MEDICAL POLICY STATEMENT

Effective Date	Next Annual Review Date	Last Review / Revision Date
8/19/2004	7/2015	7/2014

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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which 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.

A. SUBJECT

Experimental or Investigational Technologies

B. BACKGROUND

This policy defines the medical review decision process around such treatment requests. Investigational and experimental drugs, 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.

C. POLICY

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

Consistent with Medicare and Medicaid policy, CSMG does not cover experimental/ investigational drugs, devices and services. Drugs and devices are considered to be experimental if the FDA has not issued a specific indication or NDC number for the specific drug or 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.

Requests for experimental drug therapy or other 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 following additional considerations and criteria:

1. The member has a relevant diagnosis for which the drug treatment and/or other therapy may be indicated **AND**
2. Conventional treatments and therapies have been utilized and failed with no other alternative conventional therapies available **AND**
3. The risks and benefits are considered reasonable by the treating physicians **AND**
4. The drugs or technology and the clinical trials meet all standard, commonly accepted review board criteria **AND**
5. 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.

If there is no LCD or NCD present reference the CSMG Policy for coverage.

D. REVIEW / REVISION HISTORY

Date Issued: 8/19/2004
Date Revised: 7/2007, 7/2009
Date Reviewed: 7/1/2009, 7/1/2011, 7/2012, 7/2013, 7/2014

E. REFERENCES

1. Member Handbook, Member's Rights and Responsibilities Policy and Provider Manual

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