EVH Clinical Guideline 2712.CC for Experimental and Investigational Services

Guideline Number:	Applicable Codes	
EVH_CG_2712.CC		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. *© 2023 - 2025 Evolent. All rights Reserved.*		
Original Date:	**Last Revised Date:**	**Implementation Date:**
August 15, 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.*

Purpose

This clinical policy is intended to provide guidance when reviewing medical services that are considered experimental or investigational.

Special Note

See also cross-reference policy ECG_2711.CC for Clinical Trials.

INDICATIONS

CountyCare considers services **Experimental and Investigational (E&I)** if any of the following apply:

- The intervention **does not** have Food and Drug Administration (FDA) or other regulatory agency approval to be marketed for the specific relevant indication(s)
- Available scientific evidence does not permit conclusions concerning the effect of the intervention on health outcomes
- The intervention is not proven to be as safe or effective in achieving an outcome equal to or exceeding the outcome of alternative therapies
- The intervention does not improve health outcomes
- The intervention is not proven to be applicable outside the research setting

General Requirements

CountyCare considers review and approval of experimental or investigational services (see definition above) when **ALL** the following apply:

- All the following describe the services:
  - are in general use in the medical community
  - are under continued scientific testing and research
  - show a demonstrable benefit for a particular illness or disease
  - are proven to be safe and efficacious
- Whether the services result in greater benefits for a particular illness or disease than other generally available services, and do not pose a significant risk to health or safety of the member
- The supporting documentation upon which the criteria are established must be made available for review upon written request in all instances.

Device Requirements

- For devices with Investigational Device Exemptions (IDE) [1-3]:
  - **Category A** (Experimental) devices will not be covered because they are considered experimental and investigational, and therefore not considered reasonable and necessary medical services. Routine care costs of members participating in clinical trials may be covered if allowed under the member's specific benefit plan according to PA.078 Clinical Trials - Coverage of Routine Care Costs upon determination that the device is intended for the diagnosis, monitoring or treatment of an immediately life-threatening disease/condition, but the device itself will not be covered.
  - **Category B** (Nonexperimental/investigational) devices may be considered for coverage if allowed under member's specific benefit plan and all the following apply:
    - The device must be used within the context of the FDA approved clinical trial.
    - The device must be used according to the clinical trial's approved member protocol.
    - The medical necessity of the device must be established for the particular member and medical appropriateness established for the amount, duration, and frequency of use or applications of the service.
    - The setting where the service is furnished must be appropriate according to the member's medical needs, condition, and benefit plan.
- For devices with Humanitarian Device Exemptions (HDE), all of the following must apply[4]:
  - The device must be appropriate under the member's specific plan
  - A HUD may only be used in facilities that have an established local Institutional Review Board (IRB) to supervise the clinical testing of the device or service)

- IRB approval for use of the HUD must be current according to the IRB requirements (e.g., updated annually)
- The HUD must only be used for HDE approved indications specified in the product labeling

LIMITATIONS

- Category B devices will not be covered if any of the following apply:
  - When the services or technologies are in the developmental or testing stage
  - When there is no final regulatory or governmental approval
  - When IDEs are applied in the inpatient setting, where they will be included in the Diagnosis Related Group (DRG) payment.
- The service or procedure will be considered not medically necessary if the available scientific proof does not indicate that the treatment is safe and effective for treating or diagnosing the relevant medical condition or illness or the intervention has not been shown to improve health outcomes.
- In addition to the above criteria, the Medical Policy Committee (MPC) will consider recommendations of national physician specialty societies, nationally recognized professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

CODING AND STANDARDS

Codes

ICD-10 Codes

- **ICD- 10 Code Z00.6** must be reported as the secondary diagnosis
- Utilization of appropriate modifiers Q0 and/or Q1

Applicable Lines of Business

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

BACKGROUND

Definitions

- **Investigational/Experimental Procedures** are defined as a procedure, device or pharmaceutical agent that is still undergoing pre-clinical or clinical evaluation, and/or has not yet received regulatory approval. It is the use of a service, procedure or supply that is not recognized by the Plan as standard medical care for the condition, disease, illness, or injury being treated. A service, procedure or supply includes but is not limited to the diagnostic service, treatment, facility, equipment, drug, or device. When basic safety and efficacy have been demonstrated by the experimental scientific process, the investigational phase begins.
- **Category A (Experimental)** device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.
- **Category B (Non-experimental/investigational)** device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type has been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type

Evidence-Based Reviews

This assessment includes:

- A thorough review of available scientific information, which may include peer-reviewed literature, results of clinical trials, outcomes data, regulatory requirements, and input from professionals in the field of the medical service under review.
- Discussion among a multidisciplinary group of health care providers to achieve an adequate understanding of the medical science and its application.

- An appropriate coverage recommendation based on the sum of the evidence.
- Identification of medical services as “experimental and investigational” according to the definition provided in this Policy.

Services determined to be experimental and investigational are listed, and experimental and investigational services which demonstrate a significant body of scientific evidence supporting safety and effectiveness are removed from the list. If there is no documentation that the experimental and investigational service does not provide benefit, or there is not any benefit that is equal or better than the standard of care, it is experimental and investigational. Due to the frequency at which new medical services are developed and researched, this list of services should not be considered all-inclusive as it has the potential to change frequently due to the body of evidence available.

POLICY HISTORY

Date	Summary
November 20, 2025	• This guideline replaces PA.079.CC Experimental and Investigational Services • Editorial changes to match the formatting and layout of the new template, no 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

1. Centers for Medicare & Medicaid Services. Medical Devices. In: Medicare Benefit Policy Manual. Rev. 198; 2014. Accessed April 13, 2025. **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf**
2. Centers for Medicare & Medicaid Services. Benefits and Beneficiary Protections. In: Medicare Managed Care Manual. Rev. 121; 2016. Accessed April 13, 2025. **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf**
3. Investigational Device Exemptions.; 2025. Accessed April 13, 2025. **https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812**
4. Humanitarian Device Exemption. U.S Food & Drug Administration. January 13, 2025. Accessed April 13, 2025. **https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption**