



# Global Commitment Register

July 12, 2022

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GCR 21-094  
FINAL

## **Clinical Trial Routine Patient Cost Coverage**

### **Policy Summary:**

Vermont Medicaid received approval of State Plan Amendment (SPA) 22-0001 for coverage of routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial. This adds coverage for the cost of non-emergency medical transportation services for participation in a clinical trial. Coverage for other routine patient costs is already in effect. Reimbursement for both routine patient costs and non-emergency medical transportation services remains unchanged.

This change is in accordance with the Consolidated Appropriations Act of 2021, which adds a mandatory Medicaid benefit at 1905(a)(30) of the Social Security Act for coverage of routine patient costs for services provided to a beneficiary participating in a qualified clinical trial as defined at 1905(gg)(2).

Routine patient costs are services that are consistent with the usual and customary standard of care and would be covered if a patient was not enrolled in a qualified clinical trial. It includes services such as office visits, lab tests, supportive care drugs, and procedures or services that are necessary for participation in the trial.

Routine care also includes any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial. Coverage is limited to services that are otherwise covered under the Medicaid state plan.

Coverage is not included for:

- the item or service that is under investigation and not otherwise covered outside of the clinical trial under the state plan, and
- any item or service provided to the beneficiary solely for data collection purposes for the clinical trial and is not used in the direct clinical management of the patient and not otherwise covered under the state plan, or waiver.

The changes above will also be reflected in the Alternative Benefit Plan (ABP) for the New Adult Group through SPA 22-0003. The ABP replicates the full Medicaid State Plan and includes the 10 essential health benefits required under the Affordable Care Act, as well as the full range of Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services for individuals under the age of 21.

**Effective Date:**

January 1, 2022

**Authority/Legal Basis:**

[Consolidated Appropriations Act of 2021](#)

[Medicaid State Plan](#)

[Global Commitment to Health Waiver](#): Waiver authority #5 [Section 1902(a)(13), 1902(a)(30)]; Special Term and Condition #29.

**Population Affected:**

All Medicaid

**Fiscal Impact:**

The estimated gross annualized budget impact is \$96,750.

**Public Comment Period:**

The public comment period ended on January 31, 2022. No comments were received.

**Additional Information:**

The following State Plan pages were added:

- Attachment 3.1-A page 14
- Attachment 3.1-B page 2

Click here for the [Medicaid State Plan](#) on the AHS website.