STEP THERAPY POLICY

POLICY: Antiseizure Medications – Lamotrigine Step Therapy Policy

- bLamictal® (lamotrigine tablets and chewable dispersible tablets – GblaxoSmithKline, generic [including Subvenite® tablets])
- Lamictal ODT® (lamotrigine orally disintegrating tablets – GlaxoSmithKline, generic)
- Lamictal® XR™ (lamotrigine extended-release tablets – GlaxoSmithKline, generic)
- Subvenite® oral suspension (lamotrigine oral suspension – DPT Laboratories)

REVIEW DATE: 10/15/2025; selected revision 01/14/2026

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

The immediate-release formulations of lamotrigine (tablets [including Subvenite tablets], chewable dispersible tablets, orally disintegrating tablets [Lamictal, Lamictal ODT, generic], and oral suspension [Subvenite oral suspension]), an antiseizure medication (ASM) of the phenyltriazine class, are indicated for the following:[1,3]

- Adjunctive therapy in patients ≥ 2 years of age with **partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome**.
- Monotherapy in patients ≥ 16 years of age with **partial seizures** who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single ASM.
- **Maintenance treatment of bipolar I disorder** to delay the time to occurrence of mood episodes (depression, mania, hypomania, mixed episodes) in patients treated for acute mood episodes with standard therapy.

Lamotrigine extended-release tablets (Lamictal XR, generic) are indicated for the following:[2]

- Adjunctive therapy for **primary generalized tonic-clonic seizures and partial onset seizures** with or without secondary generalization in patients ≥ 13 years of age.
- **Conversion to monotherapy** in patients ≥ 13 years of age with **partial seizures** who are receiving treatment with a single ASM.

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 lamotrigine tablets, generic lamotrigine chewable dispersible tablets, generic lamotrigine extended-release tablets, and generic lamotrigine orally disintegrating tablets, Subvenite tablets

Step 2: Lamictal tablets, Lamictal chewable dispersible tablets, Lamictal ODT, Lamictal XR, Subvenite oral suspension

Antiseizure Medications – Lamotrigine 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 a patient has tried one Step 1 product, approve a Step 2 Product.

2. If the patient is unable to obtain the prescribed dose with whole lamotrigine tablets for oral suspension (dispersible tablets), approve Subvenite oral suspension.

3. If the patient cannot swallow solid oral dosage forms or has difficulty swallowing solid oral dosage forms AND the patient is unable to ingest the prescribed dosage with lamotrigine tablets for oral suspension (dispersible tablets), approve Subvenite oral suspension.
Note: Lamotrigine tablets for oral suspension (dispersible tablets) may be swallowed whole, chewed, or dispersed in water or diluted fruit juice.

REFERENCES

1. Lamictal® tablets, chewable dispersible tablets, and Lamictal ODT® [prescribing information]. Durham, NC: GlaxoSmithKline; April 2025.
2. Lamictal® XR™ extended-release tablets [prescribing information]. Durham, NC: GlaxoSmithKline; April 2025.
3. Subvenite® oral suspension [prescribing information].

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Policy Name Change:** Changed from Antiepileptics – Lamictal XR Step Therapy to Antiseizure Medications – Lamotrigine Step Therapy Policy. No criteria changes.	11/15/2023
Annual Revision	No criteria changes.	11/13/2024
Annual Revision	No criteria changes.	10/15/2025
Selected Revision	**Subvenite tablets:** Added to policy as a Step 1 Product. **Subvenite oral suspension:** Added to policy as a Step 2 Product. Clinical exceptions were added to approve Subvenite oral suspension if the prescribed dose cannot be achieved with lamotrigine tablets for oral suspension (dispersible tablets), or if the patient cannot ingest solid oral dosage forms or dispersible tablets.	01/14/2026