BlueCross BlueShield Federal Employee Program

DIACOMIT
(stiripentol)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. The mechanism by which Diacomit exerts its anticonvulsant effects 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 (1).

Regulatory Status

FDA-approved indication: Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. There is no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome (1).

Diacomit can cause somnolence. Co-administration of Diacomit with clobazam results in increased levels of clobazam and its active metabolite, which can further increase somnolence. Other CNS depressants, such as alcohol, could potentiate the somnolence effect of Diacomit (1).

Diacomit can cause a significant decline in platelet count and neutrophil count. Hematologic testing should be obtained prior to starting treatment with Diacomit, and then every 6 months (1).

As with most antiepileptic drugs, Diacomit should generally be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus. In situations where rapid withdrawal of Diacomit is required, appropriate monitoring is recommended (1).

Most patients with DS require two or more drugs to achieve seizure control, and choice of drugs should be individualized based on considerations of efficacy as well as side effects, tolerability, and access. Typically, a stepwise approach is taken, using valproate as a first-line drug in most patients and then adding clobazam if seizures remain poorly controlled despite adequate valproate dosing and serum levels (2).

The safety and effectiveness of Diacomit in pediatric patients less than 6 months of age or

weighing less than 7 kg have not been established (1).

Summary

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam 6 months of age and older and weighing 7 kg or more. The mechanism by which Diacomit exerts its anticonvulsant effects 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. The safety and effectiveness of Diacomit in pediatric patients less than 6 months of age or weighing less than 7 kg have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Diacomit while maintaining optimal therapeutic outcomes.

References

1. Diacomit [package insert]. Beauvais, France: Biocodex; July 2022.
2. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations from a North American Consensus Panel. Pediatr Neurol 2017; 68:18.