ADMINISTRATIVE POLICY STATEMENT
Georgia Medicaid

Policy Name & Number	Date Effective
Experimental or Investigational Item or Service-GA MCD-AD-0711	06/01/2024
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 alt

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

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

H. mhe opi t

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