ADMINISTRATIVE POLICY STATEMENT
Wisconsin Marketplace

Policy Name & Number	Date Effective
Experimental or Investigational Item or Service-WI MP-AD-1498	12/01/2024
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statements are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased, or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Administrative Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) for the service(s) referenced in the Administrative Policy Statement. Except as otherwise required by law, if there is a conflict between the Administrative Policy Statement and the plan contract, then the plan contract will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject

Experimental or Investigational Item or Service

B. Background

Experimental and/or investigational items or services are **not** covered. This includes, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary. This policy defines the medical review decision process around such treatment requests CareSource members have the right to refuse or participate in experimental or investigational items or services. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

C. Definitions

- **CPT Category III codes** – a set of temporary (T) codes assigned to emerging technologies, services, and procedures. These codes are intended to be used for data collection to substantiate more widespread usage or to provide documentation for the Food and Drug Administration (FDA) approval process.
- **Experimental or Investigational Items or Services** – Medical, surgical, diagnostic, psychiatric, substance use disorders treatment or other health care services, technologies, equipment, supplies, treatments, procedures, therapies, biologics drugs, or devices (each a “Health Care Item” or “Service”) that, at the time CareSource has made a determination regarding coverage in a particular case, are:
  - Not approved by the United States Food and Drug Administration (FDA) to be lawfully marketed for the proposed use
  - Not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use, or
  - Determined by the FDA to be contraindicated for the specific use
  - Subject to review and approval by any institutional review board or other body serving a similar function for the proposed use, and such final approval has not been granted
  - The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2, or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight
  - Provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment service, or supply
  - Provided pursuant to informed consent documents that describe the drug biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply as experimental or investigational, or otherwise indicate that the safety toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment procedure, treatment, service, or supply is under evaluation.
  - The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight. This includes diagnostic testing for purposes of possible inclusion in a clinical trial

Devices that are FDA approved under the Humanitarian Use Device exemption are not considered to be experimental or investigational.

Drugs used in Phase 4 trials may be covered if they are part of the formulary.

D. Policy
   I. Any health care item or service CareSource determines in its sole discretion to be experimental or investigational is not covered.

   II. Any health care item or service not deemed experimental or investigational based on the criteria in Section C. may still be deemed experimental or investigational if it is not supported by credible research that soundly demonstrates that such item or service will have a measurable and beneficial health outcome. In determining whether such health care item or service is experimental or investigational, CareSource, in its sole discretion, will consider the information and evidence from one or more of the sources in Section III below and assess whether:
      A. The scientific evidence is conclusory concerning the effect of the health care item or service on health outcomes,
      B. The evidence demonstrates the health care item or service improves net health outcomes of the total population for whom the item or service might be proposed by producing beneficial effects that outweigh any harmful effects,
      C. The evidence demonstrates the health care item or service has been shown to be as beneficial for the total population for whom the service might be proposed as any established alternatives, and
      D. The evidence demonstrates the health care item or service has been shown to improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings.

   III. When reviewing requests, CareSource will consider information and evidence from the following non-exhaustive list:
      A. Published authoritative, peer-reviewed medical or scientific literature, or the absence thereof
      B. Evaluations of national medical associations, consensus panels, and other technology evaluation bodies
      C. Documents issued by and/or filed with the FDA or other federal, state or local agency with the authority to approve, regulate, or investigate the use of the drug biologic, device, diagnostic, product, equipment, procedure, treatment, service or supply
      D. Documents of an institutional review board or other similar body performing substantially the same function
      E. Consent document(s) and/or the written protocol(s) used by providers studying substantially the same drug, biologic, device, diagnostic, product, equipment procedure, treatment, service, or supply,
      F. Medical records, or

G. The opinions of consulting providers and other experts in the field.

E. Conditions of Coverage
NA

F. Related Policies/Rules
Clinical Trial Coverage
Medical Necessity Determinations policy

G. Review/Revision History

DATES		ACTION
Date Issued	08/14/2024	New Policy. Approved at Committee.
Date Revised		
Date Effective	01/01/2025	
Date Archived		

H. References

1. Biological Products, 21 C.F.R. §§ 600.2-.90 (2023).
2. Coverage and Authorization of Services, 42 C.F.R. § 438.210 (2022).
3. *EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*. Centers for Medicare & Medicaid Services; 2020. HHS-0938-2014-F-1347. Accessed June 10, 2024. www.hhs.gov
4. Investigational Device Exemptions, 21 C.F.R. §§ 812.1-.46 (2023).
5. Medical Services Coverage Decisions That Relate to Health Care Technology, 42 C.F.R. §§ 405.201-.215 (2022).
6. *Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies*. Centers for Medicare & Medicaid Services; 2015. MLN Matters MM8921. Accessed June 10, 2024. www.cms.gov
7. Phases of an Investigation, 21 C.F.R. § 312.21 (2023).
8. Premarket Approval of Medical Devices, 21 C.F.R. §§ 814.1-.19 (2023).
9. Utilization Control, 42 C.F.R. §§ 456.1-.725 (2022).