PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Multiple Sclerosis – CD20-Directed Cytolytic Antibody Infused Products Preferred Specialty Management Policy

- Briumvi® (ublituximab-xiiy intravenous infusion – TG Therapeutics)
- Ocrevus® (ocrelizumab intravenous infusion – Genentech)

REVIEW DATE: 03/01/2023

OVERVIEW

This Preferred Specialty Management policy involves the use of CD20-directed cytolytic antibody infused products used for **multiple sclerosis**. Briumvi and Ocrevus are both indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive multiple sclerosis in adults.[1,2] Ocrevus is also indicated for the treatment of primary progressive multiple sclerosis in adults.[2] Of note, Ocrevus is the only agent FDA-approved for use in the treatment of primary progressive multiple sclerosis.

POLICY STATEMENT

The Multiple Sclerosis Preferred Specialty Management Program for CD20-Directed Cytolytic Antibody Infused Products has been developed to encourage the use of the Preferred Products (generic glatiramer injection, generic dimethyl fumarate delayed-release capsules, and generic fingolimod capsules). For all medications (Preferred and Non-Preferred) the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The Program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting a Non-Preferred Product meets the standard *Prior Authorization Policy* criteria but has not tried one Preferred Product, an offer to review for the Preferred Products will be made.

Automation: None.

Preferred Products:	generic glatiramer injection, OR generic dimethyl fumarate delayed-release capsules, OR generic fingolimod capsules
Non-Preferred Products:	Briumvi, Ocrevus

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Briumvi	**1.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Briumvi Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been started on Briumvi; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient has previously received one of Tysabri (natalizumab intravenous infusion), Ocrevus (ocrelizumab intravenous infusion), Kesimpta (ofatumumab subcutaneous injection), Mavenclad (cladribine tablets), or Lemtrada (alemtuzumab intravenous infusion). **2.** If the patient meets the standard *Multiple Sclerosis – Briumvi Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Ocrevus	**1.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Ocrevus Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, v, or vi): **i.** Patient has been started on Ocrevus; OR **ii.** Patient has primary progressive multiple sclerosis; OR **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **vi.** Patient has previously received one of Tysabri (natalizumab intravenous infusion), Briumvi (ublituximab-xiiy intravenous infusion), Kesimpta (ofatumumab subcutaneous injection), Mavenclad (cladribine tablets), or Lemtrada (alemtuzumab intravenous infusion). **2.** If the patient meets the standard *Multiple Sclerosis – Ocrevus Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

REFERENCES

1. Briumvi® intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.
2. Ocrevus® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; August 2022.