STEP THERAPY POLICY

POLICY: Antiepileptics – Levetiracetam, Brivaracetam Step Therapy Policy

- Briviact® (brivaracetam tablets and oral solution UCB)
- Elepsia[™] XR (levetiracetam extended-release tablets Tripoint)
- Keppra[®] (levetiracetam tablets and oral solution UCB, generic)
- Keppra XR[®] (levetiracetam extended-release tablets UCB, generic)
- Roweepra® (levetiracetam tablets OWP [branded generic])
- Roweepra XR[™] (levetiracetam extended-release tablets OWP [branded generic])
- Spritam[®] (levetiracetam tablets for oral suspension Prasco)

REVIEW DATE: 06/08/2022

OVERVIEW

Levetiracetam is an antiepileptic drug (AED); 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 AED 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. Both AEDs 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. Briviact has approximately a 30-fold higher affinity for SV2A than that of levetiracetam. Unlike levetiracetam, Briviact is a controlled substance (C-V).

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

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<u>Automation</u>: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: 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

Note: ER – Extended-release; DR – Delayed –release; ODT – Orally-disintegrating tablet.

Step 2: Briviact, Elepsia XR, Keppra, Keppra XR, Spritam

CRITERIA

- 1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
- 2. If the patient is currently taking or has taken Briviact at any time in the past and discontinued its use, approve Briviact.
- **3.** No other exceptions are recommended.

REFERENCES

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