Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Tysabri (natalizumab)	Policy #:	1849P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Tysabri.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Tysabri under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Active Crohn's Disease

1.1 Ordered by a Gastroenterologist (stomach doctor)

1.2 Age 18 years or older

1.3 Documented moderate to severe active Crohn's Disease (patients with prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea and vomiting, or anemia), meeting one of the following two requirements:

- Hospitalization due to severe Crohn's Disease or documentation that member's disease is severe enough that member cannot wait for the effect of other therapies
- Documented failure, intolerance, or contraindication to treatments used in mild to moderate disease
  - Corticosteroids
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)

1.4 Documented failure, intolerance, or contraindication to any one of the following:

- Covered adalimumab biosimilars
- Cimzia
- Covered ustekinumab biosimilar
- Skyrizi

2. Coverage Criteria for Multiple Sclerosis

2.1 Prescription issued by a neurologist (nervous system doctor)

2.2 Documented failure, intolerance, or contraindication to Ocrevus and one additional disease-modifying therapy for Multiple Sclerosis (MS)

2.3 One of the following qualifying diagnoses:

- Diagnosis of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations
- Diagnosis of first clinical episode and have MRI features consistent with multiple sclerosis

3. Exclusion Criteria

3.1 History of or active progressive multifocal leukoencephalopathy

3.2 Allergic reaction to murine proteins or humanized monoclonal antibody

3.3 Inadequate response to initial or previous natalizumab therapy

3.4 Patients with active infections OR latent tuberculosis

3.5 Health Alliance does not cover concurrent therapy with other immunomodulatory based upon the possible increased risk for infections and other potential pharmacological interactions.

3.6 Only certain NDCs of biosimilars are covered, please reference the most recent formulary file for most accurate list of covered NDCs

4. FDA Approved Dosages

4.1 Crohn's Disease: 300mg every 28 days; discontinue therapy for lack of therapeutic benefit by 12 weeks

4.2 Multiple Sclerosis: 300mg every 28 days

5. Approval Period

5.1 Initial Approval: 12 months

5.2 Subsequent Approvals: 12 months with documentation of beneficial response

CPT Codes	
96365–96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

HCPCS Codes	
J2323	Injection, natalizumab, 1mg [Tysabri]

References

1. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; October 2023.
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3. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021 Jun;160(7):2496-2508.
4. Grant AR, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2019 Jan 8;92(2):112.
5. Pape K, Rolfes L, Steffen F, et al. Comparative effectiveness of natalizumab versus ocrelizumab in multiple sclerosis: a real-world propensity score-matched study. Ther Adv Neurol Disord. 2022 Dec 19;15:1-15

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