

<b>POLICY NAME</b>	Tysabri (natalizumab)	<b>POLICY #</b>	<b>1849P</b>
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## Criteria

### 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

### 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

### Exclusion Criteria – Any of the following prevents coverage

- ☐ **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 Pharmacy Drug Policy & Procedure