MEDICAL MUTUAL®

Drug Policy

Policy:	**Antiseizure Step Therapy**	**Annual Review Date:** **09/22/2022**
Impacted Drugs:	**Briviact, Keppra, Keppra XR, Spritam**	**Last Revised Date:** **10/19/2023**

OVERVIEW

Levetiracetam is an antiseizure medication (ASM); the immediate-release tablets and oral solution (Keppra, generic) are indicated for the treatment of:[1]

- **Partial-onset seizures** in patients ≥ 1 month of age.
- **Myoclonic seizures**, as adjunctive therapy in patients ≥ 12 years of age with juvenile myoclonic epilepsy.
- **Primary generalized tonic-clonic seizures**, as adjunctive therapy in patients ≥ 6 years of age with idiopathic generalized epilepsy.

Levetiracetam extended-release tablets (Keppra XR, generic; Elepsia XR) are indicated for the treatment of **partial-onset seizures** in patients ≥ 12 years of age.[2,7]

Spritam is indicated as adjunctive therapy in the treatment of:[3]

- **Partial-onset seizures** in patients ≥ 4 years of age and weighing > 20 kg with epilepsy.
- **Myoclonic seizures**, as adjunctive therapy in patients ≥ 12 years of age with juvenile myoclonic epilepsy.
- **Primary generalized tonic-clonic seizures**, as adjunctive therapy in patients ≥ 6 years of age with idiopathic generalized epilepsy.

Roweepra (levetiracetam tablets) and Roweepra XR (levetiracetam extended-release tablets) are branded generics to Keppra tablets and Keppra XR, respectively, with the same indications.[4,5]

Briviact is an ASM that is indicated for the treatment of **partial-onset seizures** in patients ≥ 1 month of age.[6] Briviact has a similar mechanism of action as that of levetiracetam.[1,6] Both ASMs display a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to their anticonvulsant effect by modulating neurotransmitter release into the synapse. Unlike levetiracetam, Briviact is a controlled substance (C-V).

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POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one preferred medication within the 130-day look-back period is excluded from step therapy.

Preferred Medications:

- Generic carbamazepine (tablets, chewable tablets, ER tablets, ER capsules, oral suspension)
- generic divalproex (DR capsules, DR tablets, ER tablets)
- generic ethosuxamide (capsules, oral solution)
- generic felbamate (tablets, oral solution)
- generic gabapentin (capsules, tablets, oral solution)
- generic lamotrigine (tablets, chewable tablets, ER tablets, ODT tablets)
- generic levetiracetam (tablets, ER tablets, oral solution)
- generic oxcarbazepine (tablets, oral suspension)
- generic phenytoin (ER capsules, chewable tablets, oral suspension)
- generic pregabalin (capsules, oral solution)
- generic rufinamide oral suspension
- generic tiagabine tablets
- generic topiramate (capsules, ER capsules, tablets)
- generic valproic acid (capsules, DR capsules, oral solution)
- generic vigabatrin (tablets, powder for oral solution)
- generic zonisamide capsules
- Roweepra
- Roweepra XR

Non-Preferred Medications

- Briviact
- Keppra
- Keppra XR
- Spritam
- Elepsia XR

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

2. If the patient is currently taking or has taken Briviact at any time in the past and discontinued its use, approve Briviact.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Keppra® tablets and oral solution [prescribing information]. Smyrna, GA: UCB, Inc.; September 2020.
2. Keppra XR® extended-release tablets [prescribing information]. Smyrna, GA: UCB, Inc.; September 2020.
3. Spritam® tablets for oral suspension [prescribing information]. Mason, OH: Prasco, LLC; January 2021.
4. Roweepra™ tablets [prescribing information]. West Chicago, IL: OWP Pharmaceuticals, Inc.; February 2022.
5. Roweepra XR™ extended-release tablets [prescribing information]. West Chicago, IL: OWP Pharmaceuticals, Inc.; October 2020.
6. Briviact® tablets, oral solution, and injection [prescribing information]. Smyrna, GA: UCB, Inc.; May 2023.
7. Elepsia™ XR extended-release tablets [prescribing information]. Westfield, NJ: Tripoint; December 2020.