

Briumvi (ublituximab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple sclerosis (MS) is a chronic autoimmune disorder that affects the central nervous system (CNS), which includes the brain, spinal cord, and optic nerves. The immune system mistakenly attacks and damages the myelin sheath that surrounds and protects nerve fibers, causing communication problems between the brain and the rest of the body. This results in a wide range of symptoms, including vision problems, muscle weakness, fatigue, and difficulty with balance and coordination.

MS is a progressive disease, meaning that symptoms tend to worsen over time, and it can be classified into several types, including relapsing-remitting MS (RRMS), primary progressive MS (PPMS), and secondary progressive MS (SPMS).

Currently, there is no cure for MS, but various treatment options are available to manage symptoms, slow the progression of the disease, and improve quality of life.

- Disease-modifying therapies (DMTs) are a class of medications that target the immune system to reduce inflammation and slow down the progression of the disease. The type of DMT prescribed

will depend on the type and severity of MS, as well as the individual's medical history and preferences. Some common DMTs include interferon beta, glatiramer acetate, dimethyl fumarate, and fingolimod.

- Corticosteroids, such as prednisone, can be prescribed to reduce inflammation during acute MS relapses or exacerbations. These medications can help shorten the duration of symptoms and improve recovery.
- Symptomatic treatments are also available to manage specific symptoms of MS, such as muscle spasms, bladder problems, and depression. Physical therapy, occupational therapy, and speech therapy can help individuals with MS maintain mobility, independence, and communication skills.

Briumvi (ublituximab) 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.

Definitions

“CIS” or “clinically isolated syndrome” refers to the first symptomatic episode lasting at least 24 hours caused by inflammation and demyelination in the central nervous system. This episode is characteristic of multiple sclerosis but does not always result in a person developing MS. Early treatment of CIS has been shown to delay the onset of MS.

“Compendia” are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

“Disease modifying therapy” refers to treatments found to reduce the number of relapses, delay progression of disability, and limit new disease activity according to research and clinical trials.

“Immunoglobulins”, also known as antibodies, are proteins produced by the immune system in response to an invading pathogen, such as a virus or bacteria. They play a critical role in recognizing and

neutralizing foreign substances and protecting the body from infections. There are five main classes of immunoglobulins: IgA, IgD, IgE, IgG, and IgM, each with a different structure and function.

“MRI” or “Magnetic Resonance Imaging” refers to a medical imaging technique that creates detailed three-dimensional (3D) images of the organs and tissues in your body. A brain MRI can reveal areas of active MS disease called lesions within the central nervous system.

“Quantitative” refers to a measurement or evaluation that provides numerical data or information. Quantitative measurement of immunoglobulins in the serum can be used to assess immune function and diagnose certain conditions, such as immunodeficiency disorders and autoimmune diseases.

“Relapse” refers to an attack or exacerbation of MS (also known as a flare-up) resulting in the occurrence of new symptoms or the worsening of old symptoms.

“RRMS” or “relapsing-remitting MS” refers to the most common type of MS in which there are clearly defined attacks or relapses of increasing neurologic symptoms followed by periods of partial or complete recovery or remissions.

“Serum” refers to the clear, yellowish liquid that remains after blood has clotted and the clot has been removed. It contains various proteins, electrolytes, hormones, and other substances that are important for bodily functions.

“SPMS” or “secondary progressive MS” refers to a version of disease progression that can follow an initial relapsing-remitting course in which there is a worsening of neurologic function and increased disability over time.

Medical Necessity Criteria for Initial Authorization

The Plan considers Briumvi (ublituximab) medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with a neurologist; **AND**
2. The member is 18 years of age or older; **AND**
3. The member has **ONE** of the following forms of multiple sclerosis:
 - a. relapsing-remitting (RRMS); **or**
 - b. active secondary progressive (SPMS); **or**
 - c. clinically isolated syndrome (CIS); **AND**
4. Documentation of **BOTH** of the following:

- a. Hepatitis B virus (HBV) screening; **and**
 - b. testing for quantitative serum immunoglobulins; **AND**
5. The member does **NOT** have ANY of the following:
- a. active hepatitis B virus (HBV) infection, as evidenced by positive results for HBsAg and anti-HB tests; **or**
 - b. an active infection; **or**
 - c. documentation indicating that the member will use Briumvi (ublituximab) concomitantly with other immune-modulating or immunosuppressant drugs for the treatment of multiple sclerosis (e.g., ocrelizumab, natalizumab, ofatumumab); **or**
 - d. primary progressive multiple sclerosis (PPMS); **AND**
6. Briumvi (ublituximab) will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
7. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, the requested medication will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 6 months will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. chart documentation shows **ONE** of the following:
 - a. The member has shown a clinical improvement (e.g., reduction in neurologic disability and/or the frequency of clinical relapses) in symptoms since starting the requested medication; **or**
 - b. The member has experienced disease stability since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Briumvi (ublituximab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
J2329	Injection, ublituximab-xiyy, 1mg
ICD-10 codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
G35	Multiple Sclerosis

References

1. Briumvi (ublituximab) [prescribing information]. Morrisville, NC: TG Therapeutics, Inc; December 2022.
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3. Montalban X et al:ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. *Eur J Neurol*. 25(2):215-37, 2018
4. Rae-Grant A et al: Comprehensive systematic review 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*. 90(17):789-800, 2018
5. Rae-Grant A et al: 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*. 90(17):777-88, 2018
6. Steinman L, Fox E, Hartung HP, et al; ULTIMATE I and ULTIMATE II Investigators. Ublituximab versus teriflunomide in relapsing multiple sclerosis. *N Engl J Med*. 2022;387(8):704-714. doi:10.1056/NEJMoa2201904

Clinical Guideline Revision / History Information

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