

NHP/NHIC-Experimental-Investigational Treatment Determinations

Abstract/Purpose:

Experimental or investigation services are those treatments, procedures, services, supplies, drugs, devices or technologies (“Treatments”) that are not known to be safe or effective or that are used in a way that deviates from generally accepted standards of the U.S. medical community.

Refer to a member's applicable coverage booklet to determine a member's eligibility and coverage limitations when making a specific coverage determination because Employer Group contracts may vary. CMS coverage determinations and rules apply to Medicare Advantage products.

I. **Policy:**

Services which are experimental, investigational or for research purposes are those treatments, procedures, services, supplies, drugs, devices or technologies (“Treatment(s)”) that are not known to be safe or effective or that are used in a way that deviates from generally accepted standards of the U.S. medical community.

Services which are non-experimental are those:

- that are discrete and identifiable technologies, regimes or modalities which are regularly and customarily used to diagnose or treat illness and
- for which there is conclusive, generally accepted evidence that such technology, regimen or modality is safe and effective.

NHP/NHIC’s Medical Director or designee will determine if a treatment is experimental, investigational or for research purposes.

In making an experimental/investigational determination the Medical Director or designee takes into consideration whether the Treatment is commonly performed or used on a widespread basis, whether conventional methods have been exhausted for the member, and whether the Treatment is reimbursed by CMS or other insurers. In the absence of conclusive, generally accepted evidence the Medical Director or designee may confer with the ordering and/or like-specialty practitioner to determine if the Treatment is a generally accepted standard of the U.S. medical community.

NHP/NHIC provides notice to members of experimental/investigational treatment determinations (approvals and denials) within 5 working days of receiving all of the required clinical information upon which the determination is based. Members are notified of all denial determinations in writing per policy 03508 Utilization Management Decisions, Timeframes, Notice Content and Process (*see related policy*).

II. **Experimental/Investigational Determination Criteria:**

- A. Treatments are determined to be experimental, investigational or for research purposes when at least one of the following is met:
 1. There is reliable evidence showing that the treatment:

- a. Is the subject of an ongoing Phase I or Phase II clinical trial;
 - b. Is the research, experiment, study or investigational arm of an ongoing Phase III clinical trial; or
 - c. Is otherwise under study to determine its maximum tolerated dose, its toxicity, its efficacy or safety or its efficacy compared with a standard means of treatment or diagnosis.
2. The treatment is related to or involves a research protocol. The purpose of such a protocol must be primarily to determine the safety or effectiveness of a Treatment. This includes, but is not limited to, a protocol of the U.S. Department of Health and Human Services (HHS) or any of its Agencies, Bureaus, Institutes or Divisions.
3. An Institutional Review Board (IRB) acting for the treating institution must review and approve the Treatment on an individual basis. An IRB is any person or group of persons charged with deciding whether the treating institution will or may be used to provide a particular Treatment. Your treating Practitioner is not an IRB.
4. A consent or release that HHS or the U.S. Food and Drug Administration (FDA) requires the member to sign describes the Treatment as Experimental, Investigational, or for Research Purposes. This applies to any consent or release that a person acting on behalf of the member must sign.
5. The Treatment is any drug or device that the FDA or other federal or governmental agency must approve but, at the time the drug or device is furnished, has not been approved for marketing.
6. Reliable evidence showing that the prevailing opinion among experts regarding the Treatment is that further studies or clinical trials are needed to show it is safe and reliable. A Treatment is not safe and reliable if more studies or clinical trials are needed to determine its maximum tolerated dose, its toxicity, its efficacy, its safety or its efficacy as compared with standard means, treatment or diagnosis.
 - a. Reliable evidence includes, but is not limited to, peer-reviewed medical literature and technology assessment organizations. NHP/NHIC accesses technology assessments from Hayes, Inc. and considers a Hayes "C" rating or lower as experimental/investigational.
7. The Treatment is any FDA approved drug or compounded prescription that is used in a manner that significantly deviates from the generally accepted standards of the U.S. medical community.
8. In the absence of reliable evidence (i.e., studies or clinical trials), the Treatment is not recognized as standard of care or as acceptable medical practice to treat the member's illness or injury or is used in a way that deviates from generally accepted standards of the U.S. medical community.

B. Although a Treatment is deemed experimental/investigational according to the above criteria, the Medical Director or designee within her/his sole discretion may make a determination to approve the Treatment.

1. Experimental Treatment may be approved by the Medical Director or designee when the experimental/investigational Treatment
 - a. is for a life threatening illness or condition or for an intractable condition and all of the following are met.
 - i. lower risk conventional treatment methods have been exhausted.
 - ii. no alternative methods are available or appropriate.
 - iii. there is reasonable, generally accepted evidence that such Treatment is safe and effective (e.g., in relief of symptoms and duration).

III. COVERAGE:

- . Treatments that are experimental, investigational or for research purposes are excluded by NHP/NHIC Certificate of Coverage and State of Wisconsin Employee's It's Your Choice. NHP/NHIC Medicare Advantage Evidence of Coverage also excludes experimental treatments except as covered by Original Medicare or under an approved clinical trial.
- A. Routine patient care provided to a patient during the course of treatment in a cancer clinical trial that are consistent with the usual and customary standard of care are covered by NHP/NHIC as required by and limited to State of Wisconsin Statute 632.87 (6).
 1. Routine patient care means all health care services, items and drugs that are typically provided in health care, including those provided to a member during the course of treatment in a cancer trial (all phases) for a condition or any of its complications and those services are consistent with the usual and customary standard of care including the type and frequency of any diagnostic modality.
 2. Routine patient care **does not** include:
 - a. the health care service, item or investigational drug that is the subject of the cancer clinical trial.
 - b. any health care service, item or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the member
 - c. investigational drugs or devices that have not been approved for market by the FDA
 - d. transportation, lodging, food or other expenses for member or family member or companion of the member that are associated with travel to or from a facility providing the cancer clinical trial

- e. any services, items or drugs provided by the cancer clinical trial sponsors free of charge
 - f. any services, items or drugs eligible for reimbursement by a party other than the insurer
3. Coverage of routine patient care during the course of treatment in a cancer clinical trial is limited to cancer clinical trials meeting **all** the following criteria:
- a. A purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes
 - b. The treatment provided as a part of the trial is given with the intention of improving the trial participant's health outcomes.
 - c. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathology.
 - d. The trial does one of the following:
 - i. Tests how to administer a health care service, item, or drug for the treatment of cancer
 - ii. Tests responses to a health care service, item, or drug for the treatment of cancer
 - iii. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer
 - iv. Studies new uses of health care services, items, or drugs for the treatment of cancer.
4. The trial is approved by one of the following:
- a. A National Institute of health, or one of its cooperative groups or centers, under the federal department of health and human services.
 - b. The FDA
 - c. The Federal Department of Defense
 - d. The Federal Department of Veteran Affairs

IV. **REFERENCES:**

- . NHP/NHIC Certificate of Coverage, Defined Terms: Experimental, Investigational or for Research Purposes
- A. NHP/NHIC Medicare Advantage Evidence of Coverage: Medical care and services that are not covered.
- B. State of Wisconsin Employee's It's Your Choice, 2008 Definitions: Experimental

- C. State of Wisconsin Statute 632.855 Requirements if experimental treatment limited. & 632.87 (6) Restrictions on health care service (routine patient care)

Regulatory Body: OCI

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