

Quick Guide to Medicaid Coverage of Clinical Trials

Under the Clinical Treatment Act of 2020, all state Medicaid programs are now required to cover the routine costs of participating in clinical trials. This Quick Guide explains what is considered a qualifying clinical trial, which costs are covered by Medicaid, whether Medicaid must cover clinical trials that are out-of-state or outside of your Medicaid managed care plan's network of providers, and what to do if you are denied access to a clinical trial.

Who Pays for the Costs of a Clinical Trial?

The clinical trial's sponsor (e.g., a cancer center or a pharmaceutical company) typically pays for research costs in a clinical trial. Research costs include the cost of the treatment being tested and any tests performed only for research purposes.

But the trial does not usually pay for routine costs of your care, including doctor's visits, blood tests and imaging scans. Patients are responsible for these routine costs. Depending on the type of health insurance a patient has, some or all routine costs may be covered. Even if covered, patients may be responsible for paying out-of-pocket costs (e.g., a co-payment) under their plan. A list of routine patient costs can be found at: www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2.

About the Clinical Treatment Act of 2020 (CTA)

As of January 1, 2022, the CTA requires all state Medicaid programs to cover the routine costs of participating in a qualifying clinical trial. Qualifying clinical trials under the CTA, include research studies that have received approval or funding from the: National Institutes of Health; Centers for Disease Control and Prevention; Agency for Health Care Research and Quality (AHRQ); Department of Defense or the Department of Veterans Affairs; or Centers for Medicare & Medicaid Services (CMS). You can learn more about how the CTA defines a qualifying clinical trial and see a full list of approved entities: www.medicaid.gov/sites/default/files/2022-04/smd21005.pdf.

Medicaid is not required to cover:

- Any investigational item or service that is the subject of the clinical trial, if it is not already covered by Medicaid outside of the clinical trial setting. For example: If the clinical trial is testing an investigational drug that is not currently covered by Medicaid, the cost of the drug is not included in routine costs. But these are costs usually covered by the clinical trial.
- Any item or service provided only to collect or analyze data for the trial, if it is not used in the direct clinical management of the patient. For example: If the clinical trial that requires a monthly PET scan to collect data, the PET scans being conducted more often than standard of care, to collect data are not routine costs. These costs may be covered by the clinical trial.

Where Can I Go to Participate in a Clinical Trial?

Generally, state Medicaid programs are not required to cover care that you receive out-of-state. Also, if you have a Medicaid managed care plan, that plan will generally not cover care that you receive from a provider who is not in your plan's network of providers. Providers outside of your plan's network are called out-of-network providers. However, under the CTA, a state Medicaid plan **MUST**:

- Cover routine costs for patients who participate in out-of-state qualifying clinical trials; and
- Cover routine costs for patients who participate in a clinical trial, even if the health care provider running the clinical trial is not part of a Medicaid managed care plan's network.

For example: Sally lives in Nebraska and has a Nebraska Medicaid managed care plan. Sally's doctor has recommended a clinical trial in Massachusetts. The clinical trial is out-of-state and out-of-network for Sally's Medicaid managed care plan. But, her Medicaid plan must cover the routine costs of being in the Massachusetts clinical trial.

Keep in mind that you may need to get prior authorization from Medicaid, before you get care, in order to get coverage for an out-of-state clinical trial.

What Can I Do if Medicaid Denies Coverage for My Clinical Trial?

If Medicaid denies coverage for a clinical trial, here are some practical steps you can take:

- If Medicaid, or your Medicaid managed care plan, has told you they won't pay a claim, but has not officially issued a denial, ask for them to issue the denial in writing. Without an official denial that includes why the claim was denied, you won't be able to appeal.
- Appeal the denial with Medicaid or your Medicaid managed care plan. State Medicaid programs are required to have an appeals process that includes a fair hearing when a claim for assistance is denied or not acted upon in a timely manner. Although there are federal standards, states have some flexibility in designing their own Medicaid appeals processes. For information about how to appeal a Medicaid denial, visit Cancer Finances: [TriageCancer.org/Cancer-Finances-Appeals](https://www.triagecancer.org/Cancer-Finances-Appeals).
- If Medicaid, or your Medicaid managed care plan, tells you that you are being denied because your clinical trial is out-of-network or out-of-state, remind them that the Clinical Treatment Act states that "a state or territory may not deny coverage of routine patient costs based on where the clinical trial is conducted, including out of state, or based on whether the principal investigator or provider treating the beneficiary in connection with the clinical trial is outside of the network of the beneficiary's Medicaid managed care plan." You can point them to this resource: *CMS Letter SMD #21-005, an April 2022 letter from CMS to state Medicaid directors* - www.medicaid.gov/sites/default/files/2022-04/smd21005.pdf.
- If you need help, contact Triage Cancer's Legal & Financial Navigation Program at [TriageCancer.org/GetHelp](https://www.triagecancer.org/GetHelp).

What Can I Do if the Trial Denies Me Because I Have Medicaid?

If a clinical trial denies you because you have Medicaid, here are some practical steps you can take:

- Contact the clinical trial sponsor and remind them that the Clinical Treatment Act requires Medicaid to make coverage determinations "without limitation on the geographic location or network affiliation of the health care provider" treating a patient, or the principal investigator of the qualifying clinical trial. You can point them to this resource: *CMS Letter SMD #21-005, an April 2022 letter from CMS to state Medicaid directors* - www.medicaid.gov/sites/default/files/2022-04/smd21005.pdf.
- Contact your state's Medicaid program. You can find their contact information here: [TriageCancer.org/StateResources](https://www.triagecancer.org/StateResources). Ask them for help to tell the trial that Medicaid will cover the trial's routine costs.
- If you need help, contact Triage Cancer's Legal & Financial Navigation Program at [TriageCancer.org/GetHelp](https://www.triagecancer.org/GetHelp).

For more information about Medicaid & Clinical Trials:

- Quick Guide to Medicaid: [TriageCancer.org/QuickGuide-Medicaid](https://www.triagecancer.org/QuickGuide-Medicaid)
- Quick Guide to Clinical Trials: [TriageCancer.org/QuickGuide-ClinicalTrials](https://www.triagecancer.org/QuickGuide-ClinicalTrials)
- Clinical Trials Resource Hub: [TriageCancer.org/ClinicalTrials](https://www.triagecancer.org/ClinicalTrials)
- Triage Cancer Animated Video: How to Find & Pay for Clinical Trials: [TriageCancer.org/Video-ClinicalTrials](https://www.triagecancer.org/Video-ClinicalTrials)