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

1. 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.
2. 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. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
Authorization of 24 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 24 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

C. Crohn's Disease (CD)
Authorization of 24 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.

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 24 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Tysabri
2. Tysabri is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy.

IV. REFERENCES

1. Tysabri [package insert]. Cambridge, MA: Biogen Idec, Inc; June 2020.