Oscar Clinical Guideline: Briumvi (ublituximab) (PG134, Ver. 5)

Briumvi (ublituximab)

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), a recombinant human anti-CD20 monoclonal 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. Briumvi (ublituximab) is an intravenous infusion administered every 24 weeks, following an initial dosing schedule. weeks.

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.

"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.

"Relapse" refers to an attack or exacerbation of MS (also known as a flare-up) resulting in the occurrence 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 recent (within the last 3 months) clinical chart documentation provided indicates the member meets ALL of the following:

1. Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis*; 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. Meets ONE of the following:
    a. Documentation of highly active or aggressive disease, as demonstrated by at least ONE of the following:
        i. Frequent relapses (≥2 in the past year)*; or*
        ii. At least 1 relapse with incomplete recovery and MRI activity*; or*
        iii. Rapidly advancing disability or cognitive impairment*; or*
        iv. Disabling relapse with suboptimal response to corticosteroids*; or*
        v. MRI findings showing high disease activity (e.g., new/enlarging T2 lesions, enhancing lesions)*; or*
    b. Is unable to use, or has tried and failed at least ONE of the following:
        i. Dimethyl Fumarate (generic Tecfidera)*; and/or*
        ii. Fingolimod (generic Gilenya); *AND*
5. Has been screened for hepatitis B virus AND does not have active infection; *AND*
6.
7. Briumvi (ublituximab) will be used as monotherapy for multiple sclerosis (i.e., member is not using and will not use other disease-modifying MS therapies while on Briumvi)*; AND*
8. Briumvi (ublituximab) will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

- *First dose: 150 mg administered by intravenous infusion.*
- *Second dose: 450 mg administered by intravenous infusion 2 weeks after the first infusion.*
- *Subsequent doses: 450 mg administered by intravenous infusion every 24 weeks after the first infusion.*

If the above prior authorization criteria are met, the requested medication will be approved for up to 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if the member has recent (within the last 6-months) clinical documentation showing BOTH of the following:

1. The requested medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member has experienced at least ONE of the following:
    a. Improvement in at least ONE objective measure, such as:
        i. Reduced disease activity on MRI*; and/or*
        ii. Improved or stable disability scores*; and/or*
        iii. Reduced relapse rate*; and/or*
        iv. Improved fatigue or walking assessments; *AND/OR*
    b. The member has shown stabilization or improvement in at least ONE MS symptom, such as:
        i. Motor function*; and/or*
        ii. Fatigue*; and/or*
        iii. Vision*; and/or*
        iv. Bowel/bladder function*; and/or*
        v. Spasticity*; and/or*
        vi. Walking/gait*; and/or*
        vii. Pain/numbness/tingling.

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. Non-covered indications include, but are not limited to, the following:

- Treatment of non-relapsing forms of multiple sclerosis (e.g., primary progressive MS).
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- Use in combination with other disease-modifying therapies for MS.
- Use in pediatric members (under 18 years of age).

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
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-xiiy, 1mg
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
G35	Multiple Sclerosis

References

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3. Fox E, Lovett-Racke AE, Gormley M, et al,. A phase 2 multicenter study of ublituximab, a novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis. Mult Scler. 2021 Mar;27(3):420-429. doi: 10.1177/1352458520918375. Epub 2020 Apr 30.
4. Montalban X et al: ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. Eur J Neurol. 25(2):215-37, 2018
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6. 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.
7. Samjoo IA, Drudge C, Walsh S, et al,. Comparative efficacy of therapies for relapsing multiple sclerosis: a systematic review and network meta-analysis. J Comp Eff Res. 2023 Jul;12(7):e230016. doi: 10.57264/cer-2023-0016. Epub 2023 Jun 2.
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Clinical Guideline Revision / History Information

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