SPECIALTY GUIDELINE 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. Moderately to severely active Crohn's disease (CD)
B. Relapsing forms of multiple sclerosis (MS)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Moderately to severely active Crohn's disease (CD)

1. Authorization of 24 months may be granted to members who have received Tysabri or any other biologic indicated for the treatment of Crohn's disease in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Tysabri.

2. Authorization of 24 months may be granted for members who have an inadequate response, intolerance or contraindication to BOTH of the following:
   a. At least ONE conventional therapy option (See Appendix)
   b. At least ONE TNF-alpha inhibitor indicated for CD:
      i. Humira (adalimumab)
      ii. Remicade (infliximab)
      iii. Cimzia (certolizumab)

B. Relapsing forms of multiple sclerosis (MS)

Authorization of 24 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis.

III. CONTINUATION OF THERAPY

A. Crohn's disease

Authorization of 24 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Tysabri as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. Multiple sclerosis (MS)

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria.

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IV. APPENDIX

Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
   a. Oral budesonide, oral mesalamine
   b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
   a. Prednisone, methylprednisolone intravenously (IV)
   b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission
   a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM

V. REFERENCES

1. Tysabri [package insert]. Cambridge, MA: Biogen Idec, Inc; May 2016.
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.

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