# Experimental-Investigational-Unproven Treatment Services

## *Values*

**Accountability ● Integrity ● Service Excellence ● Innovation ● Collaboration**

## Abstract Purpose:

This procedure provides guidance for interpreting the various benefit plans offered by Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC and Network Health Third Party Administrator (NHP/NHIC/NHAS/NH-TPA). The member's/participant's coverage document (e.g. Certificate of Coverage (COC), Evidence of Coverage (EOC), Summary Plan Description (SPD), and/or Individual and Family Plan Policy (IFP policy) supersedes this document. The member's/participant's eligibility must be confirmed and the service requested must be reviewed against the language within that individual's coverage document. Variations may exist within each member's/participant's coverage document.

## Procedure Detail:

I. Description:
   A. NHP/NHIC/NHAS has defined that services which are "experimental", investigational, and/or unproven" as treatments, procedures, services, supplies, drugs, devices or technologies (Treatment(s)) that are not known and/or recognized to be safe or effective or that are used in a way that deviates from generally accepted standards of the U.S. medical community for that specific condition, illness, disease or injury) are not covered benefits and therefore not payable by the plan.

II. Medical Indications:
   A. NHP/NHIC/NHAS provides notice to commercial, marketplace members and self-insured participants of experimental/investigational or unproven treatment determinations (approvals and denials) within 5 working days of receiving all the required clinical information upon which the determination is based. Medicare members will receive a written notice within 7 business days of standard request or 72 hours for an expedited request.
   B. Experimental/Investigational Determination Criteria:
      1. Experimental, Investigational, Unproven or for Research services are not covered. Treatments are determined to be experimental, investigational, unproven or for research purposes when at least one of the following is met:
         a. There is reliable evidence showing that the treatment:
            i. Is the subject of an ongoing Phase I or Phase II clinical trial;
            ii. Is the research, experiment, study or investigational arm of an ongoing Phase III clinical trial; or

iii. 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.

b. 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.

c. An Institutional Review Board (IRB) acting for the treating institution has reviewed and approved the Treatment on an individual basis.
   i. 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. The treating practitioner is not an IRB.

d. Health and Human Services or the U.S. Food and Drug Administration (FDA) required that the member sign a consent or release that 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.

e. 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.

f. 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.
   i. Reliable evidence includes, but is not limited to, peer-reviewed medical literature and technology assessment organizations.
   ii. NHP/NHIC/NHAS accesses technology assessments from Up to Date, Cochrane or other literature reviews in the absence of:
      a. An existing relevant MCG guideline licensed by NHP/NHIC/NHAS for application to the service being requested.
      b. An existing UM delegated entity evidence-based medical necessity policy for application to the service being requested.
      c. An existing relevant Medicare National or Local Coverage Determination (Medicare Advantage only).
      d. In the case of drugs, a FDA approved label indication or a Drugdex Strength of Recommendation Class II B or higher level of evidence and Strength of Evidence Category B or higher.

g. 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.

h. In the absence of reliable evidence (i.e., studies or clinical trials), the Treatment is not recognized as a standard of care in the medical community, 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.

i. Reliable evidence must be unbiased and peer reviewed (e.g. studies provided from a device manufacturer are insufficient to determine efficacy and are considered bias opinion).

III. Coverage:

A. Self-Insured Plans: Treatments that are experimental, investigational, unproven or for research purposes may be excluded under a participant's Summary Plan Description. State of Wisconsin Statutory requirements do not apply to Self-insured plans. Self-Insured plans are administered under Federal ERISA requirements. Coverage outlined within the participant's SPD supersedes this procedure guideline.

B. Fully insured and Individual and Family membership, including health insurance exchange plans: Treatments that are experimental, investigational or for research purposes are excluded by NHP/NHIC/NHAS Certificate of Coverage, Qualified Health Plan document, Individual and Family Policy and State of Wisconsin Employee's It's Your Choice coverage documents. Coverage outlined within the member's coverage document supersedes this procedure guideline.

C. Medicare Membership: NHIC Medicare Advantage Evidence of Coverage also excludes experimental treatments except as covered by Original Medicare or under an approved clinical trial. NHIC follows Medicare National Coverage Determinations (NCD) and Local (Wisconsin) Coverage Determinations (LCD) for its Medicare Advantage membership.

D. There is an existing relevant NHP/NHIC/NHAS Medical Policy or MCG guideline licensed by NHP/NHIC/NHAS for application of the service being requested.

E. There is an existing UM delegated entity evidence based medical necessity policy for application to the service being requested.

F. 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/NHAS for fully-insured members/participants as required by and limited to State of Wisconsin Statute 632.87 (6).

G. 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.

1. 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 of a family member or companion of the member that are associated with travel to or form 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.

H. 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:
1. Please reference the clinical trial desk procedure.

IV. Limitations/Exclusions
A. Treatments which are determined to be experimental, investigational, unproven or for research purposes are non-covered services.

VI. References
A. NHP/NHIC/NHAS Certificate of Coverage, Defined Terms: Experimental, Investigational or for Research Purposes
B. NHP/NHIC/NHAS Medicare Advantage Evidence of Coverage: Medical care and services that are not covered.
C. State of Wisconsin Employee's Certificate of Coverage, Definitions: Experimental
D. State of Wisconsin Statute 632.855 Requirements if experimental treatment limited. & 632.87 (6) Restrictions on health care service (routine patient care)

## Regulatory Body:

CMS
OCI

## Regulatory Reason:

- State of Wisconsin Statute 632.855 Requirements if experimental treatment limited. & 632.87 (6) Restrictions on health care service (routine patient care)
- Managed Care Manual Chapter 4 Benefits and Beneficiary Protections, Section 90.5 Creating New Guidance
- Medicare Prescription Drug Benefit Manual Chapter 6, Part D Drugs and Formulary Requirements, Section 10.6 - Medically-Accepted Indication

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