MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/2011	1/2016	1/2015
Policy Name		**Policy Number**
Seizure Disorder		**SRx-0001**

Medical 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.

Medical 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 Medical Policy Statement. If there is a conflict between the Medical 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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Seizure Disorders

- **Repository Corticotropin Injection (H.P. Acthar Gel)**
- **Vigabatrin (Sabril) Oral Solution and Tablets**

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Seizure Disorder Program is to encourage appropriate selection of therapy for patients with Infantile spasms (West Syndrome) or refractory complex partial seizures based on product labeling, clinical literature and established guidelines as well as to encourage use of preferred agents.

C. DEFINITIONS

D. POLICY

CareSource will approve the use of H.P. Acthar Gel or Vigabatrin (Sabril) and consider its use as medically necessary when the following criteria have been met for:

Infantile Spasms

H.P. Acthar Gel is indicated for the treatment of infantile spasms, a life threatening seizure disorder of early childhood also known as West Syndrome.

Prior Authorization Criteria:

- Documented diagnosis of infantile spasms (infantile myoclonic seizures)
- Infants and children under 2 years of age
- Prescribed by a pediatric neurologist or an epilepsy physician specialist.

CareSource considers H.P. Acthar Gel not medically necessary for corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these indications, therefore failure of corticosteroids will not be considered as criteria for use of H.P. Acthar Gel for corticosteroid-responsive conditions.

Vigabatrin (Sabril) is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.

Prior Authorization Criteria:

- Documented diagnosis of Infantile Spasms
- Age 1 month to 2 years of age
- Prescribed by a pediatric neurologist or under recommendation of pediatric neurologist.

NOTE: Vigabatrin (Sabril) should be withdrawn from a pediatric patient treated for infantile spasms who fails to show substantial clinical benefit within 2-4 weeks of treatment initiation, or sooner if treatment failure becomes obvious.

Refractory Complex Partial Seizures (CPS)
Vigabatrin (Sabril) is indicated as adjunctive therapy for adult patients with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Sabril is not indicated as a first-line agent for complex partial seizures.

Prior Authorization Criteria:

- Documented diagnosis of refractory complex partial seizures
- Prescribed by a neurologist or under recommendation of neurologist
- Patient ≥10 years of age
- Patient has failed alternative treatments for control of the complex partial seizures.

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):
If there is no NCD or LCD present, reference the CareSource Policy for coverage.

Conditions of Coverage

HCPCS J0800 Acthar
J3490 Sabril

CPT

Place of Service

Office, Outpatient

*****Preferred place of service is in the office or outpatient setting*.**

Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

Authorization Period

Approved initial authorizations are valid for 6 months. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

06/15/2011, 01/18/2013, 01/18/2014 added additional specialist, revised authorization period-Acthar
12/4/2013-Sabril
1/8/2015 combined Sabril an Acthar into seizure disorder policy & added age criteria to Sabril CPS

F. REFERENCES

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