteria differ from study to study. They may include age, gender, medical history, and current health status. Eligibility criteria for treatment studies often require that patients have a particular type and stage of cancer.

Enrolling participants with similar characteristics helps to ensure that the results of the trial will be due to what is under study and not other factors. In this way, eligibility criteria help researchers achieve accurate and meaningful results. These criteria also minimize the risk of a person's condition becoming worse by participating in the study.

6. What is informed consent?

Informed consent is a process by which people learn the important facts about a clinical trial to help them decide whether to participate. This information includes details about what is involved, such as the purpose of the study, the tests and other procedures used in the study, and the possible risks and benefits. In addition to talking with the doctor or nurse, people receive a written consent form explaining the study. People who agree to take part in the study are asked to sign the informed consent form. However, signing the form does not mean people must stay in the study. People can leave the study at any time—either before the study starts or at any time during the study or the follow-up period.

The informed consent process continues throughout the study. If new benefits, risks, or side effects are discovered during the study, the researchers must inform the participants. They may be asked to sign new consent forms if they want to stay in the study.

7. Where do clinical trials take place?

Clinical trials take place in doctors' offices, cancer centers, other medical centers, community hospitals and clinics, and veterans' and military hospitals in cities and towns across the United States and in other countries. Clinical trials may include participants at one or two highly specialized centers, or they may involve hundreds of locations at the same time.

8. How are clinical trials conducted?

Clinical trials are usually conducted in a series of steps, called phases. Treatment clinical trials listed in PDQ®, the NCI's comprehensive cancer information database, are always assigned a phase. However, screening, prevention, diagnostic, and quality-of-life studies do not always have a phase. Genetics clinical trials generally do not have a phase.

- **Phase I** trials are the first step in testing a new approach in people. In these studies, researchers evaluate what dose is safe, how a new agent should be given (by mouth, injected into a vein, or injected into the muscle), and how often. Researchers watch closely for any harmful side effects. Phase I trials usually enroll a small number of patients and take place at only a few locations. The dose of the new therapy or technique is increased a little at a time. The highest dose with an acceptable level of side effects is determined to be appropriate for further testing.

- **Phase II** trials study the safety and effectiveness of an agent or intervention, and evaluate how it affects the human body. Phase II studies usually focus on a particular type of cancer, and include fewer than 100 patients.

- **Phase III** trials compare a new agent or intervention (or new use of a standard one) with the current standard therapy. Participants are randomly assigned to the standard group or the new group, usually by computer. This method, called randomization, helps to avoid bias and ensures that human choices or other factors do not affect the study's results. In most cases, studies move into phase III testing only after they have shown promise in phases I and II. Phase III trials often include large numbers of people across the country.

- **Phase IV** trials are conducted to further evaluate the long-term safety and effectiveness of a

treatment. They usually take place after the treatment has been approved for standard use. Several hundred to several thousand people may take part in a phase IV study. These studies are less common than phase I, II, or III trials.

People who participate in a clinical trial work with a research team. Team members may include doctors, nurses, social workers, dietitians, and other health professionals. The health care team provides care, monitors participants' health, and offers specific instructions about the study. So that the trial results are as reliable as possible, it is important for participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may continue to contact participants after the trial ends.

9. What are some of the benefits of taking part in a clinical trial?

The benefits of participating in a clinical trial include the following:

- Participants have access to promising new approaches that are often not available outside the clinical trial setting.
- The approach being studied may be more effective than the standard approach.
- Participants receive regular and careful medical attention from a research team that includes doctors and other health professionals.
- Participants may be the first to benefit from the new method under study.
- Results from the study may help others in the future.

10. What are some of the possible risks associated with taking part in a clinical trial?

The possible risks of participating in a clinical trial include the following:

- New drugs or procedures under study are not always better than the standard care to which they are being compared.
- New treatments may have side effects or risks that doctors do not expect or that are worse than those resulting from standard care.
- Participants in randomized trials will not be able to choose the approach they receive.
- Health insurance and managed care providers may not cover all patient care costs in a study.
- Participants may be required to make more visits to the doctor than they would if they were not in the clinical trial.

11. Who pays for the patient care costs associated with a clinical trial?

Health insurance and managed care providers often do not cover the patient care costs associated with a clinical trial. What they cover varies by health plan and by study. Some health plans do not cover clinical trials if they consider the approach being studied "experimental" or "investigational." However, if enough data show that the approach is safe and effective, a health plan may consider the approach "established" and cover some or all of the costs. Participants may have difficulty obtaining coverage for costs associated with prevention and screening clinical trials; health plans are currently less likely to have review processes in place for these studies. It may, therefore, be more difficult to get coverage for the costs associated with them. In many cases, it helps to have someone from the research team talk about coverage with representatives of the health plan.

Health plans may specify other criteria a trial must meet to be covered. The trial might have to be sponsored by a specified organization, be judged "medically necessary" by the health plan, not be significantly more expensive than treatments the health plan considers standard, or focus on types of cancer for which no standard treatments are available. In addition, the facility and medical staff might have to meet the plan's qualifications for conducting certain procedures, such as bone marrow transplants. More information about insurance coverage can be found on the NCI's *Clinical Trials and Insurance Coverage: A Resource Guide* Web page at http://www.cancer.gov/clinicaltrials/learning/insurance-coverage on the Internet.

Many states have passed legislation or developed policies requiring health plans to cover the costs of certain clinical trials. For more information, visit the NCI's Web site at http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs on the Internet.

Federal programs that help pay the costs of care in a clinical trial include those listed below:

- Medicare reimburses patient care costs for its beneficiaries who participate in clinical trials designed to diagnose or treat cancer. Information about Medicare coverage of clinical trials is available at http://www.medicare.gov on the Internet, or by calling Medicare's toll-free number for beneficiaries at 1–800–633–4227 (1–800–MEDICARE). The toll-free number for the hearing impaired is 1–877–486–2048. Also, the NCI fact sheet *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials* is available at http://www.cancer.gov/cancertopics/factsheet/support/medicare on the Internet.

- Beneficiaries of TRICARE, the Department of Defense's health program, can be reimbursed for the medical costs of participation in NCI-sponsored phase II and phase III cancer prevention

(including screening and early detection) and treatment trials. Additional information is available in the NCI fact sheet *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement*. This fact sheet can be found at http://www.cancer.gov/cancertopics/factsheet/NCI/TRICARE on the Internet.

- The Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored prevention, diagnosis, and treatment studies nationwide. All phases and types of NCI-sponsored trials are included. The NCI fact sheet *The NCI/VA Agreement on Clinical Trials: Questions and Answers* has more information. It is available at http://www.cancer.gov/cancertopics/factsheet/NCI/VA-clinical-trials on the Internet.

12. What are some questions people might ask their health care provider before entering a clinical trial?

It is important for people to ask questions before deciding to enter a clinical trial. Questions people might want to ask their doctor or nurse include the following:

The Study

- What is the purpose of the study?
- Why do the researchers think the approach being tested may be effective? Has it been tested before?
- Who is sponsoring the study?
- Who has reviewed and approved the study?
- What are the medical credentials and experience of the researchers and other study personnel?
- How are the study results and safety of participants being monitored?
- How long will the study last?
- How will the results be shared?

Possible Risks and Benefits

- What are the possible short-term benefits?
- What are the possible long-term benefits?
- What are the short-term risks, such as side effects?
- What are the possible long-term risks?
- What other treatment options are available?
- How do the possible risks and benefits of the trial compare with those of other options?

Participation and Care

- What kinds of treatment, medical tests, or procedures will the participants have during the study? How often will they receive the treatments, tests, or procedures?
- Will treatments, tests, or procedures be painful? If so, how can the pain be controlled?
- How do the tests in the study compare with what people might receive outside the study?
- Will participants be able to take their regular medications while in the clinical trial?
- Where will the participants receive their medical care? Will they be in a hospital? If so, for how long?
- Who will be in charge of the participants' care? Will they be able to see their own doctors?
- How long will participants need to stay in the study? Will there be follow-up visits after the study?

Personal Issues

- How could being in the study affect the participants' daily lives?
- What support is available for participants and their families?
- Can potential participants talk with people already enrolled in the study?

Cost Issues

- Will participants have to pay for any treatment, tests, or other charges? If so, what will the approximate charges be?
- What is health insurance likely to cover?
- Who can help answer questions from the insurance company or health plan?

13. What happens when a clinical trial is over?

After a clinical trial is completed, the researchers look carefully at the data collected during the trial before making decisions about the meaning of the findings and further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase, or stop testing the agent or intervention because it was not safe or effective. When a phase III trial is completed, the researchers look at the data and decide whether the results have medical importance.

The results of clinical trials are often published in peer-reviewed, scientific journals. Peer review is a process by which experts review the report before it is published to make sure the analysis and conclusions are sound. If the results are particularly important, they may be featured by the media and discussed at scientific meetings and by patient advocacy groups before they are published. Once a new approach has been proven safe and effective in a clinical trial, it may become standard practice. (Standard practice is a currently accepted and widely used approach.)

The National Library of Medicine's Web site offers links to resources for finding the results of clinical trials. It includes information about published and unpublished results. This resource can be found at http://www.nlm.nih.gov/services/ctresults.html on the Internet.

14. Where can people find more information about clinical trials?

In addition to the resources described in Question 3, people interested in taking part in a clinical trial should talk with their health care provider. Information about cancer clinical trials is also available from the NCI's Cancer Information Service (CIS). Information specialists at the CIS use PDQ to identify and provide detailed information about specific ongoing clinical trials. PDQ includes all NCI-funded clinical trials and some studies conducted by independent investigators at hospitals and medical centers in the United States and Europe.

People also have the option of searching for clinical trials on their own. The clinical trials page of the NCI's Web site, located at http://www.cancer.gov/clinicaltrials/ on the Internet, provides information about clinical trials and links to PDQ. Another resource is the NIH's ClinicalTrials.gov Web site. ClinicalTrials.gov lists clinical trials sponsored by the NIH, other Federal agencies, and the pharmaceutical industry for a wide range of diseases, including cancer and other conditions. This site can be found at http://clinicaltrials.gov on the Internet.

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Related Resources

Publications (available at http://www.cancer.gov/publications)

- National Cancer Institute Fact Sheet 1.2, *The National Cancer Institute Cancer Centers Program*
- National Cancer Institute Fact Sheet 1.3, *Community Clinical Oncology Program: Questions and Answers*
- National Cancer Institute Fact Sheet 1.4, *NCI's Clinical Trials Cooperative Group Program*
- National Cancer Institute Fact Sheet 1.13, *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement*
- National Cancer Institute Fact Sheet 1.17, *The NCI/VA Agreement on Clinical Trials: Questions and Answers*
- National Cancer Institute Fact Sheet 1.22, *Cancer Clinical Trials at the National Institutes of Health Clinical Center: Questions and Answers*
- National Cancer Institute Fact Sheet 8.14, *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials*
- *Taking Part in Clinical Trials: What Cancer Patients Need To Know*
- *Taking Part in Clinical Trials: Cancer Prevention Studies*

National Cancer Institute (NCI) Resources

Cancer Information Service (toll-free)
Telephone: 1-800-4-CANCER (1-800-422-6237)
TTY: 1-800-332-8615

Online
NCI's Web site: http://www.cancer.gov
LiveHelp, NCI's live online assistance:
https://cissecure.nci.nih.gov/livehelp/welcome.asp

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The Access To Cancer Clinical Trials Act of 2009 (Rep. Sue Myrick)

January 30th, 2009

Clinical trials are so critical for patients and or medical research, yet many patients find that their health insurance won't cover the rest of their routine cancer treatment if they decide to enroll in clinical trials. We're not asking insurance companies to pay for clinical trials. This bill simply state that insurers must continue to pay for routine treatments — that they would be paying for regardless — if patients enroll in a clinical trial.

No patient should ever have to fear exploring all treatment options at the cost of losing coverage. We should be encouraging participation in clinical trials, not discouraging it by removing coverage for routine care. Were it not for patients who have enrolled in past trials, the medial advancements we've experienced toward finding a cure for cancer would not be possible.

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By **N.C. GOP Rep. Sue Myrick**

This entry was posted on Friday, January 30th, 2009 at 5:08 pm and is filed under Healthcare, Lawmaker News .

- QUESTIONS & ANSWERS
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