

## **The CLINICAL TREATMENT Act, H.R. 913 Action Alert**

ASCO strongly supports the CLINICAL TREATMENT Act, H.R. 913, introduced by Representatives Ben Ray Luján (D-NM-03) and Gus Bilirakis (R-FL-12) to guarantee coverage of the routine care costs of clinical trial participation for Medicaid enrollees with a life-threatening condition. H.R. 913 has more than 30 bipartisan cosponsors and is supported by over 100 organizations.

This policy was included in the latest Cures 2.0 concept paper authored by Representatives Diana DeGette (D-CO-1) and Fred Upton (R-MI-06). ASCO recently led a community letter with over 75 signers to Congressional leadership encouraging inclusion of this policy in upcoming legislation to further address the COVID-19 crisis.

Take action today! Urge your Representative and Senators to support Medicaid coverage of routine care costs in clinical trials.

- Medicaid insures nearly one-fifth of the U.S. population and is the only major payer not required by law to provide coverage of clinical trial routine care costs.
- Clinical trial participation benefits cancer patients in ways that go beyond the value of the research data generated within the trial, as clinical trials often provide individuals with cancer with their best clinical option.
- Broadening representation improves the validity of clinical research data and the quality of new treatments. Medicaid 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 and prevents researchers from obtaining optimal results in clinical trials.
- The COVID-19 pandemic has highlighted existing disparities in health care and magnified the financial impact that the most vulnerable patients face, making covering these costs even more urgent.
- Providing coverage for routine costs for patients on clinical trials is affordable for states as several studies have demonstrated a minimal effect on overall care costs. -In most cases, Medicaid would cover these costs for patients being treated off of trials anyway. 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. The cost of the investigational device or drug would still be covered by the trial sponsor.

Sample Letter to Representatives:

Rep. XXX,

As an oncology professional in (enter your state), I am writing to ask you to cosponsor the CLINICAL TREATMENT Act, H.R. 913, which would provide Medicaid coverage of the routine care costs of clinical trials participation for patients with life-threatening conditions.

Clinical trials are a critical weapon in the fight against cancer and other life-threatening diseases, often providing patients with their best clinical option. Additionally, Medicaid disproportionately serves many minorities and ethnicities that are vastly underrepresented in clinical trial enrollment. Diversity in clinical trials participation improves the validity of research results and ultimately clinical outcomes.

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.

Studies have shown this coverage has little or no impact on overall cost of care since routine care costs are already covered by Medicaid for patients receiving standard of care treatment off of a clinical trial. The cost of the investigational device or drug would still be covered by the trial sponsor.

This coverage is assured for Medicare beneficiaries as well as individuals with private insurance coverage, leaving Medicaid as the last major payer not required to do so. Medicaid enrollees are the most vulnerable financially, and the COVID-19 pandemic has further highlighted existing disparities in health care and magnified the need to cover the routine costs that may otherwise keep them from seeking the best treatment options.

Recently, language that reflects the CLINICAL TREATMENT Act was included in the 21<sup>st</sup> Century Cures 2.0 concept paper released by Energy & Commerce Committee Members. A community sign on letter with 77 signers was sent to House and Senate leadership, urging adoption of this Cures 2.0 provision in the next COVID-19 relief package. Please cosponsor the CLINICAL TREATMENT Act, H.R. 913, helping ensure participation in clinical research and continuing development of improved treatments for cancer and other life-threatening diseases.

Thank you.

Sample letter to the Senate:

Senator XXX,

As an oncology professional in (enter your state), I am writing to ask you to support legislation that would provide Medicaid coverage of the routine care costs associated with clinical trials participation.

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Recently, a community sign on letter with 77 signers was sent to House and Senate leadership, urging adoption of a provision reflecting this policy in the next COVID-19 relief package. Please consider supporting legislation that would provide Medicaid coverage of the routine care costs of clinical trials participation, helping ensure participation in clinical research and continuing development of improved treatments for cancer and other life-threatening diseases.

Thank you.