Medical Policy:
Ocrevus® (ocrelizumab) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.302	January 31, 2024	2018

Definitions

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

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

Length of Authorization

Coverage will be provided for 12 months and can be renewed

Dosing Limits [Medical Benefit]

Approve the following dosing regimens (A or B):

A. 300 mg by intravenous infusion, followed 2 weeks later by a second 300 mg intravenous infusion; (300 billable units (300 mg) on day 1 and day 15); **OR**

B. 600 mg by intravenous infusion once every 6 months (600 billable units (600 mg) every 6 months)

Guideline

1. **Multiple Sclerosis, Relapsing Forms.** Approve if the patient meets one of the following (A or B):
   A. Initial Therapy. Approve for 1 year if the patient meets the following (i, ii, and iii):
      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. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
   B. Patient is Currently Receiving Ocrevus for ≥ 1 Year. Approve if the patient meets all of the following (i, ii, iii, and iv):

      Note: A patient who has received < 1 year of therapy or who is restarting therapy with Ocrevus should be considered under criterion 1A (Multiple Sclerosis [Relapsing Forms], Initial Therapy).

      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 multiple sclerosis.

      iii. 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.

         (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**
      iv. 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 if the patients meets the following (A and B):
   A. Patient is ≥ 18 years of age; **AND**
   B. Ocrevus 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 chart for examples:

Medication	Mode of Administration
Aubagio® (teriflunomide tablets)	Oral
Avonex® (interferon beta-1a intramuscular injection)	Injection (self-administered)

Bafiertam® (monomethyl fumarate delayed-release capsules)	Oral
Betaseron® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Briumvi™ (ublituximab-xiiy intravenous infusion)	Intravenous infusion
Copaxone® (glatiramer acetate subcutaneous injection, generic)	Injection (self-administered)
Extavia® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Gilenya® (fingolimod capsules, generic)	Oral
Glatopa® (glatiramer acetate subcutaneous injection)	Injection (self-administered)
Kesimpta® (ofatumumab subcutaneous injection)	Injection (self-administered)
Lemtrada® (alemtuzumab intravenous infusion)	Intravenous infusion
Mavenclad® (cladribine tablets)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Plegridy® (peginterferon beta-1a subcutaneous or intramuscular injection)	Injection (self-administered)
Ponvory™ (ponesimod tablets)	Oral
Rebif® (interferon beta-1a subcutaneous injection)	Injection (self-administered)
Tascenso ODT™ (fingolimod orally disintegrating tablets)	Oral
Tysabri® (natalizumab intravenous infusion)	Intravenous infusion
Vumerity® (diroximel fumarate delayed-release capsules)	Oral
Zeposia® (ozanimod capsules)	Oral

Applicable Procedure Codes

Code	Description
J2350	ocrelizumab, 1 mg

Applicable NDCs

Code	Description
50242-0150-001	Ocrevus 300MG/10ML Solution

ICD-10 Diagnoses

Code	Description
G35	Multiple Sclerosis
G35.2	Primary Progressive Multiple Sclerosis
G35.1	Relapsing-Remitting Multiple Sclerosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/31/2024	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	04/05/2023	Transfer from CCUM template to CoBranded Medical Template Retired MG.MM.PH.37
EmblemHealth & ConnectiCare	03/01/2023	Multiple Sclerosis. Relapsing Forms: For initial criteria, the criterion was removed that according to the prescriber, the patient has experienced

		inadequate efficacy or significant intolerance to one disease-modifying agent used for multiple sclerosis. The criteria regarding use of Ocrevus for < 1 year was deleted as now it is the same as initial criteria. For the criteria regarding the patient is currently receiving Ocrevus for 1 year or more, a Note was added stating that a patient who has received < 1 year of therapy or who is restarting therapy with Ocrevus should be considered under criteria for Multiple Sclerosis (Relapsing Forms) [Initial Therapy]. Conditions Not Recommended for Approval: Regarding Concurrent Use with Other Disease-Modifying Agents for Multiple Sclerosis, Briumvi was added to the list of examples provided in the Appendix table.
EmblemHealth & ConnectiCare	11/30/2022	Annual Revision: No criteria changes
EmblemHealth & ConnectiCare	7/20/2022	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
EmblemHealth & ConnectiCare	12/08/2021	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.

References

1. Ocrevus® intravenous infusion [prescribing information]. San Francisco, CA: Genentech/Roche; August 2022.