# ADMINISTRATIVE POLICY STATEMENT
# Marketplace

| Policy Name & Number | Date Effective |
|---|---|
| Experimental, Investigational and Other Non-Covered Services-MP-AD-1354 | 11/01/2023 |
| **Policy Type** | |
| **ADMINISTRATIVE** | |

Administrative Policy Statement prepared by CareSource and its affiliates 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 documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) 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.

| This policy applies to the following Marketplace(s): | | | | |
|---|---|---|---|---|
| ☒ **Georgia** | ☒ **Indiana** | ☒ **Kentucky** | ☒ **Ohio** | ☒ **West Virginia** |

Table of Contents

A. Subject

**Experimental, Investigational and Other Non-Covered Services**

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, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

To determine whether a medical technology is a proven, medically necessary service, device, or procedure, CareSource conducts literature searches and evaluates the published scientific evidence related to each technology. The published evidence is reviewed against five (5) technology assessment criteria. In order for a technology to be considered medically necessary, all five (5) criteria must be met. If any one or more of the following criteria are not met, then the technology is considered investigational:

1. The technology must have final approval from the appropriate government regulatory bodies (i.e., Food and Drug Administration [FDA]). An approval granted as an interim step (i.e., Treatment IND) in the governmental body's regulatory process is not sufficient.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes and consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the studies and the consistency of the results are considered when evaluating the evidence.
3. The technology must improve the net health outcome (the technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
4. The technology must be as beneficial as any established alternatives of a similar cost effectiveness. This means the technology should improve the net health outcome as much as or more than established alternatives.
5. The improvement must be attainable outside the investigational settings. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy technology evaluation criteria #3 and #4.

The following **additional** criteria apply to new diagnostic technologies (e.g., imaging studies, laboratory procedures, home monitoring devices):

1. Technical feasibility is demonstrated, including reproducibility and precision. For comparison among studies, a common standardized protocol for the new diagnostic technology is established.
2. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to standards are established.
3. The clinical utility of a diagnostic technique, i.e., how the results of the study can be used to benefit patient management, is established. The clinical utility of both positive and negative tests must be established.

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.

  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 by CareSource.

II. Any health care item or service not deemed experimental or investigational based on the criteria in Section III 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.

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

IV. The codes listed in this policy come from the following sources, and are typically reviewed twice a year:
   - Center for Medicare and Medicaid Services (CMS)
   - The American Medical Association

V. **The following items, procedures and services are non-covered. This list is not intended to be an all-inclusive list. Other services not included in this list may also be non-covered. The absence or removal of a code from this medical policy does not imply coverage.**

| Codes | Description | Rational for non-coverage |
|---|---|---|
| 0745T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance | As of most recent review, no FDA approval |
| 0746T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan | As of most recent review, no FDA approval |
| 0747T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia | As of most recent review, no FDA approval |
| 0749T | analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and BMD, interpretation and report. | As of most recent review, no FDA approval |

| Codes | Description | Rational for non-coverage |
|---|---|---|
| 0750T | Bone strength and fracture-risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and BMD, interpretation and report; with single-view digital X-ray examination of the hand taken for the purpose of DXR-BMD | As of most recent review, no FDA approval |
| 0776T | Therapeutic induction of intra-brain hypothermia, including placement of a mechanical temperature-controlled cooling device to the neck over carotids and head, including monitoring (eg, vital signs and sport concussion assessment tool 5 [SCAT5]), 30 minutes of treatment | The pro2cool device is not currently cleared for use by the FDA. |
| 0778T | Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function. | As of most recent review, no FDA approval |
| 0779T | Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report | As of most recent review, no FDA approval |
| 0783T | Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment. | FDA approved but experimental and investigational |

## E. Conditions of Coverage

NA

## F. Related Policies/Rules

Clinical Trial Coverage
Medical Necessity Determinations policy

## G. Review/Revision History

| | DATES | ACTION |
|---|---|---|
| **Date Issued** | 07/19/2023 | New Policy |
| **Date Revised** | | |
| **Date Effective** | 11/01/2023 | |
| **Date Archived** | | |

## H. References

1. Biological Products, 21 C.F.R. § 600 (2021). Accessed June 13, 2023. www.ecfr.gov.
2. Centers for Medicare & Medicaid Services (CMS). EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. Experimental Treatments. HHS-0938-2014-F-1347. Accessed July 14, 2023. www.hhs.gov.
3. Coverage and Authorization of Services, 42 C.F.R. § 438.210 (2021). Accessed June 13, 2023. www.ecfr.gov.

The ADMINISTRATIVE Policy Statement detailed above has received due consideration as defined in the ADMINISTRATIVE Policy Statement Policy and is approved.

4. Department of Health and Human Services Centers for Medicare & Medicaid Services. (2015, January 1). Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies MLN Matters MM8921. Accessed June 13, 2023. www.cms.gov.
4. ECFR. (n.d.). E-CFR Title 21 Part 312.21 Phases of an investigation. Accessed June 13, 2023. www.ecfr.gov.
5. ECFR. (2019, June 21). E-CFR Title 21 Part 812 Investigational Device Exemptions. Accessed June 13, 2023. www.ecfr.gov.
6. ECFR. (2019, June 21). E-CFR Title 21 Part 814 Premarket Approval of Medical Devices. Accessed June 13, 2023. www.ecfr.gov.
7. 42 Part 405 Subpart B Medical Services Coverage Decisions That Relate to Health Care Technology Authority. Accessed June 13, 2023. www.ecfr.gov.
8. ECFR. (2019, April 16). 42 CFR § 438.210 Coverage and authorization of services. Accessed June 13, 2023. www.ecfr.gov.
9. Ohio Administrative Code (OAC). Rule 5160-1-61 Non-covered services. June 13, 2023. www. codes.ohio.gov.
10. Premarket Approval of Medical Devices, 21 C.F.R. § 814 (2021). Accessed June 13, 2023. www.ecfr.gov.
11. Utilization Control, 42 C.F.R. §§ 456.1-725 (2021). June 13, 2023. www.ecfr.gov.