Depakote/Depakene Step Therapy Program

Policy Number: 5.01.590  Last Review: 7/2019
Origination: 7/2018  Next Review: 7/2020
LoB: ACA

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for brand name Depakote/Depakene when it is determined to be medically necessary because the following criteria are met. Drugs affected include:

- Depakote® (divalproex sodium delayed-release tablets – Abbott, generics)
- Depakote® Sprinkle Capsules (divalproex sodium delayed-release capsules – Abbott, generics)
- Depakote® ER (divalproex sodium extended-release tablets – Abbott, generics)
- Depakene® (valproic acid capsules and oral solution – Abbott, generics)

When Policy Topic is covered
A step therapy program has been developed to encourage the use of one generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent 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: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1: generic divalproex sodium delayed-release tablets, generic divalproex sodium extended-release tablets, generic divalproex sodium capsules, generic valproic acid capsules and oral solution
Step 2: Depakote, Depakote Sprinkle, Depakote ER/EC/DR, Depakene capsules and oral solution

Recommended Criteria
1. If a patient has tried a Step 1 product, then authorization for a Step 2 product may be given.

When Policy Topic is not covered
No other exceptions are recommended. Brand name Depakote/Depakene is considered not medically necessary without trial of generic first.

Considerations
Brand name Depakote/Depakene require prior authorization through the pharmacy services department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.
Description of Procedure or Service

Divalproex sodium and valproic acid are antiepileptic drugs (AEDs).

Divalproex sodium is comprised of sodium valproate and valproic acid. Equivalent oral doses of divalproex sodium products (Depakote, generics) and valproic acid products (Depakene, generics) 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 sprinkle 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.

All of these products are indicated as monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures and simple and complex absence seizures; and adjunctively in patients with multiple seizure types that include absence seizures. In addition, divalproex sodium tablets (Depakote, generics), divalproex sodium extended-release tablets (Depakote ER, generics), and valproic acid delayed-release capsules (Stavzor) are also indicated for prophylaxis of migraine headaches and treatment of bipolar disorder.

References


**Billing Coding/Physician Documentation Information**

| NA | Pharmacy benefit |

**Additional Policy Key Words**

Policy Number: 5.01.590

**Policy Implementation/Update Information**

| 07/2018 | New policy titled - Depakote/Depakene Step Therapy Program |
| 07/2019 | Annual review – no changes made |

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