MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
08/19/2004	07/01/2017	06/16/2016

Policy Name	Policy Number
Experimental or Investigational Technologies	AD-0006

Policy Type		
☒ Medical	☒ Administrative	☐ Payment

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medicaid health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medicaid 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 benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document

A. SUBJECT

Experimental or Investigational Technologies

B. BACKGROUND

This policy defines the medical review decision process around such treatment requests. Investigational, devices and services are not covered.

CareSource members have the right to refuse or participate in experimental or investigational treatment and research. CareSource members are notified of this right by language detailed in the member handbook or evidence of coverage.

C. DEFINITIONS

N/A

D. POLICY

Consistent with Medicaid policy, CSMG does not cover experimental/ investigational devices and services. Devices are considered to be experimental if the FDA has not issued a specific indication for the device. Medical and surgical treatments and procedures are considered experimental if they are in clinical trials phase of development and are not yet considered to be standard of care by nationally recognized technology assessment organizations, specialty societies and medical review organizations.

I. Requests for medical/surgical treatment will be reviewed by a medical director for medical appropriateness and necessity. If the requested treatment is considered experimental as defined above, treatment will be denied. In situations where the treatment option is not

clearly defined as experimental, medical necessity determination will be based on the **ALL** of the following additional considerations and criteria:

A. The member has a relevant diagnosis for which the therapy may be indicated
B. Conventional treatments and therapies have been utilized and failed with no other alternative conventional therapies available
C. The risks and benefits are considered reasonable by the treating physicians
D. Technology and the clinical trials meet all standard, commonly accepted review board criteria
E. All other policies required for such treatment as defined by state and federal regulatory bodies including CMS, pertinent state department of insurance and department of Medicaid policy are met.

CONDITIONS OF COVERAGE
HCPCS
CPT

AUTHORIZATION PERIOD

E. REVIEW/REVISION HISTORY

Date Issued:	08/19/2004
Date Reviewed:	08/19/2004, 07/01/2007, 07/01/2009, 07/01/2011, 07/01/2012, 07/01/2013, 07/01/2014, 10/06/2015, 06/16/2016
Date Revised:	07/01/2007, 07/01/2009 10/06/2015 – Remove verbiage relating to drugs.

F. REFERENCES

N/A

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