| CLINICAL MEDICATION POLICY | |
|---|---|
| **Policy Name:** | Ocrevus™ (ocrelizumab) |
| **Policy Number:** | MP-021-MC-ALL |
| **Approved By:** | Medical Management; Medical Policy |
| **Provider Notice Date:** | 07/01/2017 |
| **Original Effective Date:** | 08/01/2017 |
| **Annual Approval Date:** | 06/01/2018 |
| **Revision Date:** | N/A |
| **Products:** | Ohio Medicare Assured |
| **Application:** | All participating hospitals and providers |
| **Page Number(s):** | 1 of 4 |

**DISCLAIMER**

**Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.**

## POLICY STATEMENT

Gateway Health℠ provides coverage under the medical surgical benefits of the Company's Medicare products for medically necessary Ocrevus™ (ocrelizumab) intravenous administration for the treatment of relapsing-remitting or primary progressive multiple sclerosis (MS).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

## DEFINITIONS

**Relapsing-Remitting Multiple Sclerosis (RRMS) –** Characterized by acute attacks followed by periods of remission; primary form of MS that occurs in approximately 85% of patients.

**Secondary-Progressive Multiple Sclerosis (SPMS) –** An initial period of RRMS, followed by a steadily progressive course, with or without acute relapses; 75-85% of patients diagnosed with RRMS will transition to SPMS.

**Progressive-Progressive Multiple Sclerosis (PPMS) –** Steadily progressive course from onset with acute attacks, with or without recovery; occurs in less than 10% of MS patients.

## PROCEDURES

1. Ocrevus (ocrelizumab) is considered medically necessary as an intravenous infusion for the treatment of relapsing and primary-progressive forms of multiple sclerosis (MS) when the member meets *all* of the following criteria:

    A. Member is 18 years of age and older; AND
    B. Documentation of a diagnosis of relapsing-remitting or relapsing secondary progressive MS; AND
    C. The drug is given as monotherapy and not in combination with other therapies approved for the treatment of MS; AND
    D. Must be prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS; AND
    E. Members initiating therapy for the first time must have at least one clinical relapse documented (e.g., functional disability, hospitalization, acute steroid therapy, etc.) during the prior year; AND
    F. Must provide documentation Hepatitis B Virus (HBV) screening was performed, and no active disease is present prior to initiating treatment; AND
    G. Coverage provided for situations in which there is functional status that can be preserved. Member must still either be able to walk at least a few steps or alternatively must have some functional arm/hand use consistent with performing activities of daily living; AND
    H. Dose must not exceed FDA-approved dosing recommendations and not exceed 600 mg infused IV every 6 months; AND
    I. Administration of the medication must be done by a health care provider.

2. Contraindications
    Ocrelizumab is contraindicated in members who have active Hepatitis B virus (HBV) and those with a history of a life-threatening infusion reaction to Ocrevus.

3. When Ocrevus is not covered
    A. In members with active HBV;
    B. In members with an active infection until that infection is resolved.

    Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for the treatment of the diagnosis(es) for which it is prescribed. The request will be reviewed on a case-by-case basis to determine medical necessity.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the intravenous administration of Ocrevus (ocrelizumab) is outpatient.

## GOVERNING BODIES APPROVAL

On March 28, 2017, Ocrevus received FDA approval as therapy for individuals with primary progressive and relapsing forms of multiple sclerosis. The FDA approval for relapsing MS was based on two identical Phase III double-blind, double-dummy randomized controlled trials (OPERA I and II). The FDA approval for primary progressive MS (PPMS) was based on a randomized, double-blind, placebo control Phase III clinical trial (ORATORIO).

Ocrevus is a humanized monoclonal antibody designed to selectively target CD20-positive B cells. CD20-positive B cells are a specific type of immune cell believed to be a key contributor to myelin and axonal damage. This damage can result in various degrees of disability in people with MS. Ocrevus binds to the CD20 cell surface proteins expressed on certain B cells resulting in preservation of the immune system.

Coverage Determination
Gateway Health℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) that addresses Ocrevus.

For Ohio, please use the following link for a listing of local coverage determinations by CGS Administrators, LLC:
https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=238&name=CGS%20Administrators,%20LLC%20(15202,%20MAC%20-%20Part%20B)&DocType=Future&ContrVer=2&CntrctrSelected=238*2&s=42&bc=AggAAAIAAAAAAA%3d%3d&#ResultsAnchor

## CODING REQUIREMENTS

Procedure Codes

| HCPCS Code | Description |
|---|---|
| J3490 | Unclassified drugs (Solution for injection, Ocrelizumab, 300mg/10ml (30mg/ml) |
| J3590 | Unclassified biologics (Solution for injection, Ocrelizumab, 300mg/10ml (30mg/ml) |

Diagnosis Codes

| ICD-10 Codes | Description |
|---|---|
| G35 | Multiple sclerosis |

## REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

## POLICY SOURCE(S)


Ocrevus™ (ocrelizumab) injection for intravenous use prescribing information; March 2017.

Ocrevus™ In: Micromedex 2.0 online. Ann Arbor, MI. Truven Health Analytics; [2017; accessed April 18, 2017].

Scolding N, Barnes D, Cader S, et al. Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. Pract Neurol. Aug 2015; 15(4):273-279.

Goodin DS, Frohman EM, Garmany GP, Jr., et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. Jan 22 2002; 58(2):169-178.

National Multiple Sclerosis Society. Accessed on April 18, 2017 and available at: http://www.nationalmssociety.org/index.aspx.

Kappos L, Li D, Calabresi PA, et al. Ocrelizumab in relapsing-remitting multiple sclerosis: a Phase 2, randomised placebo-controlled, multicentre trial. Lancet. 378:1779-1787. Accessed on April 26, 2017 and available at: https://www.ncbi.nlm.nih.gov/pubmed/22047971.

Comi G, Arnold DL, Bar-Or A, et al. Effect of ocrelizumab on disability progression in patients with relapsing multiple sclerosis: Analysis of Phase III, double-blind, double-dummy, interferon beta-1a-controlled OPERA O and OPERA II studies disability progression OPERA. Presented at the American Academy of Neurology in Vancouver, BC, Canada; April 15-21, 2016. AAN Abstract #S49.008. Accessed on April 26, 2017 and available at: http://www.abstractsonline.com/pp8/#!/4046/presentation/8693.


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**Policy History**

| Date | Activity |
|---|---|
| 06/05/2017 | Initial policy developed |
| 06/21/2017 | QI/UM Committee approval |
| 08/01/2017 | Provider effective date |