Oxervate

Description

Oxervate (cenegermin-bkbj)

Background
Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity and low-affinity nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity (1).

Regulatory Status
FDA-approved indication: Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (1).

Patients should remove contact lenses before applying Oxervate and they may be reinserted 15 minutes after administration (1).

The safety and effectiveness of Oxervate in pediatric patients less than 2 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Oxervate may be considered medically necessary in patients 2 years of age and older with neurotrophic keratitis and if the conditions indicated below are met.

Oxervate is considered investigational 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:

- Neurotrophic keratitis

**AND** the following:

1. Patient or caregiver will be counseled on proper administration technique

**Prior – Approval Renewal Requirements**

None

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity**

8 kits (1 kit = 7 multiple-dose vials) per affected eye per lifetime

**Prior – Approval Renewal Limits**

None

**Rationale**

**Summary**

Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts...
through specific high-affinity and low-affinity nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity. The safety and effectiveness of Oxervate 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 Oxervate while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

Keywords

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