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Medication Policy Manual

Policy No: dru739

Topic: Briumvi, ublituximab-xiiy

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Next Review Date: 2023

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IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Briumvi (ublituximab-xiiy) is an intravenously administered medication indicated for the treatment of relapsing forms of multiple sclerosis. It works by destroying certain immune cells that are involved in the multiple sclerosis immune response.

Policy/Criteria

Most contracts require pre-authorization approval of Briumvi (ublituximab-xiiy) prior to coverage.

I. Continuation of therapy (COT): Briumvi (ublituximab-xiiy) may be considered medically necessary for COT when full policy criteria below are met.

II. New starts (treatment-naïve patients): Briumvi (ublituximab-xiiy) may be considered medically necessary when Site of Care administration requirements are met [refer to Medication Policy Manual, Site of Care Review, dru408].

III. Administration, Quantity Limitations, and Authorization Period

A. Regence Pharmacy Services considers Briumvi (ublituximab-xiiy) coverable only under the medical benefit (as a provider-administered medication).

B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met, and that the medication is effective. Clinical documentation (including, but not limited to chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, such as disease stability or improvement.

Position Statement

Summary

- Briumvi (ublituximab-xiiy) is a monoclonal antibody used as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis (MS).
- Briumvi (ublituximab-xiiy) is considered a disease-modifying multiple sclerosis treatment. Other disease-modifying multiple sclerosis treatments for relapsing forms of MS include Lemtrada (alemtuzumab), interferon beta products (Avonex, Rebif, Betaseron, Extavia, or Plegridy), fingolimod (generic, Gilenya, Tascenso ODT), glatiramer acetate, Aubagio (teriflunomide), and dimethyl fumarate. Rituximab may also be used off label for the treatment of relapsing forms of MS. [1]
- Briumvi (ublituximab-xiiy) has not been studied in combination with other disease-modifying MS medications and it is therefore not recommended that Briumvi (ublituximab-xiiy) be administered concomitantly with other disease-modifying MS medications as efficacy and safety have not been established. Concomitant use of Briumvi (ublituximab-xiiy) with any other disease-modifying therapy for MS is considered investigational.
- Briumvi (ublituximab-xiiy) is an intravenously infused medication. The starting dose is 150 mg given day one followed by a second infusion of 450 mg given two weeks later. Thereafter, Briumvi (ublituximab-xiiy) is given 24 weeks after the first infusion and every subsequent 24 weeks at a dose of 450 mg.
- The safety and effectiveness of Briumvi (ublituximab-xiiy) in conditions other than relapsing forms of MS have not been established.

Clinical Efficacy in Multiple Sclerosis [2-4]

- Briumvi (ublituximab-xiiy) has been shown to significantly reduce annual relapse rate (ARR) and slow worsening of disease based on MRI outcomes in patients with relapsing forms of MS when compared to Aubagio (teriflunomide).
    * Two identical, phase 3, randomized, double-blind, double dummy, active control 96-week studies (ULTIMATE I and ULTIMATE II, total N=1089), evaluated the effects of Briumvi (ublituximab-xiiy) compared to Aubagio (teriflunomide) in patients with relapsing forms of MS. Briumvi (ublituximab-xiiy) was significantly superior to teriflunomide in reducing annualized relapse (relative risk reduction of 59% in ULTIMATE I and 49% in ULTIMATE II). On MRI outcomes, the patients in the Briumvi (ublituximab-xiiy) groups had significantly fewer new and/or enlarging T2 lesions, and less T1 lesions relative to the Aubagio (teriflunomide) groups.

Safety [5]

- Briumvi (ublituximab-xiiy) contains warnings for infusion reactions, infections, reduction in immunoglobulins, and fetal risk.
- Common adverse events include infusion reactions and upper respiratory tract infections.

Dosing and Administration [5]

- Briumvi (ublituximab-xiiy) is administered as an intravenous (IV) infusion.
- The starting dose is 150 mg IV followed by 450 mg IV two weeks later. Subsequent doses of Briumvi (ublituximab-xiiy) are then given at 24-week intervals from the first infusion at a dose of 450 mg IV as a single infusion.

Briumvi (ublituximab-xiiy) – Use in Other Conditions

- Due to a lack of published data, the use of Briumvi (ublituximab-xiiy) in conditions other than relapsing forms of MS is considered investigational.
- While Briumvi (ublituximab-xiiy) has a similar mechanism of action to rituximab, it has not been studied for the same indications. Thus, due to a lack of data, these conditions are considered investigational.

Appendix A: Disease-Modifying Agents Used in the Treatment of Multiple Sclerosis (MS)
Aubagio (teriflunomide)
Bafiertam (monomethyl fumarate)
Briumvi (ublituximab-xiiy)
Dimethyl fumarate
Fingolimod (generic, Gilenya, Tascenso ODT)
Glatiramer acetate
Interferon beta-1a (Avonex, Rebif)
Interferon beta-1b (Betaseron, Extavia)
Kesimpta (ofatumumab)
Lemtrada (alemtuzumab)
Mavenclad (cladribine)
Mayzent (siponimod)
Novantrone (mitoxantrone)
Ocrevus (ocrelizumab)
Plegridy (peginterferon beta-1a)
Ponvory (Ponesimod)
Rituximab[1]
Tysabri (natalizumab)
Vumerity (diroximel fumarate)
Zeposia (ozanimod)

[1] Rituximab is not FDA-approved for use in MS, but has evidence for efficacy.

Cross References
Site of Care Review, Medication Policy Manual, Policy No. dru408
Non-preferred glatiramer products, Medication Policy Manual, Policy No. dru570
Non-preferred multiple sclerosis treatments, Medication Policy Manual, Policy No. dru511
Ocrevus, ocrelizumab, Medication Policy Manual, Policy No. dru479
Tysabri, natalizumab, Medication Policy Manual, Policy No. dru111
Zeposia, ozanimod, Medication Policy Manual, Policy No. dru674

References

1. Rae-Grant A, Day GS, Marrie RA, 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*. 2018;90:777-88. PMID: 29686116
2. Steinman L, Fox E, Hartung HP, et al. Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis. *The New England journal of medicine*. 2022;387(8):704-14. PMID: 36001711
3. Center for Drug Evaluation and Research; U.S. Food and Drug Administration Clinical Review for NDA 761238; ublituximab (Briumvi™). [cited 02/09/2023]. 'Available from:' https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761238Orig1s000MedR.pdf.
4. Institute for Clinical and Economic Review (ICER). Oral and Monoclonal Antibody Treatments for Relapsing Forms of Multiple Sclerosis: Effectiveness and Value. Evidence Report. December 21,.2022.
5. Briumvi® [prescribing information]. Morrisville, SC: TG Therapeutics, Inc.; December 2022

Revision History

Revision Date	Revision Summary
3/16/2023	New policy (Effective 4/15/2023): • Added Briumvi (ublituximab-xiiy) to site of care program.

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