Ocrelizumab (Ocrevus™) Ocrelizumab and Hyaluronidase-ocsq (Ocrevus Zunovo)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
B. Treatment of primary progressive MS, in adults.

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing Forms of Multiple Sclerosis
Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

B. Clinically Isolated Syndrome
Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

C. Primary Progressive Multiple Sclerosis
Authorization of 12 months may be granted to members for the treatment of primary progressive multiple sclerosis.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in section II who are experiencing disease stability or improvement while receiving the requested drug.

V. OTHER CRITERIA

A. Members will not use the requested drug concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Ocrevus (Ocrelizumab)	Multiple Sclerosis or Clinically Isolated Syndrome	Route of Administration: Intravenous Initial: 300mg followed 2 weeks later by a second 300 mg Maintenance: 600mg every 6 months
Ocrevus Zunovo (Ocrelizumab-Hyaluronidase-ocsq)	Multiple Sclerosis or Clinically Isolated Syndrome	Route of Administration: Subcutaneous 920/23,000mg-units every 6 months

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Ocrevus Zunovo [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.

EFFECTIVE DATE 10/31/2025

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