

PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Ocrevus Prior Authorization Policy

- Ocrevus® (ocrelizumab intravenous infusion – Genentech/Roche)

REVIEW DATE: 11/30/2022

OVERVIEW

Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of adults with:¹

- **Relapsing forms of multiple sclerosis (MS)** to include clinically isolated syndrome, relapsing remitting MS, and active secondary progressive MS.
- **Primary progressive MS.**

Disease Overview

MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system that impacts almost 1,000,000 people in the US.²⁻⁴ The condition is marked by inflammation and demyelination, as well as degenerative alterations. Patients usually experience relapses and remissions in their neurological symptoms. For most patients, the onset of MS symptoms occurs when patients are 20 to 40 years of age; however, children can get MS and new onset disease can occur in older adults. The MS disease course is heterogeneous but has some patterns. Approximately 85% to 90% of patients have a relapsing pattern at onset. However, this transitions over time in patients who are untreated to a worsening with very few or no relapses or magnetic resonance imaging (MRI) activity (secondary progressive MS). Around 10% to 15% of patients have a steady progression of symptoms over time (primary progressive MS), marked by some clinical manifestations or by MRI activity. Primary progressive MS is generally diagnosed in patients on the upper level of the typical age range (e.g., almost 40 years of age) and the distribution is equivalent among the two genders.²⁻⁴ Advances in the understanding of the MS disease process, as well as in MRI technology, spurred updated disease course descriptions in 2013,⁵ as well as in 2017.⁶ The revised disease courses are clinically isolated syndrome, relapsing remitting MS, primary progressive MS, and secondary progressive MS.²⁻⁶ Clinically isolated syndrome is now more recognized among the course descriptions of MS. It is the first clinical presentation of MS that displays characteristics of inflammatory demyelination that may possibly be MS but has yet to fulfill diagnostic criteria.

Guidelines

In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.² Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ocrevus. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ocrevus as well as the monitoring required for adverse events and long-term efficacy, approval requires Ocrevus to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

11/30/2022

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Coverage of Ocrevus is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Multiple Sclerosis, Relapsing Forms.** Approve 1 year if the patient meets one of the following (A or B):
 - A) **Initial Therapy.** Approve if the patient meets all the following (i, ii, iii, and iv):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - iii. According to the prescriber, the patient has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for multiple sclerosis; AND
Note: See [Appendix](#) for examples.
 - iv. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
 - B) **Patient is Currently Receiving Ocrevus.** Approve if the patient meets one of the following criteria (i or ii):
 - i. **Patient has been receiving Ocrevus for < 1 year.** Approve if the patient meets all of the following (a, b, and c):
 - a) Patient is ≥ 18 years of age; AND
 - b) Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - c) Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
 - ii. **Patient has been receiving Ocrevus for 1 year or more.** Approve if the patient meets all of the following (a, b, c, and d):
 - a) Patient is ≥ 18 years of age; AND
 - b) Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - c) Patient meets one of the following [(1) or (2)]:
 - (1) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss; OR
 - (2) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND
 - d) Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

2. **Multiple Sclerosis, Primary Progressive.** Approve for 1 year if the patient meets all of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Medication is prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis and/or a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ocrevus is not recommended in the following situations:

1. **Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.** These agents are not indicated for use in combination (See [Appendix](#) for examples). Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ocrevus® intravenous infusion [prescribing information]. San Francisco, CA: Genentech/Roche; August 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on November 17, 2022.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. No authors listed. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.

Type of Revision	Summary of Changes	Review Date
Annual Revision	Conditions Not Recommended for Approval: Regarding Concurrent Use with Other Disease-Modifying Agents for Multiple Sclerosis, examples provided in the Note were changed to an Appendix table and Ponvory was added to the list. Also, the citing of the medication routes were updated, as well as generic availability.	12/08/2021
Selected Revision	Multiple Sclerosis, Relapsing Forms: Criteria were divided into Initial Therapy and Patient Has Been Receiving Ocrevus for < 1 year and for 1 year or more. For Initial Therapy, criteria were added that according to the prescriber the patient has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for multiple sclerosis (with a Note added that the Appendix provides examples). For those receiving Ocrevus for 1 year or more, response criteria were developed for reauthorization in which the patient either experienced a beneficial clinical response when assessed by at least one objective measure (with examples provided in a Note), or the patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.	07/20/2022
Annual Revision	No criteria changes.	11/30/2022

APPENDIX