This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
3431-D

POLICY Document for LEMTRADA

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, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section 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 PRODUCT: TYSABRI

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 for the first time.

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

Table. Multiple sclerosis (MS) products

	Product(s)
Preferred	• **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.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3431-D

Coverage for the targeted product is provided when any of the following criteria is met:
A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response, intolerance or contraindication to therapy with the preferred product or any of its components.

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

LEMTRADA (alemtuzumab)

POLICY

I. INDICATIONS

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

FDA-Approved Indication

Lemtrada is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use

Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3431-D

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Multiple Sclerosis

Authorization of 30 days may be granted for treatment of relapsing forms of MS when the member had an inadequate response to two or more drugs for relapsing MS (e.g., interferons or other agents) despite adequate duration of treatment or the member has a clinical reason to avoid such treatments.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 30 days may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Lemtrada.
B. Lemtrada is being used to treat an indication enumerated in Section II.
C. The member received the previous course of treatment at least 12 months prior to the planned date of the next course of Lemtrada.
D. The member is receiving benefit from therapy.

REFERENCES:

SECTION 1

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; July 2019.
2. Tysabri [package insert]. Cambridge, MA: Biogen Inc; August 2019.

SECTION 2

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; October 2019.