Washington State Health Care Authority

Multiple Sclerosis Agents - Ocrelizumab (Ocrevus)

Medical policy no. 62.40.50.60-1 Effective Date: July 1, 2019

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Multiple sclerosis (MS) is a chronic, inflammatory disease which involves the damage and destruction of nerve fibers and myelin, the fatty substance that insulates nerve fibers. This damage can lead to distorted or interrupted signaling between the brain and spinal cord, which can cause a variety of symptoms that worsen over time.

There are four defined clinical courses of MS: relapsing-remitting (RRMS), primary progressive (PPMS), secondary progressive (SPMS), and progressive relapsing (PRMS). RRMS involves defined relapses of declining neurologic symptoms followed by periods of remission. In patients with PPMS, there is typically an absence of attacks prior to disease progression. PPMS is defined by gradual deterioration from disease onset without acute attacks.

Drug	Medical Necessity
ocrelizumab (Ocrevus)	Ocrevus may be considered medically necessary when used for the treatment of relapsing remitting multiple sclerosis (RRMS) or primary progressive multiple sclerosis (PPMS)

Clinical policy:

Indication	Clinical Criteria (Initial Approval)
Relapsing Remitting Multiple Sclerosis (RRMS)	1. Diagnosis of RRMS; **AND** 2. Patient is 18 years of age or older; **AND** 3. The patient must have an inadequate response to two or more medications FDA-approved for the same indication and/or medications that are considered the standard of care; **AND** 4. The patient is not concurrently taking other disease-modifying therapies for multiple sclerosis (MS); **AND** 5. Test results for hepatitis B viral infection are negative; **AND** 6. Dose does not exceed FDA or compendia supported limitations; **AND** 7. For patients previously treated with disease-modifying drugs with long-lasting treatment effects (e.g., natalizumab, alemtuzumab), an appropriate wash-out period has elapsed prior to planned treatment with ocrelizumab; **AND** 8. For patients with Expanded Disability Status Scale (EDSS) 6.5 or greater:

	a. Imaging evidence of active disease; **AND** b. Documentation of at least ONE relapsing event in the last 2 years; **AND** c. Documentation that the provider has discussed the benefits and risks of continuing disease-modifying therapy. If ALL criteria are met, the request will be approved for 12 months
	Criteria (Reauthorization)
	Documentation of clinical benefit as determined by prescriber. If ALL criteria are met, the request will be approved for 12 months
Primary Progressive Multiple Sclerosis (PPMS)	**Clinical Criteria (Initial Approval)**
	1. Patient has a diagnosis of PPMS according to the revised McDonald Criteria; **AND** 2. Patient is 18 years of age or older; **AND** 3. Documentation of oligoclonal IgG bands in cerebral spinal fluid; **OR** 4. T2 lesions on brain or spinal cord imaging; **AND** 5. Ambulatory stage of disease (EDSS < 7); **AND** 6. The patient is not concurrently taking other disease-modifying therapies for multiple sclerosis (MS); **AND** 7. Test results for hepatitis B viral infection are negative; **AND** 8. Dose does not exceed FDA or compendia supported limitations. If ALL criteria are met, the request will be approved for 12 months
	Criteria (Reauthorization)
	Documentation of clinical benefit as determined by prescriber If ALL criteria are met, the request will be approved for 12 months

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
ocrelizumab (Ocrevus)	Initial: • 300mg intravenous course on days 1 and 15 Maintenance: • 600mg intravenous every 6 months

Coding:

HCPCS Code	Description
J2350	Injection, ocrelizumab, 1 mg
ICD-10 Code	**Description**
G35	Multiple Sclerosis

References

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3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology Apr 2018, 90 (17) 777-788.
4. Hauser SL, Bar-Or A, Comi G et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. 2017. N Engl J Med 376(3): 221-234.
5. Montalban X, Hauser SL, Kappos L et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. 2017. N Engl J Med 367(3): 209-220.
6. Kappos L, et al. Ocrelizumab in relapsing-remitting multiple sclerosis: a phase 2, randomised, placebo-controlled, multicentre trial. Lancet. 2011;378(9805):1779-87. https://www.ncbi.nlm.nih.gov/pubmed/22047971
7. Montalban X, et al. Baseline Demographics and Disease Characteristics from ORATORIO, a Phase III Trial Evaluating Ocrelizumab in Patients with Primary Progressive Multiple Sclerosis (P7.017). Neurology April 6, 2015 vol. 84 no. 14 Supplement P7.017
8. Sorensen PS, and Blinkenberg M. The potential role for ocrelizumab in the treatment of multiple sclerosis: current evidence and future prospects. Ther Adv Neurol Disord. 2016; 9(1): 44-52.
9. Montalban X, Gold R, Thompson AJ, et al. ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. Mult Scler. 2018 Feb;24(2):96-120.
10. Lublin FD et al. Defining the clinical course of multiple sclerosis. Neurology 2014; 83:278-286

History

Date	Action and Summary of Changes
05.06.2019	New Policy
02.08.2024	1. Added version number to policy 2. Updated note 3. Updated criteria #3 for PPMS to be OR