Clinical Policy: Levetiracetam (Spritam)

Reference Number: CP.CPA.156
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Levetiracetam (Spritam®) is an antiepileptic drug.

FDA Approved Indication(s)

Spritam is indicated as adjunctive therapy in the treatment of:

- Partial onset seizures in adults and children 1 month of age and older
- Myoclonic seizures as adjunctive therapy in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy
- Primary generalized tonic-clonic seizures as adjunctive therapy in adults and children 6 years of age and older with idiopathic generalized epilepsy

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Spritam is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Seizures (must meet all)**:**

1. Diagnosis of partial onset seizures, myoclonic seizures, or primary generalized tonic-clonic seizures;
2. Medical justification supports inability to use generic levetiracetam tablets or solution (e.g., contraindications to the excipients);
3. Dose does not exceed 3,000 mg per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. Seizures (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Spritam for a covered indication and has received this medication for at least 30 days;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 3,000 mg per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
levetiracetam, immediate-release tablet, solution (Keppra®)	Partial onset seizures: *Adults and adolescents ≥ 16 years*: 500 to 1,500 mg PO BID *Pediatric patients 1 month to < 16 years*: dosing based on age and weight Myoclonic seizures: *Adults, adolescents, and children ≥ 12 years*: 500 to 1,500 mg PO BID Primary generalized tonic-clonic seizures: *Adults and adolescents ≥16 years*: 500 to 1,500 mg PO BID *Children and adolescents 6 to 15 years*: Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg twice daily).	3,000 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindications: known hypersensitivity to levetiracetam
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial onset seizures	Adults and pediatric patients 4 years and older weighing over 40 kg: 500 mg PO BID; increase as needed and tolerated by 500 mg PO BID every 2 weeks to a maximum recommended dose of 1,500 mg BID Pediatric patients 4 years and older weighing 20 to 40 kg: 250 mg PO BID; increase by 250 mg PO BID every two weeks to a maximum of 750 mg BID	3,000 mg/day (and 1,500 mg/day for pediatric patients 4 years and older weighing 20 to 40 kg)
Myoclonic seizures	Adults and pediatric patients 12 years of age and older: 500 mg PO BID; increase by 500 mg PO BID every 2 weeks to recommended dose of 1500 mg BID	3,000 mg/day
Primary generalized tonic-clonic seizures	Adults and pediatric patients 6 years of age and older weighing over 40 kg: 500 mg PO BID; increase as needed/tolerated by 500 mg BID every 2 weeks to a maximum recommended dose of 1500 mg BID Pediatric patients 6 years and older weighing 20 to 40 kg: 250 mg PO BID; increase by 250 mg BID every 2 weeks to a maximum of 750 mg BID	3,000 mg/day (and 1,500 mg/day for pediatric patients 6 years and older weighing 20 to 40 kg)

VI. Product Availability

Tablets for oral suspension: 250 mg, 500 mg, 750 mg, and 1,000 mg

VII. References

1. Spritam Prescribing Information. Blue Ash, OH: Aprecia Pharmaceuticals LLC; September 2018. Available at: https://www.spritam.com/pdfs/spritam-full-prescribing-information.pdf. Accessed August 1, 2019.
2. Keppra [Tablets, Oral Solution] Prescribing Information. Smyrna, GA: UCB, Inc.; October 2017. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021035s100,021505s040lbl.pdf. Accessed August 1, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.12.17	11.17
4Q 2018 annual review: no significant changes; updated continued therapy language to include continuity of care for seizures; references reviewed and updated.	07.10.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.01.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.