RXADVANCE
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Clinical Policy Title:	levetiracetam
Policy Number:	RxA.495
Drug(s) Applied:	Spritam®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Levetiracetam (Spritam®) is an antiepileptic drug. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
levetiracetam (Spritam®)	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

Drug Name	Indication	Dosing Regimen	Maximum Dose
levetiracetam (Spritam®)	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)

Dosage Forms

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

Clinical Policy

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

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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

- Contraindication(s):
  - Known hypersensitivity to levetiracetam

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Increased risk for increased diastolic blood pressure has been reported in pediatric patients 1 month to less than 4 years of age; monitoring recommended for this age group.
- Withdraw gradually due to risk of increased seizure frequency and status epilepticus; serious adverse reactions may prompt consideration for rapid discontinuation.
- Avoid use in older adults with a history of falls or fractures (unless used for seizure or mood disorders) as it may cause syncope, impaired psychomotor function or ataxia. Reduce dose in patients with CrCl 80 mL/min or less due to increased CNS adverse events.

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 September 9, 2020.

2. Keppra® [Tablets, Oral Solution] Prescribing Information. Smyrna, GA: UCB, Inc.; October 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021035s102,021505s042lbl.pdf .Accessed September 9, 2020.
3. Micromedex Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed September 16, 2020

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Clinical Policy title was updated. 2. Line of business policy applies to was updated to' All lines of business' 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Appendix D added general information 5. Reference was reviewed and updated.	09/16/2020	12/07/2020