Medical Necessity Guidelines for Non-Covered Investigational Services

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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.