STEP THERAPY POLICY

POLICY: Antiseizure Medications – 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: 06/11/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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).

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.

Step 1: generic carbamazepine (tablets, chewable tablets, ER tablets, ER capsules, oral suspension), generic divalproex (DR capsules, DR tablets, ER tablets), generic ethosuximide (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

Antiseizure Medications – Levetiracetam, Brivaracetam Step Therapy Policy **product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

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.

REFERENCES

1. Keppra® tablets and oral solution [prescribing information]. Smyrna, GA: UCB; March 2024.
2. Keppra XR® extended-release tablets [prescribing information]. Smyrna, GA: UCB; March 2024.
3. Spritam® tablets for oral suspension [prescribing information]. Mason, OH: Prasco; June 2024.
4. Roweepra® tablets [prescribing information]. Lisle, IL: OWP; March 2025.
5. Roweepra XR™ extended-release tablets [prescribing information]. Lisle, IL: OWP; October 2020.
6. Briviact® tablets, oral solution, and injection [prescribing information]. Smyrna, GA: UCB; May 2023.
7. Elepsia™ XR extended-release tablets [prescribing information]. Westfield, NJ: Tripoint; March 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Policy Name Change:** Changed from Antiepileptics – Levetiracetam, Brivaracetam Step Therapy to Antiseizure Medications – Levetiracetam, Brivaracetam Step Therapy Policy. No criteria changes.	06/14/2023
Annual Revision	No criteria changes.	06/26/2024
Annual Revision	No criteria changes.	06/11/2025