

Minnesota Medicaid Clinical Trial Coverage



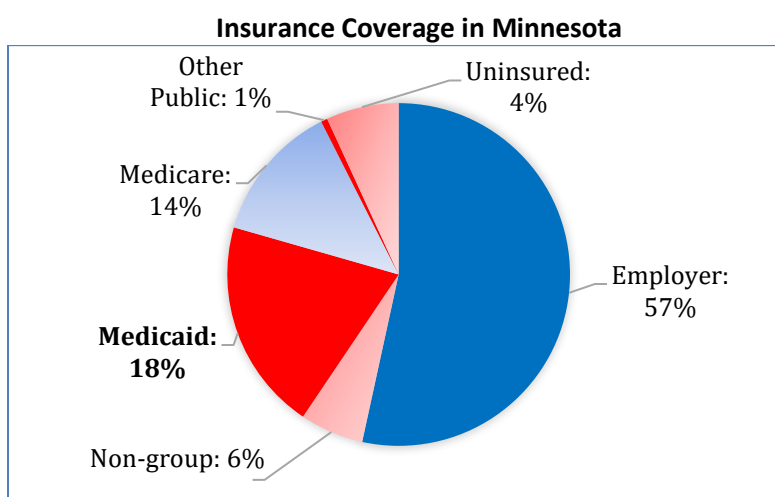
Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the clinic, and patient participation in trials is crucial to this success. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately enrolls in cancer clinical trials because of barriers that make participation difficult or even impossible. Among those barriers is often health insurance that excludes coverage for patients in clinical trials. Currently the Medicaid program is one of the few remaining insurance programs in the U.S. that is not required to cover routine care for patients in cancer clinical trials. Although several states require Medicaid plans to offer this coverage, Minnesota does not.

ACS CAN's Position

ACS CAN believes that Medicaid should cover the routine-care costs for all Medicaid beneficiaries enrolled in cancer clinical trials. ACS CAN believes that anyone with cancer should have the option to participate in a clinical trial, no matter their type of insurance coverage, and that everyone benefits when trial participation reflects the broader population. **ACS CAN supports legislation to require Minnesota Medical Assistance plans to cover routine costs associated with clinical trials.**

Medicaid in Minnesota as a Significant Source of Health Care Coverage

More than 18% of Minnesotans are covered by Medicaid, the second largest type of insurance behind Medicare. The program serves children, disabled adults, and lower income adults and seniors.

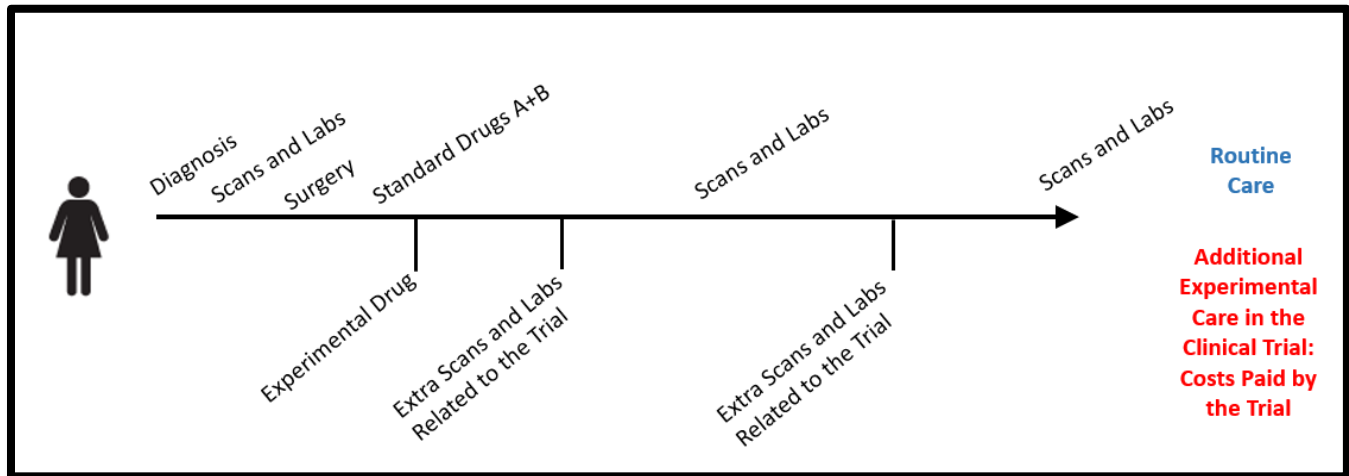


Medicaid is the second largest source of insurance in Minnesota.

Source: Kaiser Family Foundation

Costs of Routine Care in a Clinical Trial

In a cancer clinical trial, much of the treatment received is often identical to the care that patients would receive if they were not in a clinical trial, e.g., physician care and lab tests. This care is considered “routine care.” Any additional treatments, scans, drugs, and/or procedures that are administered only for the clinical trial are paid for by the trial sponsor (i.e., the research institution or the pharmaceutical company). Because routine costs would be paid for by the insurer if the patient were not on a clinical trial, it is generally assumed that there is no or minimal cost differential for the insurer in covering these costs within a clinical trial. Unfortunately, many Medicaid programs refuse to cover any care, including routine care, if a patient opts to enroll in a clinical trial.



This simplified hypothetical cancer treatment regime illustrates the difference between routine care (top line), which is the care that a patient would receive outside of a clinical trial, and experimental care received when a patient is on a clinical trial (bottom line). Experimental care is often simply added to routine care in a clinical trial. Trial sponsors pay for experimental care.

Routine Care in Cancer Clinical Trials Covered by Most Other Insurance

Medicare: Since 2000, Medicare has covered the routine costs of cancer clinical trials that are meant to treat or to cure a disease. Medicare also covers any costs due to medical complications from clinical trials but not the experimental treatment unless it would be covered outside of the trial. Medicare beneficiaries must pay their usual share of the costs of treatments (their deductible and/or co-insurance or co-pay).

Private Insurance: Prior to the passage of the Affordable Care Act (ACA), most states, including Minnesota, required private insurance carriers to provide coverage for routine care in cancer clinical trials. The ACA made this requirement consistent across the country. As of 2014, the federal government mandates all private insurance plans (employer-sponsored and non-group) that did not exist before the ACA's passage to cover routine care costs within clinical trials for cancer or other life-threatening diseases or conditions but not the experimental treatment itself. Privately insured patients must pay their usual share of the costs of treatments, e.g., their deductible and/or co-insurance.

Medicaid: There is no federal requirement for state Medicaid programs to cover routine care in cancer clinical trials, but at least thirteen states plus the District of Columbia have state-level requirements that ensure such coverage. These states include Alaska, California, Florida, Hawaii, Indiana, Maryland, Michigan, Montana, New Mexico, North Carolina, Texas, Vermont, and West Virginia.

Impact of Medicaid Coverage on Diversity of Clinical Trial Participants

Participants in cancer clinical trials often do not reflect the broader population diagnosed with cancer. The elderly, minorities, and those with lower incomes tend to be underrepresented in clinical trials. In fact, individuals with household incomes below \$50,000 are nearly 30% less likely to enroll in a clinical trial. Because Medicaid beneficiaries tend to be lower income and more diverse, ensuring their participation in clinical trials makes it more likely that new therapies will be tested in a representative population.