PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Tysabri (natalizumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Tysabri, approved by the FDA in 2004, is an integrin receptor antagonist indicated for multiple sclerosis (MS) relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. When initiating and continuing treatment, physicians should consider whether the expected benefit of is sufficient to offset this risk. Tysabri has a black box warning for PML and is only available through a REMS program.

For the treatment of CD, Tysabri is used to induce and maintain clinical response and remission in adult inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF- . It should not be used in combination with immunosuppressants or inhibitors of TNF- , and treatment should be discontinued if therapeutic benefit has not been experienced by 12 weeks.

Tysabri (natalizumab) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member must be at least 18 years of age; AND
2. Medication must be prescribed by, or in consultation with, a neurologist; AND
3. Member has a diagnosis of clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
4. Member has documentation of at least one of the following:
   a) Inadequate response to two or more drugs indicated for the treatment of MS
   b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber.
5. **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 12 months.

For **reauthorization**:

1. Chart notes must document positive clinical response such as improved disability, slowed progression of disability, or decreased frequency of relapses compared to baseline.

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

Disease (CD)

For **initial** authorization:

1. Member must be at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND

3.

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9. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed August 18, 2021.
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