

Medical Necessity Guidelines for Non-Covered Investigational 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 HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Additional Resources

[Medical Technologies Database](#)

[EmblemHealth Medical Guidelines](#)

Guideline

EmblemHealth considers a treatment or procedure to be investigative or unproven if reliable evidence shows that prevailing opinion among experts regarding the treatment is that more studies or clinical trials are necessary to determine its safety, efficacy, toxicity, maximum tolerated dose or its efficacy as compared with a standard means of treatment or diagnosis.

The plan 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. 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

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

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.