STEP THERAPY POLICY

POLICY: Antiepileptics – 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)

REVIEW DATE: 08/03/2022

OVERVIEW

All of these products are indicated:[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 antiepileptic drugs (AEDs).[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.

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

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.

2. No other exceptions are recommended.

REFERENCES

1. Depakote® delayed-release tablets [prescribing information]. North Chicago, IL: AbbVie; June 2021.
2. Depakote® Sprinkle Capsules delayed-release capsules [prescribing information]. North Chicago, IL: AbbVie; June 2021.
3. Depakote® ER extended-release tablets [prescribing information]. North Chicago, IL: AbbVie; June 2021.
4. Depakene® capsules and oral solution [prescribing information]. North Chicago, IL: AbbVie; February 2021.