

Natalizumab (Tysabri®)

Goal(s):

- Approve therapy for covered diagnosis which are supported by the medical literature.

Length of Authorization:

- Up to 12 months

Requires PA:

- Natalizumab (Tysabri®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

| Approval Criteria | | |
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| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Has the patient been screened for John Cunningham (JC) Virus? | Yes: Go to #3 | No: Pass to RPH; Deny for medical appropriateness |
| 3. Does the patient have a diagnosis of relapsing multiple sclerosis (CIS, RRMS, or SPMS)? | Yes: Go to #4 | No: Go to #6 |
| 4. Has the patient failed trials for at least 2 drugs indicated for the treatment of RRMS? | Yes: Document drug and dates trialed: 1. _____ (dates) 2. _____ (dates) Go to #5 | No: Pass to RPH. Deny; medical appropriateness. |
| 5. Is the medication being prescribed by or in consultation with a neurologist? | Yes: Approve for 12 months | No: Pass to RPH; Deny for medical appropriateness. |
| 6. Does the patient have Crohn's Disease? | Yes: Go to #7 | No: Pass to RPH; Deny for medical appropriateness. |

Approval Criteria

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| 7. Has the patient been screened for latent or active tuberculosis and if positive, started tuberculosis treatment? | Yes: Go to #8 | No: Pass to RPH; Deny for medical appropriateness. |
| 8. Has the patient failed to respond to at least one of the following conventional immunosuppressive therapies for ≥ 6 months: <ul style="list-style-type: none">• Mercaptopurine, azathioprine, or budesonide; <u>or</u>• Have a documented intolerance or contraindication to conventional therapy?• AND• Has the patient tried and failed a 3 month trial of Humira? | Yes: Approve for up to 12 months. Document each therapy with dates. If applicable, document intolerance or contraindication(s). | No: Pass to RPh. Deny; medical appropriateness. |

P&T/ DUR Action: 10/21 (DM); 10/20; 11/17

Implementation: 1/1/18