CareSource

ADMINISTRATIVE POLICY STATEMENT
Wisconsin Marketplace

Policy Name & Number	Date Effective
Experimental and Investigational Item or Service-WI MP-AD-1498	11/01/2026
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statements contain supplemental information regarding standard benefit administration and coverage details. Administrative Policy Statements do not guarantee an authorization or payment of services. The Member's plan contract (e.g., Evidence of Coverage, Member Handbook) contains specific terms and conditions, including limitations, exclusions, benefit maximums, eligibility, and other relevant conditions of coverage. Except as otherwise required by law, if there is a conflict between the Administrative Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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A. Subject

Experimental and 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 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 healthcare item or service CareSource determines to be experimental or investigational is not covered.

   II. According to Centers for Medicare & Medicaid Services: “Early and Periodic Screening, Diagnostic and Treatment services (EPSDT) does not require coverage of treatments, services, or items that are experimental or investigational.” However, requested treatments for members under the age of 21 will be reviewed individually to determine if the request is medically necessary.

   III. 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 will consider the information and evidence from one or more of the sources 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.

   IV. 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 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
G. research records
H. 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	01/14/2026 08/12/2026	Added EPSDT requirements in Sec. II. Updated references. Approved at Committee. Added IV. G. research records Updated references. Approved at Committee
Date Effective	11/01/2026	
Date Archived		

H. References

1. Biological Products, 21 C.F.R. §§ 600.2-.90 (2025).
2. Coverage and Authorization of Services, 42 C.F.R. § 438.210 (2025).
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 July 13, 2026. www.hhs.gov
4. Investigational Device Exemptions, 21 C.F.R. §§ 812.1-.46 (2026).
5. Medical Services Coverage Decisions That Relate to Health Care Technology, 42 C.F.R. §§ 405.201-.215 (2025).
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 July 13, 2026. www.cms.gov
7. Phases of an Investigation, 21 C.F.R. § 312.21 (2026).
8. Premarket Approval of Medical Devices, 21 C.F.R. §§ 814.1-.19 (2026).
9. Utilization Control, 42 C.F.R. §§ 456.1-.725 (2026).