Ocrevus (ocrelizumab)
PAM – 011

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/20/2017
Revision Number	5	**Last Reviewed**	04/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	04/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	11/27/2017

Overview

Medication: [1]	ocrelizumab
Brand Name:	Ocrevus®
Pharmacologic Category:	CD20-directed cytolytic antibody

FDA-Approved Indication(s):	• Relapsing forms of multiple sclerosis in adults, to include:
	  ○ Clinically isolated syndrome (CIS)
	  ○ Relapsing-remitting multiple sclerosis (RRMS)
	  ○ Active secondary progressive multiple sclerosis (SPMS)
	• Primary progressive multiple sclerosis (PPMS) in adults

How Supplied:	300 mg/10 mL (30 mg/mL) in a single-dose vial
Dosage and Administration:	Administered via intravenous (IV) infusion: • Initial dose: 300 mg IV, followed 2 weeks later by a second 300 mg IV • Subsequent doses: single 600 mg IV infusion every 6 months
Benefit Category:	Medical

Descriptive Narrative

Multiple sclerosis (MS) affects more than 400,000 people in the United States, and more than 2.3 million people have multiple sclerosis worldwide. It is the most common immune-mediated inflammatory demyelinating disease of the central nervous system and is a leading cause of disability in young adults.

The core phenotypes of MS are relapsing-remitting and progressive disease. The pattern and course of MS is further categorized into the following subtypes:

1. Clinically isolated syndrome (CIS) (often representing the first attack of MS);
2. Relapsing-remitting multiple sclerosis (RRMS);
3. Secondary progressive multiple sclerosis (SPMS);
4. Primary progressive multiple sclerosis (PPMS).

Clinically isolated syndrome (CIS) is the first clinical episode that is consistent with a demyelinating etiology and suggestive of multiple sclerosis (MS). Symptoms usually develop over the course of hours to days, and then gradually

remit over the ensuing weeks to months, although remission may not be complete. CIS is considered as a precursor to MS in most patients. The long-term (i.e., 10- to 20-year) likelihood of developing MS ranges from 60 to 80 percent. In patients with a CIS who have a normal baseline MRI, limited data suggests that the long-term prevalence of MS is approximately 20 percent.

Relapsing-remitting multiple sclerosis (RRMS) accounts for 85 to 90 percent of cases at onset. It is characterized by clearly defined attacks (also known as relapses, flares, or exacerbations) with full or incomplete recovery. Symptoms and signs associated with a relapse usually reach a peak in days to weeks, followed by a remission during which the symptoms and signs resolve to a variable extent.

Secondary progressive multiple sclerosis (SPMS) begins as relapsing-remitting disease, but over time the disease enters a stage of steady deterioration in function. There are no established criteria to determine when RRMS converts to SPMS; the diagnosis of SPMS is made retrospectively. SPMS ultimately develops in up to 90 percent of patients with RRMS after 25 years and causes the greatest amount of neurologic disability attributable to MS.

Primary progressive multiple sclerosis (PPMS) is characterized by progressive accumulation of disability from disease onset with occasional plateaus, temporary minor improvements, or acute relapses still consistent with the definition. A diagnosis of PPMS is made exclusively on patient history, and there are no imaging or exam findings that distinguish PPMS from RRMS. PPMS represents about 10 percent of adult multiple sclerosis cases at disease onset.[2]

Ocrevus® (ocrelizumab) selectively depletes CD20-expressing B-cells. It reduces relapse rates and indicators of disease activity in patients with RMS and delays the worsening of disability in patients with RMS and PPMS.[3]

Guidelines

The American Academy of Neurology (AAN) published practice guidelines in 2018 regarding disease-modifying therapies (DMTs) for adults with multiple sclerosis. Recommendations regarding starting, switching, and stopping DMT were reviewed and assigned one of three designations: A, B, or C. Each designation denotes the level of recommendation strength. These guidelines were reaffirmed on October 19, 2024.[4]

Level	Helping Verb	Description
A	MUST	Level A is the strongest recommendation level. These recommendations are rare, as they are based on high confidence in the evidence and require both a high magnitude of benefit and low risk.
B	SHOULD	These recommendations are more common, as the requirements are less stringent but still based on the evidence and benefit-risk profile.
C	MAY	Level C represents the lowest allowable recommendation level the AAN considers useful within the scope of clinical practice and can accommodate the highest degree of practice variation.

Starting disease-modifying therapy (DMT): Level A ("must") Recommendation Statements	
2a	Clinicians must ascertain and incorporate/review preferences in terms of safety, route of administration, lifestyle, cost, efficacy, common adverse effects, and tolerability in the choice of DMT in people with MS being considered for DMT.
2b	Clinicians must engage in an ongoing dialogue regarding treatment decisions throughout the disease course with people with MS.
3b	Clinicians must counsel people with MS on DMTs to notify the clinicians of new or worsening symptoms.

Switching DMT: Level A ("must") Recommendation Statements	
9a	Physicians must counsel people with MS considering natalizumab discontinuation that there is an increased risk of MS relapse or MRI-detected disease activity within 6 months of discontinuation.

Discontinuing DMT: Level A ("must") Recommendation Statements	
	There are not any Level A recommendations regarding discontinuing DMT.

Criteria

Prior authorization is required.

Ocrevus® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of one of the following clinical subtypes of multiple sclerosis (MS) (a, b, c, or d); **AND**
    a. Clinically isolated syndrome (CIS); **OR**
    b. Relapsing-remitting multiple sclerosis (RRMS); **OR**
    c. Active secondary progressive multiple sclerosis (SPMS); **OR**
    d. Primary progressive multiple sclerosis (PPMS); **AND**
2. Member is 18 years of age or older; **AND**
3. Member meets **ONE** of the following (a or b):
    a. Diagnosis of relapsing remitting multiple sclerosis (including CIS, RRMS, or active SPMS) and is able to ambulate without aid or rest for at least 100 meters; **OR**
    b. Diagnosis of PPMS and is able to ambulate more than 5 meters (not considered wheelchair bound); **AND**
4. Member does **NOT** have any of the following:
    a. Active hepatitis B virus infection; **AND/OR**
    b. History of life-threatening infusion reaction to Ocrevus®; **AND**
5. Ocrevus® is not prescribed or administered concurrently with other disease-modifying therapies for multiple sclerosis (MS) (with the exception of dalfampridine,* which may be used in combination with Ocrevus®); **AND**
6. Prescribed by, or in consultation with, a neurologist; **AND**
7. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed an initial dose of 300 mg, a second 300 mg dose 2 weeks later, then a maintenance dose of 600 mg every 6 months; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Ocrevus® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy; **AND**
3. Ocrevus® is not prescribed or administered concurrently with other disease-modifying therapies for multiple sclerosis (MS) (with the exception of dalfampridine*, which may be used in combination with Ocrevus®); **AND**
4. Prescribed by, or in consultation with, a neurologist; **AND**
5. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 600 mg every 6 months; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

* Dalfampridine may require a separate pharmacy prior authorization (see Iowa Medicaid preferred drug list for more information).

Approval Duration and Quantity Limits

	Approval Duration	Quantity Limits
Initial and Subsequent Authorizations	12 months	600 mg every 6 months

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J2350	Injection, ocrelizumab, 1 mg

ICD-10	Description
G35	Multiple sclerosis

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
50242-0015-01 (single-dose vial, 300 mg/10 mL [30 mg/mL])	Genentech, Inc. (50242)	1 mg	1	EA	300

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Ocrevus® prescribing information (06/2024). Genentech, Inc.: South San Francisco, CA. Available online: www.ocrevus-hcp.com. Accessed March 5, 2025.

[2] Olek MJ, Howard J. Clinical presentation, course, and prognosis of multiple sclerosis in adults. Dashe JF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 5, 2025.

[3] Lamb YN. Ocrelizumab: A Review in Multiple Sclerosis. Drugs. 2022 Feb;82(3):323-334. Epub 2022 Feb 22. PMID: 35192158.

[4] Rae-Grant A, 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. 2018 Apr 24;90(17):777-788. Erratum in: Neurology. 2019 Jan 8;92(2):112. PMID: 29686116. Reaffirmed on October 19, 2024.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
04/18/2025	CAC	Annual review. Added package description to NDC table. Added notation in Guidelines section: the 2018 AAN Guidelines were reaffirmed on October 19, 2024.	5
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/19/2024	CAC	Annual review. Updated references.	4
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/21/2023	CAC	Annual review. Added dosing regimen into criteria.	3
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/15/2022	CAC	Annual review. Rewrite.	2
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
11/27/2017	Medical Director		1
Signature			
C. David Smith, MD		William (Bill) Jagiello, DO	

CAC = Medicaid Clinical Advisory Committee