

Medical Necessity Guidelines: Experimental, Investigational or Unproven Services

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Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth 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). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program 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 EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc

Guideline

EmblemHealth 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.
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

Limitations/Exclusions

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.

EmblemHealth 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.

Revision History

Jun. 14, 2019 — title changed from *Medical Necessity Guidelines for noncovered investigational services* to *Medical Necessity Guidelines: Experimental, Investigational or Unproven Services* to coincide with definitional enhancements.