CareSource

Administrative Policy Statement
GEORGIA MEDICAID

Policy Name	Policy Number	Effective Date
Experimental or Investigational Technologies	AD-0711	2/1/2020-06/30/2021

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) 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 CSMG Co. and its affiliates (including CareSource) 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.

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A. Subject

Experimental or Investigational Technologies

B. Background

Experimental or investigational devices and services are not covered. This policy defines the medical review decision process around such treatment requests.
CareSource members have the right to refuse or consent to experimental or investigational treatment and research.

C. Definitions

- **Category A (Experimental) device** per Centers for Medicare and Medicaid Services "a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective".
- **Category B (Non-experimental/investigational) device** per Centers for Medicare and Medicaid Services "a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type".
- **Experimental/investigational/unproven item**: Any procedure, treatment, service, supply, or product that meets one or more of the following:
  - Is subject to Institutional Review Board review or approval
  - Effectiveness on health outcomes is unproven based on clinical evidence in peer-reviewed medical literature
  - Cannot be legally marketed in the United States without final approval from appropriate government regulatory or licensing body

D. Policy

I. CareSource does not cover experimental, investigational, or unproven items or devices.

II. If a prior authorization is completed, an experimental or investigational item or device will be reviewed by a medical director for medical appropriateness and necessity.
   A. If the requested item is considered experimental or investigational as defined above, treatment will be denied.
   B. In situations where the treatment option is not clearly defined as experimental or investigational, the following information will be considered (this list is NOT all inclusive):
      1. Conclusory scientific evidence concerning the effect of the service on the member's health outcomes
      2. Evidence that demonstrates item improves member health outcomes by producing beneficial effects that outweigh any harmful effects
      3. Evidence that demonstrates item improves member health outcomes under the usual conditions of medical practice outside clinical investigatory settings.

E. Conditions of Coverage

F. Related Policies/Rules

Archived

G. Review/Revision History

DATES		ACTION
Date Issued	**2/1/2020**	
Date Revised		
Date Effective	**02/01/2020**	New Policy
Date Archived	**06/30/2021**	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Georgia Department of Community Health Division of Medicaid (2019*). Policies and Procedures for Physician Services*. Retrieved on 1/24/2019 from https://www.mmis.georgia.gov/portal/portals/0/staticcontent/public/all/handbooks/physician%20services%20jan%202019%2020190122163618.pdf
2. Medicare and Medicaid Services Medicare Learning Network (2015). MLN Matters. Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies. Retrieved on 4/5/2019 from https://www.cms.gov/Medicare/Coverage/IDE/Downloads/MM8921.pdf

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

GA-P-0780 **Date Issued 2/1/2020** **DCH Approved 10/7/2019**

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