MEDICAL MUTUAL®

Drug Policy

Policy:	**201708**	**Initial Effective Date: 04/27/2017**
Code(s):	**HCPCS J2350**	**Annual Review Date: 04/18/2024**
SUBJECT:	**Ocrevus ® (ocrelizumab)**	**Last Revised Date: 04/18/2024**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

POLICY STATEMENT

This policy involves the use of Ocrevus. Prior authorization is recommended for medical benefit coverage of Ocrevus. Approval is recommended for those who meet the conditions of coverage in the **Initial Approval and Renewal Criteria, Preferred Drug (when applicable), Dosing/Administration, Length of Authorization, and Site of Care (when applicable)** for the diagnosis provided. The requirement that the patient meet the Criteria and Preferred Drug for coverage of the requested medication applies to the initial authorization only. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Relapsing Forms of Multiple Sclerosis (MS).** Approve for 1 year if the patient meets all of the following criteria (A, B, C, D, E, F and G):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient has a relapsing form of multiple sclerosis (MS) [relapsing forms of MS are relapsing-remitting MS {RRMS}, secondary-progressive MS {SPMS} with relapses, or progressive-relapsing MS {PRMS}] ; AND
   - **C)** The patient meets one of the following (i or ii):

i. The patient has highly active/aggressive MS as determined by one of the following [documentation required] :
   a. The patient has had 2 or greater relapses in the past year and the presence of 1 or greater gadolinium-enhancing (Gd+) lesions;
   b. an EDSS score of 6 or greater within 5 years of symptom onset;
   c. 2 or greater MRI with new or enlarging T_2 lesions or Gd+ lesions during the past 12 months while the patient is receiving disease modifying treatments

ii. The patient has previously tried at least one generic MS therapy including (NOTE examples of generic MS agents: interferon beta 1-a, interferon beta-1b, peginterferon beta-1a, glatiramer acetate); AND

D) Ocrevus is prescribed by, or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist; AND

E) Ocrevus is used as a single agent therapy (Note: Patient is not using Ocrevus with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS) Ocrevus should not be given in combination with other disease-modifying agents used for MS (e.g., Avonex, Betaseron, Briumvi, Extavia, Rebif, Plegridy, Copaxone, Glatopa, Gilenya, Aubagio, Tecfidera, Tysabri, or Lemtrada). Ocrevus is not indicated for use in combination with other MS disease-modifying therapies and the safety and efficacy have not been adequately established.); AND

F) Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests); AND

G) Site of care medical necessity is met*

Ocrevus is indicated for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis.[1] Many disease-modifying MS medications are available with established efficacy in relapsing forms of MS with a known safety profile.

2. **Progressive Multiple Sclerosis (MS).** Approve for 1 year if the patient meets all of the following criteria (A, B, C, D, and E).

A) The patient is ≥ 18 years of age; AND

B) Ocrevus is prescribed by, or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist.; AND

C) Ocrevus is used as a single agent therapy (Note: Patient is not using Ocrevus with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS) Ocrevus should not be given in combination with other disease-modifying agents used for MS (e.g., Avonex, Betaseron, Extavia, Rebif, Plegridy, Copaxone, Glatopa, Gilenya, Aubagio, Tecfidera, Tysabri, or Lemtrada). Ocrevus is not indicated for use in combination with other MS disease-modifying therapies and the safety and efficacy have not been adequately established.); AND

D) Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests); AND

E) Site of care medical necessity is met*

Ocrevus is indicated for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis.[1] No other disease-modifying MS medications are indicated for use in primary progressive MS.

3. Patient has been Established on Ocrevus. Approve for 1 year if the patient has been taking Ocrevus AND has had a beneficial response to therapy AND Site of care medical necessity is met*

Dosing: IV: 300 mg on day 1, followed by 300 mg 2 weeks later; subsequent doses of 600 mg are administered once every 6 months (beginning 6 months after the first 300 mg dose)

Duration of Therapy is indefinite or until toxicity occurs.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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11. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol. 2018 Feb;17(2):162-173. doi: 10.1016/S1474- 4422(17)30470-2.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J2350