

Guarantee Coverage of Routine Care Costs of Clinical Trials for Medicaid Patients

The American Society of Clinical Oncology (ASCO) calls on Congress to pass the CLINICAL TREATMENT Act, HR 913, introduced by Representatives Ben Ray Lujan (D-NM) and Gus Bilirakis (R-FL) to require states to cover the routine care costs of participation in an approved clinical trial for Medicaid enrollees.

Routine care costs include the non-experimental costs of treating a patient who is participating in a clinical trial, such as physician visits and laboratory studies.

Medicare and private and commercial payers already guarantee this coverage. Medicare has paid for these services for over a decade through a National Coverage Decision. Private payers are required to provide coverage under the provisions of the Public Health Service Act section 2709 – enacted as part of the Affordable Care Act.

Medicaid insures nearly one-fifth of the U.S. population and is the only major payer that is not required by federal law to provide this coverage. Removing the states that already guarantee this coverage, there are still approximately 42.2 million Medicaid patients potentially without needed protection.

Twelve states plus the District of Columbia have written, publicly-available statutes, regulations and/or policies that require the coverage of the routine costs of clinical trials under Medicaid. These states are: Alaska, California, Florida, Indiana, Maryland, Michigan, Montana, New Mexico, North Carolina, Texas, Vermont, and West Virginia.

Clinical trial participation benefits cancer patients in ways that go beyond the value of the research data generated within the trial, and clinical trials often provide individuals with cancer with their best clinical option.

Medicaid also serves a large portion of under-represented minorities and ethnicities that are not well represented in clinical trial enrollment. Failure to address the coverage barrier that Medicaid patients face could further exacerbate existing disparities.

Providing coverage for the routine costs of clinical trials is affordable as several studies have demonstrated a minimal effect on overall care costs. Because in most cases, this is coverage for care patients would be receiving anyway.

Medicaid does not require state programs to provide coverage for the routine costs of clinical trials participation. The absence of a federal requirement limits patient access to cancer treatments that are the best clinical option for many patients.

TAKE ACTION

- **House:** Cosponsor the *CLINICAL TREATMENT Act*, H.R. 913.
- **Senate:** Consider sponsoring companion legislation.

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