Evolent Clinical Guideline 5024.CC for Ocrelizumab Products

Guideline Number: EVH_CG_5024.CC	Applicable Codes	
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Original Date: March 2022	**Last Revised Date:** March 2025	**Implementation Date:** May 2025

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*

- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for the ocrelizumab products (Ocrevus® and Ocrevus Zunovo™).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL AUTHORIZATION CRITERIA

- Must be prescribed by, or in consultation with, a neurologist
- Must have a diagnosis of relapsing form of MS or primary progressive MS
    - Relapsing forms of MS include clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease
- Must be age 18 years or older
- Must have previously had an inadequate response or intolerance to at least ONE of the following preferred multiple sclerosis therapies: Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Gilenya (fingolimod), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)
    - Previous trial of another multiple sclerosis agent is NOT required members with primary progressive MS
    - Only Gilenya (fingolimod) is required for members with "highly active" MS or considered to have prognostic factors of poorer clinical course
- Must have documentation of the following:
    - Hepatitis B virus (HBV) screening showing the member does not have active HBV
    - Quantitative serum immunoglobulin screening

- NOTE: If either screening above is abnormal, documentation must be submitted showing consultations with associated disease experts (i.e., liver specialist for HBV and immunology specialist for immunoglobulins).

- Must have chart note documentation or an attestation from the provider of all the following:
  - Must not have an active infection
  - Must not be receiving other disease modifying agents for multiple sclerosis (e.g., interferon beta-1a, interferon beta-1b, fingolimod, glatiramer acetate, rituximab, alemtuzumab, or ublituximab-xiiy) or have systemic medical conditions resulting in significant compromised immune system function
  - The member is updated on all vaccinations in accordance with current vaccination guidelines at least 2 weeks prior to treatment initiation
  - The member will be pre-medicated with methylprednisolone (or equivalent corticosteroid), an antihistamine (e.g., diphenhydramine), and an antipyretic (if applicable) prior to each infusion
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based or stabilized upon the prescriber's assessment while on therapy.

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Up to 1 year

CODING AND STANDARDS

Codes

Code	Brand	Description
J2350	Ocrevus	Injection, ocrelizumab, 1mg
J3590	Ocrevus Zunovo	Ocrelizumab and hyaluronidase-ocsq

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Both Ocrevus® (ocrelizumab) and Ocrevus Zunuvo™ (ocrelizumab and hyaluronidase-ocsq) are indicated for relapsing or primary progressive forms of multiple sclerosis (MS) in adults. Relapsing forms of MS include clinically isolated syndrome, relapsing, remitting disease, and active secondary progressive disease.[1,2]

POLICY HISTORY

Date	Summary
March 2025	• Guideline title change from "Ocrevus (ocrelizumab)" to "Ocrelizumab Products" • Addition of Ocrevus Zunovo • Select revisions: addition of Gilenya as a prerequisite & removal of exception criteria; addition of serum immunoglobulin testing requirement prior to initiation

Date	Summary
March 2022	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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2. Ocrevus Zunovo (ocrelizumab and hyaluronidase) [prescribing information]. South San Francisco, CA: Genentech Inc; September 2024.
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4. Hauser SL, Bar-Or A, Comi G, et al; OPERA I and OPERA II Clinical Investigators. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Engl J Med. 2017;376(3):221-234. doi:10.1056/NEJMoa160127
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6. Freedman MS, Devonshire V, Duquette P, et al. Treatment Optimization in Multiple Sclerosis: Canadian MS Working Group Recommendations. Canadian Journal of Neurological Sciences / Journal Canadien des Sciences Neurologiques. 2020;47(4):437-455. doi:10.1017/cjn.2020.66