POLICY NUMBER: RX.PA.080.MPC
REVISION DATE: 07/2023

RX.PA.080.MPC Briumvi (ublituximab-xiiy**)**

The purpose of this policy is to define the prior authorization process for Briumvi™ (ublituximab-xiiy) intravenous infusion

Briumvi, a CD20-directed cytolytic antibody, 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.

PROCEDURE

A. Initial Authorization Criteria:

1. **Multiple Sclerosis. All requests must meet the following criteria:**
   - Must be age 18 years or older
   - Must have a documented diagnosis of relapsing form of multiple sclerosis
     Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
   - Must have experienced at least one relapse in the previous year, two relapses in the previous two years, or has a presence of a T1 gadolinium (Gd) enhancing lesion in the previous year
   - Must have a documented baseline Expanded Disability Status Scale (EDSS) score of 0 to 5.5
   - Must be prescribed by or in consultation with a neurologist
   - Dose does not exceed FDA approved indication
   - Patient has a documented Hepatitis B virus screening and quantitative serum immunoglobulin screening before first initial dose
   - Patient must not have an active infection
   - Must have a documented trial and failure for at least 3 months, contraindication to, or intolerance to two of the following multiple sclerosis treatments:
     - Dimethyl fumarate
     - Glatiramer acetate
     - Interferon β-1b
     - Interferon β-1a
   - Must have a documented trial and failure for at least 3 months, contraindication to, or intolerance to Rituximab or its biosimilars
   - Must not use Briumvi concurrently with other disease modifying agents used for multiple sclerosis such as Aubagio, Kesimpta, Ocrevus, Tysabri, etc.

B. Reauthorization Criteria:

1. Multiple Sclerosis

MPC Renewal:

- All prior authorization renewals are reviewed on a 6 month interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a clinical response, as determined by the prescriber
- Patient meets one of the following [a or b]:
    a. Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.
    b. Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation
- Must be prescribed by or in consultation with a neurologist
- Must not use Briumvi concurrently with other disease modifying agents used for multiple sclerosis such as Aubagio, Kesimpta, Ocrevus, Tysabri, etc.

Non-MPC Renewal:

- Members who have previously been taking Briumvi (ublituximab-xiiy) and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for Briumvi (ublituximab-xiiy)
- Provider has a documented clinical response of the member's condition which has improved based or stabilized upon the prescriber's assessment

C. Briumvi (ublituximab-xiiy) will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 6 months

Codes:

Code	Description
J2329	Injection, ublituximab-xiiy, 1mg

REFERENCES

1. Briumvi™ intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on December 30, 2022.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. The Medical Letter on Drugs and Therapeutics. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*07/2023*