



## PHARMACY POLICY STATEMENT

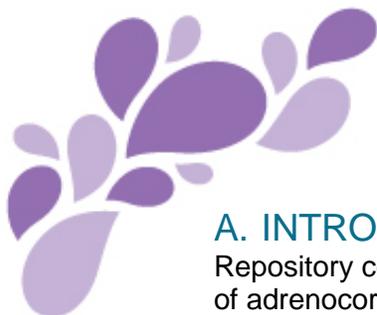
<b>Original Effective Date</b>		<b>Next Annual Review</b>		<b>Last Revision</b>	
06/15/2011		01/18/2018		11/29/2016	
<b>Policy Name</b>				<b>Policy Number</b>	
Seizure Disorders (H.P. Acthar Gel (repository corticotropin injection) and Sabril (vigabatrin) oral solution and tablets)				SRx-0001	
<b>Policy Type</b>					
Medical		Administrative		<b>PHARMACY</b>	Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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. INTRODUCTION

Repository corticotropin (H.P. Acthar gel) is a purified, sterile preparation of the natural form of adrenocorticotrophic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH is produced and secreted by the pituitary gland. H.P. Acthar gel uses ACTH obtained from porcine pituitary glands. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and aldosterone.

Repository corticotropin is effective in the management of children with a rare seizure disorder known as infantile spasms. When infantile spasms are accompanied by neurodevelopmental regression and electroencephalogram findings of hypsarrhythmia, the condition is known as West syndrome. Although it has been approved for a variety of inflammatory conditions, corticotropin was approved by the FDA prior to the Kefauver-Harris Drug Amendments of 1962. There is insufficient evidence to establish efficacy for inflammatory conditions because they were exempt from this legislation. Therefore, the use of repository corticotropin for indications other than infantile spasms may not be medically necessary due to availability of more efficacious agents.

In 2012, the American Academy of Neurology and the Practice Committee of the Child Neurology Society publish an updated evidence-based guideline on treatment of infantile spasms. The guideline recommends: ACTH or vigabatrin (Sabril) may be useful for the short-term management of infantile spasm, ACTH should be preferred over vigabatrin, and hormonal therapy (ACTH or prednisolone) may be considered for treatment of infantile spasms.

Complex partial seizures (CPS) are a subset of epilepsy. They are the largest seizure type, originating from a single region of the brain, causing impaired consciousness. Sabril is an add-on treatment option for CPS in patients who have not responded to treatment alternatives. While there is potential benefit of Sabril, there is also risk of permanent vision loss. Very few patients with CPS will initiate and maintain treatment with Sabril as adjunctive therapy.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

*NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.*

## B. DEFINITIONS

1. None applicable.



## C. POLICY COVERAGE CRITERIA

### 1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient	<p><b>Preferred place of service is in the practitioner’s office or outpatient setting.</b></p> <p>CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient’s medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member’s current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.</p>

### 2. Coverage Criteria

CareSource will approve the use of H.P. Acthar Gel (repository corticotropin) or Sabril (vigabatrin) and consider use medically necessary when the criteria have been met for each condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Condition	H.P. Acthar Gel Coverage criteria:
<b>Infantile spasms (West syndrome, X-linked infantile spasms syndrome)</b>	<ol style="list-style-type: none"> <li>1) Documented diagnosis of infantile spasms</li> <li>2) Infants and children under 2 years of age</li> <li>3) Prescribed by a pediatric neurologist or an epilepsy physician specialist</li> </ol>

**H.P. Acthar Gel may not be medically necessary for corticosteroid-responsive conditions (e.g., systemic lupus erythematosus, multiple sclerosis, Stevens-Johnson’s syndrome, ophthalmic diseases, rheumatic disorders, serum sickness, and symptomatic sarcoidosis) as it has not been proven to be any more effective than corticosteroids for these indications.**

**All other uses of H.P. Acthar Gel (e.g., acute gout, childhood epilepsy, and use in tobacco cessation) are considered experimental/investigational; and therefore, will follow CareSource’s off-label policy.**



Condition	Sabril Coverage criteria:
<b>Infantile spasms (West syndrome, X-linked infantile spasms syndrome)</b>	<ol style="list-style-type: none"> <li>1) Documented diagnosis of infantile spasms</li> <li>2) Age 1 month to 2 years of age</li> <li>3) Prescribed by a pediatric neurologist or under recommendation of pediatric neurologist</li> <li>4) Sabril must be used as a single agent</li> <li>5) Documentation of vision testing at baseline and every 3 months, up to 6 months following discontinuation of therapy.</li> </ol> <p><i>Note: Only use Sabril if potential benefits outweigh the potential risk of vision loss.</i></p>
<b>Refractory complex partial seizures</b>	<ol style="list-style-type: none"> <li>1) Documented diagnosis of refractory complex partial seizures</li> <li>2) Prescribed by a neurologist or under recommendation of neurologist</li> <li>3) Member is 10 years of age or older</li> <li>4) Documentation of failure of two alternative treatments for control of the complex partial seizures</li> <li>5) Sabril must be used as adjunctive therapy</li> <li>6) Documentation of vision testing at baseline and every 3 months, up to 6 months following discontinuation of therapy.</li> </ol>

**All other uses of Sabril are considered experimental/investigational; and therefore, will follow CareSource’s off-label policy.**

*Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.*

**Notes:**

- Documented diagnosis must be confirmed by portions of the individual’s medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider’s office, or hospital admission notes.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

**3. Dosage and Quantity Limits (listed if applicable)**

*Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.*

Condition	Dosage and Quantity Limit of H.P. Acthar Gel
<b>Infantile spasms</b>	Two-5mL vials per 26 days



Condition	Dosage and Quantity Limit of Sabril Oral Solution and Tablets
Infantile spasms	Maximum dose of 150 mg/kg/day (2,250 mg if 15kg)
Refractory complex partial seizures	Maximum dose of 1.5 g twice daily

#### 4. Authorization Period

Condition	Approval Period
Infantile spasms	<p>The initial authorization for H.P. Acthar gel or Sabril for infantile spasms is valid for 1 month.</p> <p>Continued treatment may be considered when member has shown substantial clinical benefit from therapy. Member must meet all initial criteria for continued coverage. A reauthorization after successful initiation period will be placed for 1 month.</p> <p><b>ALL</b> authorizations are subject to continued eligibility.</p>
Refractory complex partial seizures	<p>The initial authorization for Sabril is valid for 6 months.</p> <p>Continued treatment may be considered when member has shown substantial clinical benefit from therapy which outweighs risks of treatment. Member must meet all initial criteria for continued coverage. A reauthorization after successful initiation period will be placed for 1 year.</p> <p><b>ALL</b> authorizations are subject to continued eligibility.</p>

#### 5. Coding

HCPCS	
J0800	Acthar
J3490	Sabril
CPT	
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

### D. RELATED POLICIES

**AD-0004:** Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs



## E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
06/15/2011	Issued/Reviewed
01/18/2013	Reviewed
12/04/2013	Added Sabril
01/18/2014	Added additional specialist, revised authorization period
01/08/2015	Combined Sabril and Acthar into seizure disorder policy and added age criteria to Sabril CPS
01/14/2016	Criteria change in policy from adults $\geq 10$ years of age. Documentation of 2 failures of treatment.
11/21/2016	Updated policy format, separated by line of business, added codes, background information and rationale for use, quantity limits, tuberous sclerosis complex criteria, vision testing criteria, revised authorization period, and updated references

## F. REFERENCES

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**The Pharmacy Policy detailed above has received due consideration and is approved.**