



CLINICAL POLICY AND PROCEDURE MANUAL

Policy Number: PA.078.CC
Last Review Date: 08/21/2025
Effective Date: 09/01/2025

PA.078.CC Clinical Trials

Summary

A clinical trial is a research program conducted with members to evaluate a new medical treatment, drug, or device. The purpose of clinical trials is to find new and improved methods of treating, preventing, screening for, and diagnosing different diseases and are often used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.

Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials.

County Care considers routine care costs of members in **Clinical Trials** medically necessary for the following indications:

General Requirements ⁽¹⁻⁴⁾

- The member is a participant in a qualifying clinical trial. NOTE: Documentation confirming enrollment in the clinical trial must be submitted along with the participation request.
- Documentation of 8-digit clinical trial number on items or services provided in clinical trial (Clinical trials that are also an Investigational Device Exemptions (IDE) must document associated IDE number).
- Items, medications or services for which coverage is requested are typically provided to members who are not part of a clinical trial.
- Treatment with the items or services is included in medical record documentation of the provider(s).

Federally Funded Trials ⁽⁵⁾

- Trials conducted under an Investigational New Drug (IND) application reviewed by the United States Food and Drug Administration (FDA) and drug trials that are exempt from having an IND will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time:
 - The principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain coverage of routine costs.

- The certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.
- Other clinical trials that are deemed to be automatically qualified include those either funded by or supported by centers or cooperative groups that are funded by NIH, Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs.

Limitations

Coverage will not include any of the following:

- The investigational item and/or associated services (including medications) that are rendered in connection with the clinical trial.
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in a direct clinical management of a member (e.g., monthly CT scans for a condition usually requiring only a single scan).
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
- Services that are not health care services (e.g., administrative services).
- Services not routinely provided for the direct clinical management of the member. The services must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic benefit.
- Laboratory services and imaging surveillance ordered for the sole purpose of gauging what effect the clinical trial drug is having on the member's condition.
- Coverage of routine care costs for members participating in clinical trials at out-of-network facilities is governed by the benefit design of the member's plan.

Note: See PA.079 Experimental and Investigative Services regarding coverage of Investigational Device Exemptions (IDE) and Humanitarian Use Devices (HUD).

References

1. Centers for Medicare & Medicaid Services. National Coverage Analysis Decision Memo: Clinical Trial Policy.; 2007. Accessed April 9, 2025.
<https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=210&NcaName=Clinical+Trial+Policy&NCDId=1&lsPopup=y&bc=AAAAAAAAACAAAAA%3D%3D&>
2. Department of Health & Human Services, Centers for Medicare & Medicaid Services. Pub 100-04 Medicare Claims Processing: Transmittal 2955.; 2014. Accessed April 9, 2025.
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2955CP.pdf>
3. Department of Health and Human Services. FAQs About Affordable Care Act Implementation (Part XV).; 2013. Accessed April 9, 2025.

PA.078.CC Clinical Trials

Policy Number: PA.078.CC
Last Review Date: 08/21/2025
Effective Date: 09/01/2025

<https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-implementation-faqs-part-xv-2013.pdf>

4. Department of Health & Human Services, Centers for Medicare & Medicaid Services. Pub 100-20 One-Time Notification: Transmittal 131.; 2004. Accessed April 9, 2025.
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R131OTN.pdf>
5. Public Law 110-85. 110th Congress; 2007. Accessed April 9, 2025.
<https://www.congress.gov/110/plaws/publ85/PLAW-110publ85.pdf>
6. Centers for Medicare & Medicaid Services. NCD 310.1 Routine Costs in Clinical Trials.
<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncid=1&ncdver=3&fromdb=true; 2024>
7. Center for Medicare & Medicaid Services. Billing Requirements for Special Services. In: Medicare Claims Processing Manual. Rev. 12883. ; 2024. Accessed April 9, 2025.
<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf>

Revision History

Revision	Date
Policy Adopted	03/01/2023
Annual Review, formatting updates	09/14/2023
Annual Review, corrected date in Reference #2; replaced invalid link in Reference #4	08/15/2024
Annual Review; formatting updates throughout the Policy; added in-text citations; updated Indications and Limitations; replaced outdated References with updated References	08/21/2025

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall

PA.078.CC Clinical Trials

Policy Number: PA.078.CC
Last Review Date: 08/21/2025
Effective Date: 09/01/2025

be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent. Any sale, copying, or dissemination of said policies is prohibited.