Policy Title: Ocrevus (ocrelizumab) (Intravenous)

Department: PHA

Effective Date: 01/01/2020

Review Date: 05/20/2019, 09/18/2019, 12/20/2019, 01/22/2020, 06/10/2021

Revision Date: 05/20/2019, 09/18/2019, 12/20/2019, 01/22/2020, 06/10/2021

Purpose: To support safe, effective and appropriate use of Ocrevus (ocrelizumab) in the treatment of Multiple Sclerosis.

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:
Ocrevus (ocrelizumab) is covered under the medical benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:
Coverage of Ocrevus (ocrelizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:
- Patient is at least 18 years of age; and
- Patient is diagnosed with primary progressive multiple sclerosis (PPMS) or relapsing form of multiple sclerosis as documented by laboratory report (i.e. MRI); and
- Must be prescribed by a neurologist; and
- Will be used as single agent therapy; and
- For members with relapsing forms of multiple sclerosis, they will need to provide documentation of one of the following:
  - The Member is newly diagnosed with relapsing multiple sclerosis
  - The Member’s current or previous disease modifying therapy does not adequately control the disease as evidenced by disease progression or the member is experiencing intolerable adverse events; and
- Initial dose does not exceed 300mg (300 billable units) initially followed two weeks later by a second dose of 300 mg (300 billable units); and
- Maintenance dose does not exceed 600mg (600 billable units) every 6 months;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.
Continuation of therapy criteria:

- Patient diagnosed with PPMS:
  - Patient has not received a dose of ocrelizumab within the past 5 months
  - Patient is tolerating treatment with ocrelizumab
  - Patient has experienced a slowing of disease worsening (e.g., no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy

- Patient diagnosed with a relapsing form of MS:
  - Patient has not received a dose of ocrelizumab within the past 5 months
  - Patient is tolerating treatment with ocrelizumab
  - Patient has experienced disease improvement or slowing of disease worsening (e.g., no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy

Coverage durations:

- Initial coverage criteria = 6 months
- Continuation of therapy = 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 1 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Sclerosis</td>
<td><strong>Initial dose:</strong> 300 mg intravenous infusion, followed two weeks later by a second 300 mg IV infusion&lt;br&gt;<strong>Subsequent doses:</strong> 600 mg IV infusion every 6 months Administer first subsequent dose 6 months after infusion of the initial dose</td>
<td><strong>Initial dose:</strong> 300 billable units (mg) on day 1 and day 15&lt;br&gt;<strong>Subsequent doses:</strong> 600 billable units (mg) every 6 months</td>
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</tbody>
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Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.
Applicable Codes:
Below is a list of billing codes applicable to covered treatment options for multiple sclerosis. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria are provided in the procedure section.

Codes:
The following HCPCS/CPT codes are:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2350</td>
<td>Injection, ocrelizumab, 1mg</td>
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References: