Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 2019

Prior Authorization: Diacomit

Products Affected: Diacomit (stiripentol) oral capsules, Diacomit (stiripentol) powder for oral suspension

Medication Description:
Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There is no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome. The mechanism by which DIACOMIT exerts its anticonvulsant effect in humans is unknown. Possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid (GABA)A receptor and indirect effects involving inhibition of cytochrome P450 activity with resulting increase in blood levels of clobazam and its active metabolite.

Dravet syndrome, previously known as Severe Myoclonic Epilepsy of Infancy (SMEI), is a rare, catastrophic, lifelong form of epilepsy that begins in the first year of life with frequent and/or prolonged seizures. Approximately 80% of those diagnosed with Dravet syndrome have a SCN1A mutation, but the presence of a mutation alone is not sufficient for diagnosis, nor does the absence of a mutation exclude the diagnosis. A mutation causes sodium channel dysfunction in the brain. It's important to avoid antiepileptic drugs that block sodium channels as these can worsen seizures in Dravet syndrome. This includes phenytoin (Dilantin), carbamazepine (Tegretol), oxcarbazapine (Trileptal), lamotrigine (Lamictal), and rufinamide (Banzel).

Diacomit is dosed at 50mg/kg/day in 2 or 3 divided doses. The maximum recommended total daily dose is 3,000mg/day. Diacomit powder for suspension contains phenylalanine. Phenylalanine can be harmful to patient with phenylketonuria (PKU). Consider total daily intake of phenylalanine from all sources, including Diacomit. Diacomit oral capsules do not contain phenylalanine.

Covered Uses: Treatment of seizures associated with Dravet syndrome in patients taking clobazam

Exclusion Criteria: N/A

Required Medical Information:
1. Diagnosis
2. Current therapy regimen

Age Restrictions: 2 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist, specializing in seizure therapy.

Coverage Duration: 12 months

Other Criteria:
A. Patient has a diagnosis of seizures associated with Dravet syndrome; **AND**
B. Patient will be receiving Diacomit in combination with clobazam.

References:
1. Diacomit [prescribing information]. Beauvais, France: Biocodex; August 2018.

Confidential Information

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2. Shafer PO, Kiriakopoulos E. Dravet Syndrome. Epilepsy Foundation. https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome. Sep 2018. Accessed March 12, 2019.
3. Dravet Syndrome Foundation. What is Dravet syndrome? https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed March 12, 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	04/23/2019
2	Annual Review	N/A	N/A	3/30/2020

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