Ocrevus

Description

Ocrevus (ocrelizumab)

Background
Ocrevus is a multiple sclerosis (MS) disease-modifying agent. Ocrevus can potentially alter the course of disease by lessening the frequency of relapses and disease progression. Ocrevus is a recombinant humanized monoclonal antibody that targets CD20 proteins on premature and mature B cells. Ocrevus binds to CD20 on B cells which results in antibody-dependent cellular cytolyis and complement-mediated lysis. Ocrevus depletes circulating B cells after each treatment (1).

Regulatory Status
FDA-approved indication: Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of: (1)

- Relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active-secondary progressive disease, in adults
- Primary progressive MS, in adults

Ocrevus is contraindicated in patients with active hepatitis B virus (HBV) infection. Complete HBV screening prior to the initiation of Ocrevus. There are no reports of HBV reactivation in MS patients treated with Ocrevus. However, HBV reactivation has occurred in other anti-CD20 antibodies which resulted in fulminant hepatitis, hepatic failure, and death (1).
The administration of Ocrevus should be delayed in patients with active infections until the infection has resolved. Ocrevus increases the risk for upper/lower respiratory tract, skin, and herpes-related infections (1).

Administer all immunizations 6 weeks prior to drug initiation or after the repletion of B cells following drug discontinuation. Live, attenuated vaccines are generally not recommended (1).

Safety and effectiveness of Ocrevus in pediatric patients have not been established (1).

**Related policies**
Acthar Gel, Ampyra, Aubagio, Gilenya, Lemtrada, Mavenclad, Mayzent, MS Injectables, Tecfidera, Tysabri

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

Ocrevus may be considered *medically necessary* for patients 18 years of age or older for the treatment of relapsing or primary progressive forms of multiple sclerosis and if the conditions indicated below are met.

Ocrevus may be considered *investigational* in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age and older

**Diagnoses**

Patient must have **ONE** of the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
   a. Ineffective response due to continued clinical relapse, intolerance or contraindication two or more MS drugs
2. Primary Progressive Multiple Sclerosis (PPMS)

**AND ALL** of the following:
1. Patient is not at risk for HBV infection OR patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
2. Absence of active infection
3. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids
4. **NOT** given concurrently with live vaccines or live attenuated vaccines

**Prior – Approval Renewal Requirements**

**Age** 18 years of age and older

**Diagnoses**

Patient must have **ONE** of the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
2. Primary Progressive Multiple Sclerosis (PPMS)

**AND ALL** of the following:

1. Absence of active infection
2. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids
3. **NOT** given concurrently with live vaccines or live attenuated vaccines

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Duration** 2 years

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

Summary
Ocrevus is indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. Ocrevus is a monoclonal antibody that targets CD20, a protein prominent on premature and mature B cells, and decreases the amount of circulating B cells through antibody-dependent cellular cytolysis and compliment-mediated lysis. Safety and effectiveness of Ocrevus in pediatric patients have not been established (1).

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

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>April 2017</td>
<td>Addition to PA</td>
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<tr>
<td>June 2017</td>
<td>Annual Review</td>
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<tr>
<td></td>
<td>Removed “not used in combination with another MS disease modifying agent” and changed to “not used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids”</td>
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<td>Addition of no live attenuated vaccines requirement to the live vaccines per SME</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
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November 2018  Annual review and reference update
March 2019  Addition of PA Renewal Requirements and changed PA duration from lifetime to 2 years
June 2019  Annual review and reference update
September 2019  Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.