Reference number(s)
1633-A

Standard Medicare Part B Management Tysabri-Tyruko

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tysabri	natalizumab
Tyruko	natalizumab-sztn

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 Indications[1,2]

- As monotherapy 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.
- For inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor alpha (TNF-α).

Limitations of Use

In CD, Tysabri and Tyruko should not be used in combination with immunosuppressants or inhibitors of TNF-α.

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

Documentation

The following documentation must be available, upon request, for all submissions:

Crohn's disease (CD)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting benefit of therapy.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis[1,2]

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) and who have been tested for anti-John Cunningham virus (JCV) antibodies.

Clinically Isolated Syndrome[1,2]

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis and who have been tested for anti-JCV antibodies.

Crohn's Disease (CD)[1-4]

Authorization of 12 months may be granted to members who have received any other biologic indicated for the treatment of moderately to severely active Crohn's disease and who have been tested for anti-JCV antibodies.

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Continuation of Therapy

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

All Indications

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tysabri and Tyruko
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- ACG Clinical Guideline: Management of Crohn's disease in adults
- An Evidence-Based Systematic Review on Medical Therapies for Inflammatory Bowel Disease

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tysabri and Tyruko are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Tysabri [package insert]. Cambridge, MA: Biogen Inc.; March 2025.
2. Tyruko [package insert]. Princeton, NJ: Sandoz Inc; August 2023.
3. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.

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4. Lichtenstein GR, Loftus EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120(6):1225-1264.

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