Diacomit

Description

Diacomit (stiripentol)

Background
Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. 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 2 years of age and older taking clobazam. 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As with most antiepileptic drugs, Diacomit should generally be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus.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 2 years of age have not been established (1).

Related policies
Epidiolex

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Diacomit may be considered medically necessary in patients 2 years of age and older with seizures associated with Dravet syndrome and if the conditions indicated below are met.

Diacomit is considered investigative in patients less than 2 years of age and for all other indications.

Prior-Approval Requirements

Age 2 years of age and older

Diagnosis

The patient must have the following:

Seizures associated with Dravet syndrome (DS)

AND ALL of the following:
1. Must be used in combination with clobazam
   a. Patient has had an inadequate response to clobazam
2. Prescriber agrees to monitor blood counts before initiating therapy and then every 6 months while on therapy
3. Inadequate treatment response, intolerance, or contraindication to at least ONE of the following medications:
   a. Valproate / Valproic acid (i.e. Depakote, Depacon)
   b. Lamotrigine
   c. Levetiracetam
   d. Banzal (rufinamide)
   e. Topiramate
   f. Felbamate
4. Prescriber will not exceed the FDA labeled dose of 50 mg/kg/day

**Prior – Approval Renewal Requirements**

**Age**
2 years of age and older

**Diagnosis**

The patient must have the following:

Seizures associated with Dravet syndrome (DS)

AND ALL of the following:
1. Must be used in combination with clobazam
2. Prescriber agrees to monitor blood counts every 6 months while on therapy
3. Prescriber will not exceed the FDA labeled dose of 50 mg/kg/day

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Quantity**
Maximum daily dose of 50 mg/kg/day

**Duration**
12 months

**Prior – Approval Renewal Limits**
Same as above
Rationale

Summary
Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. 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)\textsubscript{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 2 years of age 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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2018</td>
<td>Addition to PA</td>
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<tr>
<td>November 2018</td>
<td>Annual review</td>
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<tr>
<td>March 2019</td>
<td>Annual review. Removed brand name of clobazam from criteria and reworded max dose of 50 mg/kg/day requirement per SME</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.