EVH Clinical Guideline 2711.CC for Clinical Trials

Guideline Number:	Applicable Codes	
EVH_CG_2711.CC		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.		
Original Date:	**Last Revised Date:**	**Implementation Date:**
March 1, 2023	November 20, 2025	December 1, 2025

TABLE OF CONTENTS

STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines, and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Special Note

See ECG_2712 for Experimental and Investigative Services regarding coverage of Investigational Device Exemptions (IDE) and Humanitarian Use Devices (HUD).

INDICATIONS

CountyCare 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 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 a 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.

CODING AND STANDARDS

Codes

N/A

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

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.

POLICY HISTORY

Date	Summary
November 20, 2025	• This guideline replaces PA.078.CC Clinical Trials • Editorial changes to match the formatting and layout of the new template, changes to clinical content

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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