Stiripentol (Diacomit®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO063

Description

Stiripentol (Diacomit) is an orally administered anticonvulsant with direct effects mediated through the GABAa receptor.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

stiripentol (Diacomit)	Indication	Quantity Limit	DDID
250 mg capsules	Dravet syndrome	180 capsules/30 days	179386
500 mg capsules		180 capsules/30 days	179387
250 mg powder for oral suspension		180 packets/30 days	179389
500 mg powder for oral suspension		180 packets/30 days	179390

Initial Evaluation

I. Stiripentol (Diacomit) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by or in consultation with a neurologist; **AND**
   B. A diagnosis of **Dravet Syndrome** when the following are met:
      i. History of use of clobazam (Onfi); **AND**
      ii. History of use of valproate (Depakote) unless documentation of contraindication or intolerance; **AND**
      iii. Use in combination with clobazam (Onfi); **AND**
      iv. Use in combination with valproate (Depakote) unless documentation of contraindication or intolerance;

II. Stiripentol (Diacomit) is considered <u>investigational</u> when used for all other conditions, including but <u>not limited to</u>:
   A. Epileptic encephalopathies associated with SCN1A mutations

B. Other non-FDA approve seizure disorder
C. Primary Hyperoxaluria
D. Stiripentol (Diacomit) as monotherapy
E. Use in combination with cannabidiol (Epidiolex)

Renewal Evaluation

I. Documentation of treatment benefit with use of stiripentol (Diacomit) indicated by reduction in generalized tonic-clonic or clonic seizures; **AND**
II. Ongoing use of clobazam (Onfi) and valproate (Depakote) unless documentation of contraindication or intolerance

Supporting Evidence

I. Stiripentol (Diacomit) was studied in two Phase III, multicenter, randomized, placebo-controlled trials with on-going use of clobazam and valproate and demonstrated lack of disease management on clobazam and valproate without stiripentol (Diacomit).
II. The use of stiripentol (Diacomit) has not been studied as monotherapy or in combination with anticonvulsant regimens that do not contain clobazam and valproate.

Investigational or Not Medically Necessary Uses

I. Epileptic encephalopathies associated with SCN1A mutations
    A. Ongoing clinical trials in this setting
II. Other non-FDA approve seizure disorder
    A. Ongoing clinical trials in this setting
III. Primary Hyperoxaluria
    A. Ongoing clinical trials in this setting
IV. Stiripentol (Diacomit) as monotherapy
    A. Stiripentol (Diacomit) has not been studied as monotherapy in Dravet syndrome. Package label also notes lack of clinical data to support the use as monotherapy
V. Use in combination with cannabidiol (Epidiolex)
    A. Stiripentol (Diacomit) has not been studied as combination use with cannabidiol.

References

1. Diacomit [Prescribing Information]. Redwood City, CA: Biocodex, Gentilly, France. August 2018.
2. Stiripentol (Diacomit): For Severe Myoclonic Epilepsy in Infancy (Dravet Syndrome) [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2015 Apr. 3, RESULTS. Available from: https://www.ncbi.nlm.nih.gov/books/NBK349320/

3. Chiron C, Marchand MC, Tran A, Rey E, d'Athis P, Vincent J, et al. Stiripentol in severe myoclonic epilepsy in infancy: a randomised placebo-controlled syndrome-dedicated trial. STICLO study group. Lancet. 2000 Nov 11;356(9242):1638–1642.

Policy Implementation/Update:

Date Created	February 2019
Date Effective	May 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date