

<p>SUBJECT: CLINICAL POLICIES – INJECTABLE MEDICATIONS – BRIUMVI FOR THE TREATMENT OF MULTIPLE SCLEROSIS</p> <p>POLICY NUMBER: HS-CP-MA I3m</p> <p>EFFECTIVE DATE: June 25, 2025</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> FEHB</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service.

- A. All reviewers must first identify member eligibility, and all decisions of this clinical policy are subject to current state and/or federal law. This Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.
- B. Sharp Health Plan provides coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan’s service area.
- C. Sharp Health Plan complies with CMS’s national coverage determinations and general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare.

II. REGULATORY: N/A

III. DESCRIPTION

- A. This clinical policy should be utilized referencing the member’s specific Member Handbook to confirm the member’s coverage benefit(s).
- B. This policy defines the Sharp Health Plan (Plan) requirements for determination of medical necessity in order for **BRIUMVI** to be covered.
- C. This policy is to be used when there is no CMS criteria (NCD,LCD, NCA, Medicare Manual) for the drug in question.
- D. This policy defines the Sharp Health Plan (Plan) criteria for coverage of medications with a parenteral (IM, SQ, IV, Intrathecal) route of administration. These are also referred to as a “medical benefit” medication. A separate policy governs medications administered through the pharmacy benefit (Sharp Health Plan Pharmacy Procedure for Formulary and Pharmaceutical Management Procedures Development

This policy provides information about the use of the following drugs for the treatment of multiple sclerosis:

Drug	Dose
Briumvi (ublituximab)	150mg IV day 1, then 450mg 2 weeks later, then 450mg every 24 weeks (beginning 24 weeks after 150mg dose)

IV. DEFINITIONS

- A. A Qualified Individual is a Sharp Health Plan (Plan) member.
- B. Experimental and Investigational drugs and devices:
 - 1. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.
 - 2. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.
- C. Biosimilars: A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the original biologic or reference product). Biosimilars are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar provides the same treatment benefits as the original biologic.
- D. Injection: The introduction of a medicinal substance into the body; either subcutaneous, intramuscular, intravenous, intra-arterial or into other canals or cavities of the body. For purposes of this medical policy, a medication is provided either by a member (self-injectable) or by a medical provider. It is a “shot” or a dosage of medication given by way of a syringe and needle rather than over a period of time, though not to be given as part of a procedure.
- E. Infusion: The slow diagnostic, prophylactic, or therapeutic introduction of fluid or medicinal substance into a vein or tissue given over a period of time.
- F. Multiple sclerosis is a chronic, progressive disease caused by immune-mediated damage to the myelin

sheaths of nerves in the central nervous system. Relapsing-remitting multiple sclerosis is characterized by clear periods of relapse followed by partial or complete recovery. Secondary progressive multiple sclerosis starts as relapsing-remitting, then develops into ongoing progression without remission. Primary progressive multiple sclerosis involves long-term progression without relapses or remission.

- G. Clinically isolated syndrome is defined as a first episode of neurologic symptoms consistent with demyelination. Clinically isolated syndrome may be a precursor to multiple sclerosis.

V. MEDICAL NECESSITY

- A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership.
- B. Additionally, the provision of physician samples does not guarantee coverage.
- C. Medications must be prescribed from a contracted Plan provider.
- D. **Ublituximab (Briumvi)**
1. **INITIAL CRITERIA:** Ublituximab is considered medically necessary for members who meet **all** of the following criteria for an initial authorization:
 - a. Member has **one** of the following documented diagnoses:
 - i) **Relapsing Forms of Multiple Sclerosis**, including relapsing-remitting disease, clinically isolated syndrome, and secondary progressive disease for those who continue to experience relapse. In addition, member meets ONE of the following:
 - (a) Member must have tried and failed two of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: oral fumarates, oral spingosine 1-phosphate receptor (S1PR) modulators, glatiramer, interferon beta-1a/b, or teriflunomide; OR,
 - (b) Member is noted by neurologist to have highly active disease.
 - b. Member will not use Ublituximab concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.
 2. **REAUTHORIZATION CRITERIA:**
 - a. Member met initial criteria.
 - b. For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Briumvi.

VI. NOT MEDICALLY NECESSARY

- A. The Plan is not required to cover services or benefits that are not otherwise covered under the terms and conditions of the Plan contract.

VII. PROCEDURE/ATTACHMENTS

- A. Review and confirm the member's coverage benefit for the member's specific member

VIII. CODES: N/A

IX. REFERENCES

- A. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc., January 2023.
- B. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018 Apr 24;90(17):777-788.
- C. UpToDate, 2025. Olek MJ, Howard J. Management of clinically and radiologically isolated syndromes suggestive of multiple sclerosis. Retrieved online from <https://www.uptodate.com/contents/management-of-clinically-and-radiologically-isolated-syndromes-suggestive-of-multiple-sclerosis>.
- D. UpToDate, 2025. Olek, MJ, Mowry, E. Treatment of primary progressive multiple sclerosis in adults. Retrieved online from <https://www.uptodate.com/contents/treatment-of-primary-progressive-multiple-sclerosis-in-adults>.
- E. UptoDate, 2025. Olek, MJ, Mowry, E. Initial disease-modifying therapy for relapsing-remitting multiple sclerosis in adults. Retrieved only from <https://www.uptodate.com/contents/initial-disease-modifying-therapy-for-relapsing-remitting-multiple-sclerosis-in-adults>.

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
6/25/25	Original

Approved by: (Signature of VP /CMO) 	Approval date: 6/25/25
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