Pharmacy Policy Bulletin

Title: Antiepileptic Agents
Policy #: Rx.01.185

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**
The intent of this policy is to communicate the medical necessity criteria for brivaracetam (Briviact) as provided under the member's pharmacy benefit.

**Description:**
Epilepsy is the fourth most common neurological disease, affecting approximately 2.2 million people in the United States. An epileptic seizure is defined as a transient occurrence of signs and/or symptoms due to abnormal excessive or synchronous neuronal activity in the brain. Epilepsy is defined by the occurrence of at least 2 unprovoked seizures occurring greater than 24 hours apart. The primary treatment objectives are to achieve lifelong seizure freedom, reduce morbidity and mortality, and improve quality of life, ideally without intolerable adverse events.

The precise mechanism by which brivaracetam exerts its anticonvulsant activity is not known. Brivaracetam, a chemical analog of levetiracetam, displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect.

Brivaracetam (Briviact) is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

**Policy:**
Brivaracetam (Briviact) is approved when BOTH of the following are met:

A. An indication approved by the FDA or acceptable in compendia
B. ONE of the following:
   1. Inadequate response or inability to tolerate levetiracetam
2. Continuation of therapy with brivaracetam

- **Black Box Warning:**
  N/A

- **Guidelines:**
  Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


**Applicable Drugs:**

- Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Briviact</td>
<td>brivaracetam</td>
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**Cross References:**

<table>
<thead>
<tr>
<th>Policy Version Number:</th>
<th>1.00</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>October 13, 2016</td>
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<tr>
<td>Policy Effective Date:</td>
<td>December 01, 2016</td>
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Next Required Review Date: October 13, 2017

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