

## BACKGROUNDER

### CLINICAL TREATMENT Act: Addressing One Barrier to Inclusive Research

**As of January 1, 2022, Medicaid – one of the largest U.S. health payers – is required in all 50 states to cover routine costs associated with clinical trial participation, bringing parity in insurance coverage for clinical trials among Medicaid enrollees and Americans enrolled in Medicare or private insurance.**

Without clinical trials, treatment options and improvements to medical care would not be possible. For patients with life-threatening conditions, clinical trials may also be the only way to access investigational treatments when approved options are nonexistent or have been exhausted. Clinical trials are used to determine if and how new treatments will be used in broader clinical settings. Without sufficient representation, the ability for physicians and patients to generalize research findings is inadequate.

#### Key Facts: The CLINICAL TREATMENT Act

The CLINICAL TREATMENT Act aims to improve access to clinical trial participation among Americans who receive healthcare coverage through Medicaid. If leveraged, it has the potential to help expand access to investigational therapies and improve research findings.

State Medicaid programs are now required to cover costs of routine medical care for enrollees who participate in qualifying clinical trials. Other major U.S. payers such as Medicare and private insurers have been required to cover routine costs associated with clinical trials for years.<sup>i</sup>

100+ professional medical associations and patient advocacy groups lobbied for the passage of the CLINICAL TREATMENT Act, making the case that:

“Medicaid serves many demographics, including ethnic minorities, women and children that are underrepresented in current clinical trial enrollment. Lack of participation in clinical trials from the Medicaid population means these patients are being excluded from potentially life-saving trials and are not reflected in the outcome of the clinical research.”<sup>ii</sup>

Routine care costs include doctor visits, hospital stays, laboratory tests, and imaging tests such as magnetic resonance imaging. These costs are typically covered by health insurance.

Research costs include costs related to the study drug or lab tests or imaging needed solely for research purposes. These costs are typically covered by the trial sponsor.

#### Key Facts: Medicaid enrollees

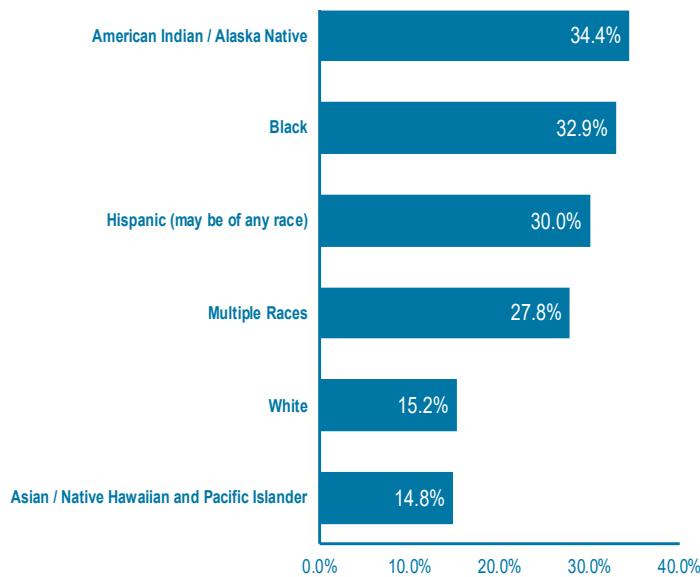
Medicaid delivers health care benefits to individuals and families with low incomes and is a key source of health coverage for many communities currently underrepresented in clinical research.

Medicaid covers approximately one in four Americans<sup>iii</sup> including:<sup>iv</sup>

**1 in 7**  
adults under 64

**1 in 3**  
individuals with disabilities

## Medicaid enrollees by subpopulation<sup>v</sup>



Medicaid is a safety net for many who lose their insurance along with their jobs due to illness or are not offered insurance through work and cannot afford commercial plans – like the five million essential and frontline workers who are covered by Medicaid.<sup>vi</sup>

Nearly twice the proportion of Americans who identify as Black, Native American or Hispanic are enrolled in Medicaid compared to those who identify as White.

While most research looking at clinical trial enrollment does not include data on enrollment by insurance type, one study did just that. In an analysis of enrollment in pancreatic cancer studies from 2004-2016, just 3%-5% were Medicaid-insured.<sup>vii</sup> Another study showed that people seeking cancer care with annual household incomes of less than \$50,000 were nearly 30% less likely to participate in a clinical trial. As income levels decreased, so did rates of participation.<sup>viii</sup>

### Addressing One Barrier to Inclusive Research

There is a rising and long overdue industry scientific and ethical imperative for more diverse trial participation; an imperative underscored repeatedly by differences in disease causality, presentation and progression in diverse patient populations, as well as divergence in drug safety and efficacy.

Advancing inclusive research is complex, involves genomic intricacies and recognition of multiple, intersecting social determinants of health.

Achieving broader diversity, equity and inclusion goals will require nothing less than a full-court press that prioritizes:

- the integration of diverse patient perspectives into trial design, eligibility criteria and recruitment strategies
- a strong pipeline of diverse investigators and study staff
- patient and community education on the nuances and benefits of trial participation
- thoughtful decentralized approaches
- outreach materials meet the mark on cultural resonance and health literacy

In November 2020, The U.S. Food and Drug Administration highlighted the lack of diversity in trials that led to drug approvals from 2015 to 2019. Just seven percent of participants in these trials identified as Black and thirteen percent identified as Hispanic/ Latino.<sup>ix</sup> That same month, the agency released guidance that clinical trials should enroll the patient population most relevant to the epidemiology of a disease and most likely to use the drug if approved for a specific indication.<sup>x</sup>

**Like any policy change, the CLINICAL TREATMENT Act is not a panacea. It is a step forward. Its real-world impact hinges on appropriate state-level implementation, stakeholder awareness and patient utilization.**

i Cancer.net. ASCO Answers: Clinical Trials Coverage Through the Affordable Care Act. Available at: [https://www.cancer.net/sites/cancer.net/files/clinical\\_trials\\_coverage\\_aca\\_fact\\_sheet.pdf](https://www.cancer.net/sites/cancer.net/files/clinical_trials_coverage_aca_fact_sheet.pdf)

ii Community Endorsement Letter 913. February 18, 2020. Available at: [https://media.cancercare.org/documents/108/2020-Community-Endorsement-Letter\\_HR-913.pdf](https://media.cancercare.org/documents/108/2020-Community-Endorsement-Letter_HR-913.pdf)

iii The New York Times. Medicaid Enrollment Surpassed 80 million, a Record, During the Pandemic. Published July 6, 2021. ); July 2021 Medicaid and CHIP Enrollment Trend Snapshot. Available at: <https://www.medicaid.gov/medicaid/program-information/medicaid-chip-enrollment-data/medicaid-and-chip-enrollment-trend-snapshot/index.html>

iv Kaiser Family Foundation. Medicaid in the United States Fact Sheet. October 2019. Available at: <https://files.kff.org/attachment/fact-sheet-medicaid-state-US>

v Kaiser Family Foundation. Health Insurance Coverage of the Nonelderly (0-64) with Incomes below 100% Federal Poverty Level (FPL) Available at:

vi Center on Budget and Policy Priorities, States That Have Expanded Medicaid Are Better Positioned to Address COVID-19 and Recession | Center on Budget and Policy Priorities.) Available at: [States That Have Expanded Medicaid Are Better Positioned to Address COVID-19 and Recession | Center on Budget and Policy Priorities \(cbpp.org\)](https://www.cbpp.org/research/state-budget-and-tax/states-that-have-expanded-medicaid-are-better-positioned-address-covid-19-and-recession)

vii Eskander, M.F., Gil, L., Beal, E.W. et al. Access Denied: Inequities in Clinical Trial Enrollment for Pancreatic Cancer. *Ann Surg Oncol* 29, 1271–1277 (2022).

viii Unger JM, Gralow JR, Albain, KS, et al. Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study. *JAMA Oncol.* Jan;2(1):137-9. (2016).

ix Milken Institute: Achieving Diversity Across Clinical Trials. Available at: [milkeninstitute.org](https://milkeninstitute.org).

x FDA, gov. Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry. November 2020. Available at: [Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry | FDA](https://www.fda.gov/regulations-guidance/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial-designs-guidance-industry)