Reference number(s)
6644-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Multiple Sclerosis

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Medical Benefit and Medical Benefit Advanced Biosimilars First.

Plan Design Summary

This program applies to the multiple sclerosis products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Tyruko. This program also applies to members who are new to treatment with Briumvi or Lemtrada for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis (MS) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Ocrevus (ocrelizumab) • Tysabri (natalizumab)
Target	• Briumvi (ublituximab-xiiy) • Lemtrada (alemtuzumab) • Tyruko (natalizumab-sztn)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Briumvi

Coverage for Briumvi is provided when either of the following criteria is met:

- Member is currently receiving treatment with Briumvi, excluding when Briumvi is obtained as samples or via manufacturer's patient assistance programs.
- Member meets both of the following criteria:
  - Member has a documented intolerable adverse event to Ocrevus.
  - Member has a documented inadequate response, intolerable adverse event, or contraindication with Tysabri.

Lemtrada

Coverage for Lemtrada is provided when either of the following criteria is met:

- Member is currently receiving treatment with Lemtrada, excluding when Lemtrada is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response, intolerable adverse event, or contraindication with both of the preferred products (including any of their components).

Tyruko

Coverage for Tyruko is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to Tysabri, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).
- Member has a documented inadequate response, intolerable adverse event, or contraindication with Ocrevus.

References

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; December 2022.
2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Tysabri [package insert]. Cambridge, MA: Biogen Inc; October 2023.
5. Tyruko [package insert]. Princeton, NJ: Sandoz Inc.; August 2023.