POLICY Document for Ocrevus

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA

MULTIPLE SCLEROSIS

PREFERRED PRODUCTS: TYSABRI and OCREVUS

POLICY
This policy informs prescribers of preferred products and provides an exception process for non-preferred 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 the targeted product.

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

Table. Multiple sclerosis (MS) products

	Product(s)
Preferred	• **Ocrevus** (ocrelizumab) • **Tysabri** (natalizumab)
Targeted	• **Lemtrada** (alemtuzumab)

II. EXCEPTION CRITERIA

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

Coverage for the targeted product is provided when any of the following criteria is met:

1. Member is currently receiving treatment with the targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs.

2. Member has experienced documented inadequate response(s) and/or intolerable adverse event(s) to treatment with BOTH of the preferred products.
3. Member has documented contraindications to therapy with BOTH of the preferred products (including any of their components).

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

OCREVUS (ocrelizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications:

Ocrevus is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Ocrevus is also indicated for the treatment of primary progressive MS, in adults.

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

A. Relapsing Forms of Multiple Sclerosis
Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

B. Clinically isolated syndrome
Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

C. Primary Progressive Multiple Sclerosis
Authorization of 12 months may be granted to members for the treatment of primary progressive MS.

III. CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Ocrevus.

IV. OTHER CRITERIA

Members will not use Ocrevus concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.

REFERENCES

SECTION 1

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; December 2017.
2. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; March 2017.
3. Tysabri [package insert]. Cambridge, MA: Biogen Inc; April 2018.

SECTION 2

1. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; July 2019.