STEP THERAPY POLICY

POLICY: Antiseizure Medications – Depakote/Depakene Step Therapy Policy
- Depakote® (divalproex sodium delayed-release tablets – AbbVie, generic)
- Depakote® Sprinkle Capsules (divalproex sodium delayed-release capsules – AbbVie, generic)
- Depakote® ER (divalproex sodium extended-release tablets – AbbVie, generic)
- Depakene® (valproic acid capsules and oral solution – AbbVie, generic [branded product discontinued])

REVIEW DATE: 08/09/2023

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

All of these products are indicated for the following uses:[1-4]
- As monotherapy and adjunctive therapy in the treatment of patients with **complex partial seizures** and **simple and complex absence seizures**.
- Adjunctively in patients with multiple seizure types that include **absence seizures**.
- In addition, divalproex sodium tablets (Depakote, generic) and divalproex sodium extended-release tablets (Depakote ER, generic) are also indicated for **prophylaxis of migraine headaches** and treatment of **bipolar disorder**.[1,3]

Divalproex sodium and valproic acid are antiseizure medications.[1-4] Divalproex sodium is comprised of sodium valproate and valproic acid.[1] Divalproex sodium and valproic acid each dissociate to the valproate ion in the gastrointestinal (GI) tract.[1-4] Equivalent oral doses of divalproex sodium products (Depakote, generic) and valproic

acid products (Depakene, generic) deliver equivalent quantities of valproate ion systemically. Although the rate of valproate ion absorption may vary with the formulation administered (liquid, solid, or sprinkle), conditions of use (e.g., fasting or postprandial) and the method of administration (e.g., whether the contents of the capsule are sprinkled on food or the capsule is taken intact), these differences should be of minor clinical importance under the steady state conditions achieved in chronic use in the treatment of epilepsy. Experience administering dosing regimens from once daily to four times daily indicate that total daily systemic bioavailability (extent of absorption) is the primary determinant of seizure control and differences in the ratios of plasma peak to trough concentrations between valproate formulations are inconsequential from a practical clinical standpoint.

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 – Depakote/Depakene 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 divalproex sodium capsules, generic divalproex sodium delayed-release tablets, generic divalproex sodium extended-release tablets, generic valproic acid capsules, generic valproic acid oral solution

Step 2: Depakene capsules and oral solution, Depakote, Depakote ER/EC/DR, Depakote Sprinkle

CRITERIA

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

REFERENCES

1. Depakote® delayed-release tablets [prescribing information]. North Chicago, IL: AbbVie; February 2023.
2. Depakote® Sprinkle Capsules delayed-release capsules [prescribing information]. North Chicago, IL: AbbVie; February 2023.
3. Depakote® ER extended-release tablets [prescribing information]. North Chicago, IL: AbbVie; February 2023.
4. Depakene® capsules and oral solution [prescribing information]. North Chicago, IL: AbbVie; May 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/03/2022
Annual Revision	**Policy Name Change:** Changed from Antiepileptics – Depakote/Depakene to Antiseizure Medications – Depakote/Depakene Step Therapy Policy. No criteria changes.	08/09/2023