Tysabri (natalizumab) is a non-preferred product and will only be considered for coverage under the medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**CROHN’S DISEASE (CD)**

For **initial** authorization:

1. Medication is prescribed by a gastroenterologist; AND
2. Member must be at least 18 years or older moderate to severe CD; AND
3. Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
4. Medication is not being used in combination with immunosuppressant’s or TNF-alpha inhibitors; AND
5. Member has documented inadequate response or contraindication to trial of at least two different therapies such as:
   a) Corticosteroids (e.g. budesonide (Entocort), prednisone));
   b) Methotrexate (e.g. Rheumatrex);
   c) Immunosuppressants (e.g. 6-mercaptopurine (Purinethol), Azathioprine (Imuran) or cyclosporine (Neoral, Sandimmune, Gengraf)); AND
6. Member must have tried and failed treatment with Humira.
7. **Dosage allowed:** 300 mg intravenous infusion over one hour every 4 weeks.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*
RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For initial authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
4. Member has documented trial and failure or contraindication to at least two preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug). Treatment failure requires at least 3 months of therapy without an adequate response.
5. Dosage allowed: 300 mg intravenous infusion over one hour every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For reauthorization:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Tysabri (natalizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Primary Progressive Multiple Sclerosis

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/10/2017</td>
<td>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.</td>
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<tr>
<td>12/06/2017</td>
<td>Age coverage expanded.</td>
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</tbody>
</table>

References:

Effective date: 12/20/2017
Revised date: 12/06/2017