Multiple Sclerosis Products:(Ocrelizumab [Ocrevus™], Ocrelizumab and Hyaluronidase-ocsq [Ocrevus Zunovo™], Ublituximab-xiiy [Briumvi™])

Requires Step Therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at: https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

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.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

Briumvi is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Ocrevus and Ocrevus Zunovo are indicated for:

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

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

PRESCRIBER SPECIALITIES

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

COVERAGE CRITERIA

Relapsing Forms of Multiple Sclerosis (MS)

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).

Clinically Isolated Syndrome

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

Primary Progressive MS (Ocrevus and Ocrevus Zunovo only)

Authorization of 12 months may be granted to members for treatment of primary progressive multiple sclerosis.

CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted for all members (including new members) who achieve or maintain a positive clinical response as evidenced by experiencing disease stability or improvement while receiving the requested medication.

Other Criteria

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

For all products FDA-approved in adults only: 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
Briumvi (Ublituximab-xiiy)	Multiple Sclerosis or Clinically Isolated Syndrome	Route of Administration: Intravenous First Infusion: 150mg once Second Infusion: 450mg given 2 weeks after the first infusion Subsequent Infusion: 450mg every 24 weeks, starting 24 weeks after the first infusion
~~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 (Ocrelizumab)	Multiple Sclerosis or Clinically Isolated Syndrome	Route of Administration: Intravenous ≥18 year(s) Initial: 300mg followed 2 weeks later by a second 300 mg Maintenance: 600mg every 6 months
Ocrevus (Ocrelizumab)	Multiple Sclerosis	Route of Administration: Intravenous ≥10 to <18 year(s) ≥35kg

		Initial: 300mg followed 2 weeks later by a second 300 mg Maintenance: 600mg every 6 months 25 - <35kg Initial: 150mg followed 2 weeks later by a second 150 mg Maintenance: 300mg 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. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc.; August 2025.
2. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; August 2025.
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4. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17)777-788.
5. Walsh R, Chitnis T. Therapeutic Advances in Pediatric Multiple Sclerosis. Children. 2025;12(3):259.
6. Sladowska K, Mocko P, Brzostek T, et al. Efficacy and safety of disease-modifying therapies in pediatric-onset multiple sclerosis: A systematic review of clinical trials and observational studies. Mult Scler Relat Disord. 2025. doi: 10.1016/j.msard.2025.106263
7. Pediatric MS. National Multiple Sclerosis Society. Updated March 2023. Accessed August 22, 2025. https://www.nationalmssociety.org/for-professionals/for-healthcare-professionals/managing-and-treating-ms/pediatric-ms.

EFFECTIVE DATE

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