Reference number(s)
3431-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☐

Medicare Part B Step Therapy Multiple Sclerosis

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

These criteria were developed to align with the following: Medicare Part B

Plan Design Summary

This program applies to the multiple sclerosis products specified in this document. Coverage for the non-preferred product is provided based on clinical circumstances that would exclude the use of the preferred product 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis

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

	Product(s)
Preferred	• Ocrevus (ocrelizumab) • Tysabri (natalizumab)
Non-preferred	• Briumvi (ublituximab-xiiy) • Lemtrada (alemtuzumab) • Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) • Tyruko (natalizumab-sztn)

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Step Therapy Criteria

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

Lemtrada or Briumvi

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

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

Ocrevus Zunovo

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

- Member has received treatment with the non-preferred product in the past 365 days.
- Member meets both of the following criteria:
    - Member has had a documented intolerable adverse event with the preferred product, Ocrevus, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
    - Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Tysabri, or any of its components.

Tyruko

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

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

References

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc.; November 2024.
2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Ocrevus Zunovo [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
5. Tyruko [package insert]. Princeton, NJ: Sandoz Inc.; August 2023.
6. Tysabri [package insert]. Cambridge, MA: Biogen Inc.; March 2025.