POLICY Document for BRIUMVI (ublituximab-xiiy)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Intravenous Briumvi

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT-HOSPITAL SETTING

This policy provides coverage for administration of Briumvi in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Briumvi in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
C. The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
E. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home
F. The member is less than 14 years of age.

For situations where administration of the Briumvi does not meet the criteria for outpatient hospital infusion, coverage for the Briumvi is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

CVS/caremark

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
B. Medical records supporting the member is medically unstable
C. Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
E. Records supporting alternative infusion sites are greater than 30 miles from the member's home.
F. Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management
Briumvi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-Counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Briumvi	ublituximab-xiiy

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[1]

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 are considered experimental/investigational and not medically necessary.

Prescriber Specialties

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

Coverage Criteria

Relapsing Forms of Multiple Sclerosis[1]

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[1]

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

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Briumvi.

Other

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

REFERENCES

SECTION 1

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

SECTION 2

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