

Policy: MP015

Section: Medical Benefit Policy

Subject: Experimental, Investigational or Unproven service or treatment.

I. Policy: Experimental, Investigational or Unproven service or treatment.

II. Purpose/Objective:

To provide a policy of coverage regarding Experimental, Investigational or Unproven service or treatment.

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

Peer-reviewed, published medical literature: Documents from a minimum of two scientific publications that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Medline, EMBASE, MEDLARS or STAR, and/or medical journals recognized by the Secretary of Health and Human Services, that require submitted manuscripts be reviewed by acknowledged experts who are not part of the editorial staff before publication, and that publication is made on the basis of their recommendation.

Experimental Services- Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use, or not identified in the American Hospital Formulary Service as appropriate for the proposed use.

Experimental Procedure (Medicaid Business Segment)—A procedure that deviates from customary standards of medical practice, is not routinely used in the medical or surgical treatment of a specific illness or condition, or is not of proven medical value.

Investigational Services- The subject of an ongoing clinical trial that meets the definition of a Phase I, II, or III clinical trial set forth in the FDA regulation, regardless of whether the trial is subject to FDA oversight

Unproven Services - services which regardless of approval by the appropriate governmental regulatory body including but not limited to the U.S. Food and Drug Administration, CLIA, etc., are:

- not consistent with conclusions of published, peer-reviewed literature that demonstrates that the service has an equivalent or superior beneficial effect on health outcomes when compared to established treatments or technologies; **and**
- equivalent or superior safety profile when compared to established treatments or technologies; **or**
- not based on trials that meet either of the following designs:
 - Well-conducted randomized placebo-controlled trials. (Two or more treatments are compared to each other, and the patient is randomly assigned to one treatment or the other); **or**
 - Well-conducted cohort studies. (Patients who receive the study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.); **and**
 - The sample size of the study is of sufficient power to allow calculation of statistically significant results, and from which one can draw clinically significant conclusions.

CRITERIA:

Experimental or Investigational Services or Procedures

Experimental or Investigational Services or Procedures are any medical, surgical, psychiatric, substance abuse or other health care technologies, supplies, treatments, diagnostic procedures, drug therapies or devices that are determined by the Plan, in its sole discretion, to be:

- a) Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use, or not identified in the American Hospital Formulary Service as appropriate for the proposed use, and is referred to by the treating Provider as being investigational, experimental, research based or educational; **or**
- b) The subject of an ongoing clinical trial that meets the definition of a Phase I, II, or III clinical trial set forth in the FDA regulation, regardless of whether the trial is subject to FDA oversight; **or**
- c) The subject of a written research or investigational treatment protocol being used by the treating Provider or by another provider who is studying the same service.

Unproven Services or Procedures

If the requested service is not represented by criteria a, b, or c as listed above, the Plan reserves the right to require demonstrated evidence available in the published, peer-reviewed medical literature. This demonstrated evidence should support:

- The service has a measurable, reproducible positive effect on health outcomes as evidenced by well-designed investigations, and has been endorsed by national medical bodies, societies or panels with regard to the efficacy and rationale for use; and
- The proposed service is at least as effective in improving health outcomes as are established treatments or technologies or is applicable in clinical circumstances in which established treatments or technologies are unavailable or cannot be applied; and
- The improvement in health outcome is attainable outside of the clinical investigation setting; and
- The majority of Providers practicing in the appropriate medical specialty recognize the service or treatment to be safe and effective in treating the particular medical condition for which it is intended; and
- The beneficial effect on health outcomes outweighs any potential risk or harmful effects

Services not meeting the bulleted criteria will be determined at the Plan's sole discretion to be of unproven value.

PROCEDURE:

The appropriate Plan committee will review and discuss requests for technology, or treatment protocols. The Plan or the Technology Assessment Committee will make determinations regarding the experimental vs. non-experimental or Unproven status of the technology, biologic or protocol using information gathered by the requester or his/her designee, the Plan Medical Director, Plan pharmacist as applicable, Plan Director of Medical Policy and the Plan Medical Policy Research Coordinator. A contract is maintained by the Plan with independent technology assessment programs. Each review will include any and all information available from the currently contracted technology assessment vendor databases.

All new pharmaceuticals/pharmaceutical procedures will be taken through the Pharmacy and Therapeutics committee.

The Geisinger Clinic Technology Assessment Committee (TAC) is a committee that provides technological assessments to Geisinger Health Plan (Plan). The committee meets to evaluate new medical technologies and new applications of existing technologies. This may include medical technologies, behavioral health procedures, or other devices. This process, known as "Technology Assessment" or "Technology Evaluation", is conducted on an ongoing basis by the TAC.

The Plan designates the authority to make recommendations regarding the status of a new or evolving technology to the Technology Assessment Committee which is comprised of physicians representing multiple medical and/or surgical specialties. The determinations and recommendations of the Technology Assessment Committee are considered to be the specialty input for final determinations of coverage.

Provider appeals will follow the process outlined in MM Policy 21.

Member appeals will follow the process outlined in the appropriate line of business specific Member Resolution Dept. policy and/or benefit document.

Investigational, Experimental or Unproven treatments or services are not covered as defined in the applicable benefit document(s)

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

The guidelines regarding experimental, investigational or unproven treatments or services will apply to all Plan members unless otherwise specified by line of business contract.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 07/11/01

Revised: 7/03 (definition, process); 7/04; 7/05 (grammatical); 5/06 (definition); 10/10 (Table); 11/11 (Removed Table); 10/17 (department name change); 10/23 (separate Unproven services)

Reviewed: 7/02, 7/07, 7/08, 7/09, 11/12, 11/13, 11/14, 8/16, 10/18, 10/19, 10/20, 10/21, 10/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.