



Senate Financial Institutions & Insurance
Committee:
SB 629 – Coverage for Routine Care Associated
with Cancer Clinical Trials

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Definition: Costs Related to Clinical Trials

- **Research/Clinical Trial costs:**
 - Costs associated with conducting clinical trial: data collection and management, research physician and nurse time, analysis of results, tests purely performed for research purposes. Such costs are usually covered by the sponsoring organization, such as the National Cancer Institute (NCI) or a pharmaceutical company.
- **Routine care costs:**
 - Costs for doctor visits, hospital stays, clinical laboratory tests, x-rays, etc., whether patient is participating in a trial or receiving standard treatment.

Background: Coverage of Routine Care

- **State Coverage:**
 - As of 2007, 20 States have passed legislation or instituted special agreements requiring health plans to cover cost of routine medical care for participants in clinical trials.
- **Federal Coverage:**
 - In 2000, Medicare began covering the cost of routine care for participants in cancer clinical trials. TriCare and the Veterans Administration also pay for the cost of routine care for participants in clinical trials.
- **Private Insurance Coverage.**
 - Lack of insurance coverage is a barrier for certain patients who might otherwise wish to be in a clinical trial for their cancer treatment. In one survey, 60% of patients said they feared having their insurance denied as a major reason for not signing up to take part in a clinical trial.

Kansas State Employee Health Plan Coverage

- **Routine health care service costs covered.**

- SEHP covers cost of routine health care services for patients enrolled in a clinical trial (not limited to cancer)

- **Clinical trials/research costs not covered.**

- Coverage of cost of clinical trials are generally excluded from coverage.

- **Contract Language.**

- Covered trials are referred to as “research urgent care.”
- Consists of treatment of life threatening or severely and chronically disabling conditions with a high probability of causing premature death when all other conventional treatments have failed.
- Clinical trial treatment has to be clinically significant and show potential for substantial improvement in net health outcome compared to the most effective conventional treatment.

State Employee Health Plan Costs

- **Cost of routine care not delineated.**
 - Because routine services pay under regular codes submitted to health plan, these expenses are lumped together with all other routine services.
- **Literature on cost of routine care:**
 - Most comprehensive research finds that treatment costs for clinical trial participants are on average 6.5% higher than what they would be if patients did not enroll. “Overall, the additional treatment costs of an open reimbursement policy for government-sponsored cancer clinical trials appear minimal¹”.

¹Goldman et al (2003). **Incremental treatment costs in national cancer institute-sponsored clinical trials.** Journal of the American Medical Association.

Kansas Medicaid Coverage & Cost

- **Routine health care service costs covered.**
 - Medicaid covers cost of routine health care services for patients enrolled in a clinical trial (not limited to cancer)
- **Cost of Care not delineated.**
 - Because routine services pay under regular codes submitted, these expenses are lumped together with all other routine services.

State of Kansas: Covers Routine Costs

- Clinical trials offer patients access to new and potentially life saving drugs and cures.
 - 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.
 - 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.
 - For cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment.
- Participation in clinical trials is low -- only two to three percent of eligible adult patients enroll in clinical trials with health insurance coverage of routine care being a barrier.
- **KHPA** covers the cost of routine care for patients enrolled in a clinical trial in both the State Employee Health Plan and in Medicaid



<http://www.khpa.ks.gov/>