Reference number(s)
1633-A

STANDARD MEDICARE PART B MANAGEMENT

TYSABRI (natalizumab)

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 Indications

A. 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.
B. 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 TNF- α.

Important Limitations:
In CD, Tysabri should not be used in combination with immunosuppressants or inhibitors of TNF-α.

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. DOCUMENTATION

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

Crohn's disease (CD):

A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. 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. Crohn's Disease (CD)
Authorization of 12 months may be granted for treatment of moderately to severely active CD in members who have had an inadequate response to, or has a clinical reason to avoid, conventional CD therapies and inhibitors of TNF-α and who have been tested for anti-JCV antibodies.

IV. CONTINUATION OF THERAPY

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

A. Relapsing forms of multiple sclerosis and clinically isolated syndrome
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Tysabri
2. The member is receiving benefit from therapy.

B. Crohn's disease
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Tysabri
2. The member is receiving benefit from therapy. Benefit is defined as one of the following:
    i. Member has achieved or maintained remission.
    ii. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
        a. Abdominal pain or tenderness
        b. Diarrhea
        c. Body weight
        d. Abdominal mass
        e. Hematocrit
        f. Endoscopic appearance of the mucosa
        g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Tysabri.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. ACG Clinical Guideline: Management of Crohn's disease in adults
4. 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 are covered.

VI. EXPLANATION OF RATIONALE

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

VII. REFERENCES

1. Tysabri [package insert]. Cambridge, MA: Biogen Inc; June 2022.
2. 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.
3. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.