Ocrevus® (ocrelizumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months thereafter (365 days).

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Initial dose:

- 300 billable units (300 mg) on day 1 and day 15

Subsequent doses:

- 600 billable units (600 mg) every 6 months

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient must have a contraindication, intolerance, or failure to ONE generic disease-modifying agent prior to the consideration of Ocrevus®; **AND**
- Member is at least 18 years of age; **AND**
- Member has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive results for Hepatitis B surface antigen [HBsAg] and anti-HBV tests); **AND**
- Member has had baseline serum immunoglobulins assessed; **AND**

Universal Criteria [1]

- Member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Provider will confirm that member will not receive live or live-attenuated vaccines while on therapy or within 4 weeks prior to initiation of treatment; **AND**
- Member does not have an active infection; **AND**
- Member will have serum aminotransferases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]), alkaline phosphatase, and bilirubin levels measured at baseline and periodically throughout therapy; **AND**
- Used as single agent therapy; **AND**

- Member has not received a dose of ocrelizumab or ublituximab within the past 5 months; **AND**

Multiple Sclerosis † [1,7,11,16]

- Member must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
  - Member 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**
  - Member has a diagnosis of primary progressive MS (PPMS); **AND**
    - Member is less than 65 years of age; **AND**
    - Member has an expanded disability status scale (EDSS) score of ≤ 6.5

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,6,10,14]

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy, malignancy, hypogammaglobulinemia, immune-mediated colitis, clinically significant liver injury, 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 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)]

> *Note:
> – 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.

PPMS

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

V. Dosage/Administration [1]

Indication	Dose
Multiple Sclerosis	Initial dose: 300 mg intravenous (IV) infusion, followed two weeks later by a second 300 mg IV

Indication	Dose
	infusion Subsequent doses: 600 mg IV infusion every 6 months • Administer first subsequent dose 6 months after infusion 1 of the initial dose

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B1	Active primary progressive multiple sclerosis

ICD-10	ICD-10 Description
G35.B2	Non-active primary progressive multiple sclerosis
G35.C0	Secondary progressive multiple sclerosis, unspecified
G35.C1	Active secondary progressive multiple sclerosis
G35.C2	Non-active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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