

This policy applies to the following:

|  |                  |  |          |  |                                   |  |                                    |   |                                    |                       |
|--|------------------|--|----------|--|-----------------------------------|--|------------------------------------|---|------------------------------------|-----------------------|
|  | Standard Opt-in  |  | PDPD     |  | Marketplace                       |  | Medical Benefit                    | ✓ | Medicare Part B                    | Reference #<br>3431-D |
|  | 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            |                       |

## 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)                      |
|------------------|---------------------------------|
| <b>Preferred</b> | • <b>Tysabri</b> (natalizumab)  |
| <b>Targeted</b>  | • <b>Lemtrada</b> (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:

- 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.

#### REFERENCES

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