MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	01/18/2017	01/18/2016

Policy Name	Policy Number
Seizure Disorders (Repository Corticotropin Injection (H.P. Acthar Gel) and Vigabatrin (Sabril) Oral Solution and Tablets)	SRx-0001

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

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 members 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

N/A

D. POLICY

I. 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:
   A. Infantile Spasms

1. **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 and X-linked Infantile Spasms Syndrome (ISSX).
   1.1 **Prior Authorization Criteria:**
      a. Documented diagnosis of infantile spasms (infantile myoclonic seizures)
      b. Infants and children under 2 years of age
      c. Prescribed by a pediatric neurologist or an epilepsy physician specialist

Note: 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.

2. **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.
   2.1 Prior Authorization Criteria:
      a. Documented diagnosis of Infantile Spasms
      b. Age 1 month to 2 years of age
      c. 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.

B. Refractory Complex Partial Seizures (CPS)
   1. **Vigabatrin (Sabril)** is indicated as adjunctive therapy for patient's ≥ 10 years of age with refractory complex partial seizures (CPS) who have inadequately responded to two 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.
      1.1 Prior Authorization Criteria:
         a. Documented diagnosis of refractory complex partial seizures
         b. Prescribed by a neurologist or under recommendation of neurologist
         c. Patient ≥10 years of age
         d. Documentation of failure of two 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.

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 a clinical response to treatment. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 01/18/2013, 12/04/2013, 01/18/2014, 01/08/2015, 01/14/2016
Date Revised:	01/18/2013 12/04/2013 – added Sabril 01/18/2014 - added additional specialist, revised authorization period-Acthar 01/08/2015 combined Sabril and Acthar into seizure disorder policy & added age criteria to Sabril CPS 01/14/2016 - Criteria change in policy from adults to ≥ 10 years of age. Documentation of 2 failures of treatment.

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.