STEP THERAPY POLICY

POLICY: Antiseizure Medications – Lamotrigine Step Therapy Policy
- Lamictal® (lamotrigine tablets and chewable dispersible tablets – GlaxoSmithKline, generic)
- Lamictal ODT® (lamotrigine orally disintegrating tablets – GlaxoSmithKline, generic)
- Lamictal® XR™ (lamotrigine extended-release tablets – GlaxoSmithKline, generic)

REVIEW DATE: 11/15/2023

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. 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, chewable dispersible tablets, and orally disintegrating tablets [Lamictal, Lamictal ODT, generic]), an antiseizure medication (ASM) of the phenyltriazine class, are indicated for the following:[1]

- 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.

Antiseizure Medications – Lamotrigine 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.

Step 1: generic lamotrigine tablets, generic lamotrigine chewable dispersible tablets, generic lamotrigine extended-release tablets, and generic lamotrigine orally disintegrating tablets

Step 2: Lamictal tablets, Lamictal chewable dispersible tablets, Lamictal XR, Lamictal ODT

CRITERIA

1. If a patient has tried one Step 1 product, approve a Step 2 Product.

REFERENCES

1. Lamictal® tablets, chewable dispersible tablets, and Lamictal ODT® [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.
2. Lamictal® XR™ extended-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/07/2022
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