Ocrevus™ (ocrelizumab) (Intravenous)

Last Review Date: 09/03/2019
Date of Origin: 04/25/2017

I. Length of Authorization

Coverage will be provided for 6 months and is eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Ocrevus 300 mg single-dose vial: 2 vials in first 2 weeks, then 2 vials per 6 months

B. Max Units (per dose and over time) [Medical Benefit]:
   Initial dose:
   - 300 billable units (mg) D1 and D15
   Subsequent doses:
   - 600 billable units (mg) every 6 months

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Multiple Sclerosis †
   - Patient is 18 years or older (unless otherwise specified): AND
   - Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests): AND
   - Patient will not receive live vaccines concurrently with ocrelizumab: AND
   - Patient does not have an active infection: AND
   - Patient must have a confirmed diagnosis* of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI): AND
   - Must be used as single agent therapy: AND
     - Patient has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)***]: OR
- Patient has a diagnosis** of primary progressive MS (PPMS): **AND
  - Patient is less than 65 years: **AND
  - Patient has an expanded disability status scale (EDSS) score of ≤ 6.5

- For patients with relapsing forms of MS ONLY: Documented trial and failure of ONE preferred treatment for MS, unless contraindicated, such as Rebif, Avonex (Interferon Beta-1a), Plegridy (Peginterferon Beta-1a), Copaxone (glatiramer), Tecfidera (dimethyl fumarate), Aubagio (teriflunomide) and Gilenya (fingolimod).

† FDA Approved Indication(s)

*Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).

<table>
<thead>
<tr>
<th>Dissemination in time</th>
<th>Dissemination in space</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Development/appearance of new CNS lesions over time)</td>
<td>(Development of lesions in distinct anatomical locations within the CNS: multifocal)</td>
</tr>
<tr>
<td>- ≥ 2 clinical attacks: **OR</td>
<td>- ≥ 2 lesions: **OR</td>
</tr>
<tr>
<td>- 1 clinical attack <strong>AND</strong> one of the following:</td>
<td>- 1 lesion <strong>AND</strong> one of the following:</td>
</tr>
<tr>
<td>- MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRI compared to baseline scan</td>
<td>- Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location</td>
</tr>
<tr>
<td>- CSF-specific oligoclonal bands</td>
<td>- MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, cortical or juxtacortical, infratentorial, or spinal cord)</td>
</tr>
</tbody>
</table>

**Active secondary progressive MS (SPMS) is defined as the following:

- Minimum Expanded Disability Status Scale (EDSS) score of 3.0: **AND
  - ≥ 1 relapse within the previous 2 years: **OR
  - Patient has new and unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

***Definitive diagnosis of CIS is based upon ALL of the following:

- A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
- Neurologic symptom duration of at least 24 hours, with or without recovery
- Absence of fever or infection
- Patient is not known to have multiple sclerosis

****Definitive diagnosis of MS with a primary progressive course is based upon the following:

- 1 year of disability progression independent of clinical relapse: **AND
- TWO of the following:
  - ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS (periventricular, cortical or juxtacortical, or infratentorial)
IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III: **AND**

- Patient has not received a dose of ocrelizumab within the past 5 months: **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, severe infections, malignancy, etc.: **AND**

- Continuous monitoring of response to therapy [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by EDSS, timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)].

  - Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period

  **Note:** patients with primary progressive MS generally do not have clinical relapses and do not typically develop new lesions on MRI

PPMS

- Patient continues to be ambulatory, defined as an EDSS score of <7.5

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</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</td>
</tr>
<tr>
<td></td>
<td><strong>Subsequent doses:</strong> 600 mg IV infusion every 6 months</td>
</tr>
<tr>
<td></td>
<td>• Administer first subsequent dose 6 months after infusion of the initial dose</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

- **Jcode:**
  - J2350 - Injection, ocrelizumab, 1 mg; 1 mg = 1 billable unit

- **NDC:**
  - Ocrevus 300 mg/10 mL single-dose vial: 50242-0150-xx
VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G35</td>
<td>Multiple Sclerosis</td>
</tr>
</tbody>
</table>
Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corporation (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corporation (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
</tr>
</tbody>
</table>