



Louisiana

Select Anti-Epileptic Drugs

Policy # 00541

Original Effective Date: 01/01/2017

Current Effective Date: 12/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select anti-epileptic drugs [e.g., Briviact^{®†} (brivaracetam), Spritam^{®‡} (levetiracetam)] to be **eligible for coverage** when the patient selection criterion is met.

Patient Selection Criterion

Coverage eligibility for select anti-epileptic drugs [e.g., Briviact (brivaracetam), Spritam (levetiracetam)] will be considered when the following patient selection criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO alternative anti-epileptic agents for the condition being treated (ONE of which MUST be generic levetiracetam) unless there is clinical evidence or patient history that suggests the use of at least TWO alternative anti-epileptic agents (ONE of which MUST be generic levetiracetam) will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select anti-epileptic drugs [e.g., Briviact (brivaracetam), Spritam (levetiracetam)] when the patient selection criterion is not met to be **not medically necessary****

Background/Overview

Briviact is indicated for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Briviact has a similar structure and mechanism of action as levetiracetam, which is available in generic form as tablets, an oral solution, as well as an injection (similar to the available dosage forms of Briviact). Levetiracetam is indicated in a broader patient population than Briviact. Briviact is a controlled substance while levetiracetam is not a controlled substance. Given the lack of any clinically significant breakthrough in the treatment of the indicated condition, it joins the ranks of multiple other drugs that are indicated for the treatment of partial onset seizures, including, but not limited to topiramate, lamotrigine, gabapentin, zonisamide, pregabalin, oxcarbazepine, levetiracetam, levetiracetam extended release, divalproex, Aptiom^{®‡} (eslicarbazepine), Potiga^{®‡} (ezogabine), Vimpat^{®‡} (lacosamide), Oxtellar XR^{™‡} (oxcarbazepine extended release), and Fycompa^{®‡} (perampanel).

Spritam is indicated for adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy 4 years of age and older, myoclonic seizures in patients 12 years of age and older with juvenile myoclonic

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epilepsy, and primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy. Spritam contains the active ingredient levetiracetam, which is available in generic form as a tablet, an oral solution, and as an injectable. Spritam is a tablet that disintegrates when taken with a sip of liquid. The clinical efficacy of Spritam was based on studies that were previously done with levetiracetam tablets. Given the various dosage forms of levetiracetam available, coupled with multiple alternative options for treatment, Spritam offers minimal additional clinical value in current treatment regimens as compared to other existing products on the market. Various options exist for partial onset seizures (mentioned in the above paragraph). Other treatment options for juvenile myoclonic epilepsy include, but are not limited to drugs such as valproate, levetiracetam, lamotrigine, topiramate, etc. Other treatment options for primary generalized tonic clonic seizures include, but are not limited to valproate, phenytoin, carbamazepine, lamotrigine, topiramate, levetiracetam, etc.

The products mentioned in this policy do not offer any new clinical significance in the treatment of their respective disease(s) and equally efficacious, less expensive alternative products are currently available on the market.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Briviact was approved in February 2016 for use in adjunctive therapy in the treatment of partial onset seizures. The label was expanded in September 2017 to allow for use as monotherapy for the treatment of partial onset seizures.

Spritam was approved in July of 2015 for the treatment of partial onset seizures, myoclonic seizures, and primary generalized tonic-clonic seizures.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests TWO alternative anti-epileptic agents for the condition being treated (ONE of which MUST be generic levetiracetam) will be ineffective or will cause an adverse reaction to the patient. The products mentioned in this policy do not offer any new clinical significance in the treatment of their respective disease(s) and equally efficacious, less expensive alternative products are available on the market.

References

1. Briviact [package insert]. UCB. Smyrna, Georgia. March 2016.
2. Spritam [package insert]. Aprelia Pharmaceuticals. East Windsor, New Jersey. February 2016.
3. UpToDate. Treatment of Juvenile Myoclonic Seizures. Accessed 11/29/2016.
4. UpToDate. Overview of Management of Epilepsy in Adults. Accessed November 2016.
5. Briviact Drug Evaluation. Express Scripts. Updated March 2016.

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12/01/2016 Medical Policy Committee review

12/21/2016 Medical Policy Implementation Committee approval. New policy.

12/07/2017 Medical Policy Committee review

12/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2018

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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