

# Medical Necessity Guidelines: Experimental, Investigational or Unproven Services



POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
MG.MM.AD.11a	6/14/2019	MPC (Medical Policy Committee)

## **IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies(LMRP). All coding and web site links are accurate at time of publication.

## **Guideline**

ConnectiCare, Inc. restricts coverage to those devices, treatments or procedures for which the safety and efficacy have been proven, and which are comparable or superior to conventional therapies. The plan defines the terms "investigational", "experimental" or "unproven" as 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. A service is considered investigational, experimental or unproven, if any of the following criteria are met:

1. The services, procedures or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.

# Medical Necessity Guidelines: Experimental, Investigational or Unproven Services



2. There is insufficient or inconclusive medical and scientific evidence to permit the Plan to evaluate the therapeutic value of the service, procedure or supply. (Adequate evidence is defined as at least two documents of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member.)
3. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure or supply has a beneficial effect on health outcomes.
4. The service, procedure or supply under consideration is not as beneficial as any established alternatives.
5. There is insufficient information or inconclusive scientific evidence that, when used in a non- investigational setting, the service, procedure or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.
6. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and is not considered to be medically necessary or appropriate.

To determine whether a device, medical treatment or procedure is proven safe and effective, the following hierarchy of reliable evidence is used:

1. Published formal technology assessments and /or high quality meta analyses
2. Well-designed randomized studies published in credible, peer-reviewed literature
3. High quality case-control or cohort studies
4. Historical control studies
5. Reports of expert opinion from national professional medical societies or national medical policy organizations

## Limitation/Exclusion



With respect to clinical studies, only those reports and articles, which contain scientifically valid data and published in the referred medical and scientific literature, shall be considered reliable evidence.

Specifically, not included in the meaning of reliable evidence are reports, articles or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also, not included is the fact that a provider or a number of providers have elected to adopt a device, medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

ConnectiCare, Inc. adheres to Federal and state government program directives. Therefore, if there is a discrepancy between the overarching clinical coverage position and the member's benefits program, the benefits program will govern.

## Applicable Coding

*To access the codes, please download the policy and click on the links below.*

	<a href="#">List of E&amp;I Codes – Commercial Plans</a>
	<a href="#">List of E&amp;I Codes – Medicare Plans</a>

# Medical Necessity Guidelines: Experimental, Investigational or Unproven Services



## Revision history

DATE	REVISION
11/2019	<ul style="list-style-type: none"><li>• Title changed from Medical Necessity Guidelines for noncovered investigational services to Medical Necessity Guidelines: Experimental, Investigational or Unproven Services to coincide with definitional enhancements.</li><li>• Reformatted and reorganized policy, transferred content to new template with new Medical Policy Number</li></ul>