

**Experimental & Investigational Procedures**  
**Policy Number: SU0190**

**Active policy, not scheduled for routine review.**

**Definition:**

An experimental or investigational procedure is defined as the use of a service, supply, drug or device not recognized as standard medical care for the condition, disease, illness or injury being treated as determined by the Executive Administrator and Board of Trustees upon the advice of the Claims Processing Contractor. Determinations are made after independent review of scientific data. Opinions of experts in a particular field and opinions and assessments of nationally recognized review organizations shall also be considered by the Plan but are not determinative or conclusive. The fact that an experimental/investigational treatment is the only available treatment for a particular medical condition or that the patient has tried other more conventional therapies without success may not necessarily result in coverage.

**Coverage:**

1. Benefits are excluded for any service, supply, drug or device which has been determined by the Executive Administrator and Board of Trustees upon the advice of the Claims Processing Contractor to be experimental or investigational. In determining whether benefits should be excluded, the prevailing criteria for consideration will be whether the service is recognized as standard medical care for the condition, disease, illness, or injury being treated.
2. Benefits are available for phases III and IV of clinical trials (subject to prior approval for transplants) for life-threatening medical conditions such as cancer, cardiovascular disease, heart disease, diabetes, kidney failure, respiratory diseases, and AIDS. Benefits may also be available for phase II clinical trials subject to a review made by the CPC of substantiating medical documentation which must include relevant scientific data, expert opinions from relevant medical fields, and a determination from the treating physician.

**Approval Procedures:**

1. Prior approval is required for covered transplants regardless of the clinical trial phase.
2. In addition to the required documentation for transplants, phase II clinical trials involving transplants must also include relevant scientific data, expert opinions from relevant medical fields, and a determination from the treating physician. The CPC is required to make a determination on benefit coverage for phase II clinical trials within 30 days of receiving all required information. (The CPC may request additional forms of relevant documentation, other than those listed above, and to extend the 30-day time limit when necessary to make a benefits determination.)

**Limitations and Exclusions:**

1. No benefits are provided for any service, supply, drug or device which has been determined by the Executive Administrator and Board of Trustees upon the advice of the Claims Processing Contractor to be experimental or investigational.
2. When a service has been determined to be experimental or investigational, benefits are excluded for all doctors', hospitals', and other providers' services associated with the procedure, even if the charges would have been covered if rendered in connection with an otherwise covered service.
3. No benefits are provided for complications or side effects arising from any experimental or investigational procedures, which were known at the time the non-covered services were provided.
4. The Plan will not provide coverage for any services directly or indirectly related to any service determined to be experimental or investigational for a period of up to 12 months after the noncovered procedure was performed.

5. No benefits are provided for services or supplies involving the treatment of a non-life threatening medical condition (e.g., cochlear implant for hearing loss) requiring federal or other governmental body approval, such as drugs and devices that do not have market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body.
6. No benefits are provided when there is insufficient or inconclusive scientific evidence provided in appropriate peer review medical literature concerning a service, phase II clinical trial, supply, drug or device which prohibits the Claims Processing Contractor from making a conclusive evaluation.
7. No benefits are provided for any services when the beneficial effect and health outcomes have not been proven.
8. No benefits are provided for services, supplies, drugs or devices when:
  - a. the services are provided as part of a phase I research or clinical trial;
  - b. the services are provided as part of a phase II research or clinical trial when, in the opinion of the CPC, relevant scientific data, expert opinions from relevant medical fields, and a determination from a treating physician do not support conclusive or positive outcomes;
  - c. the attending physician(s) fails to submit for review required documentation;
  - d. there is a written protocol in which the evaluation of the service's toxicity, safety or efficacy is noted among its objectives; or
  - e. the ability to perform the service is contingent upon:
    - f. approval or review by an Institutional Review Board (IRC) or other body that approves or reviews research; or obtaining informed consent documents from the patient that describes the service as experimental, investigational or part of a phase I or unapproved phase II research study.
    - g. These items will not be used to exclude benefits as investigational, if the proposed treatment is recognized as standard medical care for the condition, disease, illness, or injury being treated upon the advice of the Claims Processing Contractor.
9. Experimental/investigational procedures include, but are not limited to:
  - a. Insertion of gastric bubble (balloon).
  - b. Thermography.
  - c. Cardiointegrath.
  - d. Immuno-augmentative therapy.
  - e. Immune therapy for malignant disease.
  - f. Cryosurgical ablation of the prostate.
  - g. Keratoprosthesis.
  - h. Tilt table evaluation.
  - i. surgical procedures, organ and bone marrow transplants determined by Executive Administrator and Board of Trustees upon the advice of the Claims Processing Contractor to be experimental.

**Authority:**

G.S. 135-40.1(7.1)  
G.S. 135-40.6(1)  
G.S. 135-40.6(5)a  
G.S. 135-40.6(6)h  
G.S. 135-40.6(6)i  
G.S. 135-40.6(6)j  
G.S. 135-40.6(8)a  
G.S. 135-40.7(16)  
G.S. 135-40.7(19)  
G.S. 135-40.7(20)  
G.S. 135-40.7(21)

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