

STANDARD MEDICARE PART B MANAGEMENT

BRIUMVI (ublituximab-xiyy)

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 Indication

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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. 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.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Briumvi.
- B. Briumvi is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

- 1. The prescribing information for Briumvi.
- 2. The available compendium

Reference number(s)
5738-A

- a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- b. Micromedex DrugDex
- c. American Hospital Formulary Service- Drug Information (AHFS-DI)
- d. Lexi-Drugs
- e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Briumvi are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; December 2022.