PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	**Tysabri (natalizumab)**
BENEFIT TYPE	

2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active CD; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least one of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate. Note: Trial is not required if member is switching from another biologic agent; AND
5. Member has tried and failed an anti-TNF drug (e.g., Cimzia, Humira, Remicade) unless not tolerated or contraindicated. Note: trial is not required if member has multiple sclerosis and CD; AND
6. Medication is not being used in combination with immunosuppressants or TNF-alpha inhibitors.
7. **Dosage allowed/Quantity limit**: 300 mg intravenous infusion every 4 weeks. (1 vial per 28 days).

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, ability to taper off corticosteroid, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tysabri (natalizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Tysabri created. Policy SRx-0041 archived. For diagnosis of CD: trial of Humira required. For RRMS and SPMS diagnoses trial of two formulary agents required. List of diagnoses considered not medically necessary was added.
12/06/2017	Age coverage expanded.
02/26/2019	Humira trial removed from criteria for CD.
11/23/2020	For CD: Changed the trial to only ask for 1 conventional therapy rather than 2. Also added a trial of an anti-TNF in accordance with package insert and guidelines. Changed initial auth to 3 months to observe benefit (must discontinue if no benefit after 3 months).
07/15/2022	Transferred to new template. MS: Updated and added references. Specified types of MS indicated. Added highly active disease option as alternative to trying 2 other drugs first. Specified that the JCV test should be negative. Added clinical criteria for renewal. CD: Added ability to taper off steroids as option to meet renewal criteria.
11/16/2023	Removed JCV antibody test requirement.
01/25/2024	Approved by ODM

References:

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