HEALTH TRADITION P.O. Box 21171 | Eagan, Minnesota 55121 | 877.832.1823 | healthtradition.com

# Medical Policy

## Experimental and Investigational Services

**Policy Number:** 1086

| Policy History | | | |
|---|---|---|---|
| Approve Date: | 06/01/2018 | Effective Date: | 06/01/2018 |
| Reviewed/Revised Dates: | 5/29/2019, 09/01/2019, 09/01/2021 | | |

| Preauthorization | |
|---|---|
| All Plans | Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details. |

**Policy**

## Indications of Coverage

I. Health Tradition's benefit plans provide for exclusions, limitations and exceptions to services, tests, treatments, supplies, devices, or drugs which are considered to be experimental or investigational. Coverage is not provided unless provisions in 2 through 7 below are met, if applicable.

II. A service, test, medical or surgical treatment, supply, device, or drug, is experimental or investigational for a member's condition if any of the following statements apply at the time the service is or will be provided to the member:
   A. The service cannot be lawfully marketed without approval of the US Food and Drug Administration (FDA) and approval for marketing has not been given at the time the service is provided OR
   B. Reliable evidence shows that the service is the subject of ongoing Phase I, II, or III clinical trials.
      i. Phase I – clinical trials determine the safe dosages of medication
      ii. Phase II – clinical trials define acute effects on normal tissue
      iii. Phase III – clinical trials determine clinical response OR
   C. Reliable evidence shows that the service is under study to determine its maximum tolerated dose, toxicity, safety, efficacy or efficacy as compared with the standard means of treatment or diagnosis.

III. Health Tradition requires prior authorization of experimental/investigational treatment/services and new technology in order to evaluate it per this Policy. The Medical Director or Associate Medical Director is authorized to make a determination for services, tests, treatments, supplies, devices, or drugs which are considered experimental, investigational, or are no longer consistent with the current standard of care.

IV. Notwithstanding the above, the Plan may determine that a service is not experimental or investigational if the Plan finds, on a case-by-case basis, that the service meets the following criteria:
   A. Reliable evidence preliminarily suggests a high probability of improved outcomes compared to standard treatment (e.g. significantly increased life expectancy or significantly improved function) OR
   B. Reliable evidence suggests conclusively that beneficial effects outweigh any harmful effects OR

C. If applicable, the FDA has indicated that the approval of the service for other proposed use is pending and likely to occur in the near future.

V. Reliable evidence includes only published reports and articles in authoritative medical and scientific literature that delineate the written protocol(s) used by the treating facility or by another facility studying substantially the same drug, device, health care service, or procedure and that describe among the objectives determinations of safety, efficacy, efficacy in comparison to conventional alternatives, or toxicity. If the source is the inventor or originator of the experimental/investigational item/service, additional sources are required.

VI. In determining whether a service is experimental or investigational, the sources of information that will be relied upon include, but are not limited to:
A. Member's medical records.
B. The written protocol(s) or other document(s) pursuant to which the service has been or will be provided.
C. Any consent document(s) that the member or the member's representative has executed or will be asked to execute to receive the service.
D. The published authoritative medical or scientific literature regarding the service as applied to the member's illness or injury, including but not limited to the Hayes Medical Technology Directory (Hayes, Inc.).
E. HAYES, Inc.
F. Regulations, records, applications and other documents or actions issued by, filed with or taken by the FDA or other agencies within the US Department of Health and Human Services, or any state agency performing similar functions.
G. Expert health care providers may be consulted, as needed, and use the criteria described above to decide if a particular service is experimental or investigational.
H. Other national insurers and their current Experimental/Investigational policies, including CMS for Medicare coverage.

VII. If multiple services are part of the same plan of treatment or diagnosis, all services are excluded when one of the services is experimental, unless the medically necessary and experimental services can be billed separately by the provider.

## Definitions

I. "Pre-service Claim" means any claim for a benefit that requires approval before obtaining medical care. This includes any benefits requiring a referral, prior authorization or pre-certification, including prior authorization for prescription drugs. A Pre-service Claim also includes any situation when a member receives less of a benefit than what the member requested in terms of time, services, or duration.

II. "Urgent Care Claim" means a pre-service claim that requires immediate determination. Urgent care refers to an actual medical condition, not going to an urgent care clinic. The criteria for an urgent care claim are:
A. Could seriously jeopardize life, health or ability to regain maximum function. This determination must be made by an individual acting on behalf of the plan (for example, utilization review staff or a medical director) or a physician with knowledge of the member's medical condition OR
B. Would subject the member to severe pain that cannot be adequately managed without such care or treatment, determined by a physician with knowledge of the member's medical condition

## References

1. URAC Health Plan for Health Insurance Marketplace (HIM) Accreditation, Version 7.2, P-HUM 25- Clinical Rationale for Non-Certification Requirements
2. WI St. 632.855

3. Department of Labor Regulations 2650.503-1 of the Employer Retirement Income
4. Security Act of 1974 – Claims Procedure