Ocrevus™ (ocrelizumab)
(Intravenous)

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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) [NDC unit]:

- 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) [HCPCS Unit]:

Initial dose:

- 300 billable units (mg) D1 and D15

Subsequent doses:

- 600 billable units (mg) every 6 months

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- 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**

Universal Criteria [1]

- Patient will not receive live vaccines concurrently with ocrelizumab; **AND**
- Patient does not have an active infection; **AND**

Multiple Sclerosis † [1,7,11]

- 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)***]; **AND**

For relapsing MS: Patient must have had an inadequate response to an adequate trial of one of the following drugs: Avonex, Tecfidera, Gilenya, Glatopa, or glatiramer acetate, unless contraindicated or not tolerated; **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

† FDA Approved Indication(s)

***Definitive diagnosis of MS with a relapsing-remitting course is based upon <u>BOTH</u> dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).**	
<u>Dissemination in time</u> (*Development/appearance of new CNS lesions over time*)	**<u>Dissemination in space</u>** (*Development of lesions in distinct anatomical locations within the CNS; multifocal*)

• ≥ 2 clinical attacks; **OR**
• 1 clinical attack <u>AND</u> one of the following:
  ○ 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
  ○ CSF-specific oligoclonal bands
	• ≥ 2 lesions; **OR**
	• 1 lesion <u>AND</u> one of the following:
	  ○ Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location
	  ○ 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)

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

• Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND**
• Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤5.5 or increase by 0.5 in patients with EDSS ≥6); **AND**
  ○ ≥ 1 relapse within the previous 2 years; **OR**
  ○ Patient has gadolinium-enhancing activity or new and unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

*****Definitive diagnosis of CIS is based upon <u>ALL</u> 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)
  ○ ≥ 2 T2-hyperintense lesions in the spinal cord
  ○ Presence of CSF-specific oligoclonal bands

IV. Renewal Criteria [1,6,10]

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant 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 indicates a beneficial response [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 expanded disability status scale (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

Indication	Dose
Multiple Sclerosis	Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg IV infusion Subsequent doses: 600 mg IV infusion every 6 months • Administer first subsequent dose 6 months after infusion of the initial dose

VI. Billing Code/Availability Information

HCPCS:

- J2350 - Injection, ocrelizumab, 1 mg; 1 mg = 1 billable unit

NDC:

- Ocrevus 300 mg/10 mL single-dose vial: 50242-0150-xx

VII. References

1. Ocrevus [package Insert]. South San Francisco, CA; Genentech, Inc.; May 2020. Accessed October 2020.
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3. Hauser SL, Bar-Or A, Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Engl J Med. 2017 Jan 19;376(3):221-234.
4. Gawronski KM, Rainka MM, Patel MJ, Gengo FM. Treatment Options for Multiple Sclerosis: Current and Emerging Therapies. Pharmacotherapy. 2010; 30(9):916-927.
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13. Lorscheider J, Buzzard K, Jokubaitis V, et al, on behalf of the MSBase Study Group. Defining secondary progressive multiple sclerosis. Brain, Volume 139, Issue 9, September 2016, Pages 2395–2405, https://doi.org/10.1093/brain/aww173.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35	Multiple Sclerosis

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

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