

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

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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.

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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.