This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**		**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
6398-D

EXCEPTIONS CRITERIA

MULTIPLE SCLEROSIS PRODUCTS

PREFERRED PRODUCTS: OCREVUS AND TYRUKO

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the multiple sclerosis products specified in this policy. 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 members who are new to treatment with a targeted product for the first time.

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

Table. Multiple Sclerosis (MS) Products

	Products
Preferred*	• **Ocrevus** (ocrelizumab) • **Tyruko** (natalizumab-sztn)
Targeted	• **Briumvi** (ublituximab-xiiy) • **Lemtrada** (alemtuzumab) • **Tysabri** (natalizumab)

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

II. EXCEPTION CRITERIA

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

A. Briumvi and Lemtrada

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with both of the preferred products or any of their components.

B. Tysabri

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

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**		**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
6398-D

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets both of the following criteria:
   a. Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Ocrevus, or any of its components.
   b. Member has a documented intolerable adverse event to the preferred product, Tyruko, 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 products).

REFERENCES

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