



Policy Title	Clinical Trial Reimbursement Policy
Policy Department	Payment Strategy and Operations
Effective Date	1/1/2022
Revision Date(s)	1/1/2022
Next Review Date	

Disclaimer:

Clover Health applies CMS criteria and guidelines, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), Clover Policies, and MCG for determining medical necessity. Clover Policies are intended to provide a standard guideline but are not used to preempt providers' judgment in rendering services. Providers are expected to provide care based on best practices and use their medical judgment for appropriate care.

Description:

This policy addresses claims billed to Clover Health that qualify for clinical trials. CMS has defined specific criteria on how these claims should be billed and processed. Using that criteria, providers should be aware that some Clinical Trial claims are billed directly to Medicare based on the Clinical Trial categorization by CMS.

Definitions:

- **Clinical Trial**
 - A CMS approved research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes



Policy:

Claims may qualify for payment for items and services in clinical research studies under three policies: (1) the Clinical Trial Policy (CTP), (2) the Investigational Device Exemption (IDE) policy, and, (3) Coverage with Evidence Development (CED).

In accordance with applicable Medicare fee-for-service and Medicare Advantage guidelines, Medicare Administrative Contractors (MACs) will directly pay providers for covered clinical trial services furnished to a Clover Health member. (Medicare Managed Care Manual Chapter 8, section 40.4.3)

For qualified clinical trials, CMS covers routine costs associated with that trial. As a Medicare Advantage Plan, Clover is responsible for certain defined clinical trial costs.

In order for payment to be made on clinical trials, Providers are required to meet the billing requirements as listed by CMS for Clinical Trials. Those requirements can include:

- A valid Condition Code indicating Clinical Trial
- The appropriate Value Code
- Required for all claim types - the Clinical Trial Number
- Required for all claim types - a diagnosis code that indicates that the claim is being submitted for a Clinical Trial

When correctly billed, Clover Health will reimburse providers for Clinical Trials that fall into the following CMS categories:

- IDE (Category A and Category B)
- CED Studies
- Clinical Trials that Qualify for Coverage Under a Specific NCD (Unless CMS determines that a significant cost threshold was exceeded)

Claims that do not fall into one of the above categories will be denied and should be billed directly to CMS. Additionally, claims that are not billed with all required Clinical Trial information will be denied.

Clinical Trials that Qualify for Coverage under the CTP should be billed directly to Medicare and not Clover Health.

References

[Medicare Clinical Trials Policy](#)

[Medicare Coverage - Clinical Trials](#)



[Mandatory reporting of NCT number](#)

[Medicare Managed Care Manual, Chapter 8](#)

[Coverage with Evidence Development Studies List](#)

[CMS Approved IDE Studies](#)