

Generic Name: Natalizumab

Preferred: N/A

Therapeutic Class or Brand Name: Tysabri

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 5/29/2018

GPI Code: 6240505000.

Date Last Reviewed / Revised: 5/29/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met. Please see policy "MS Biologics" for use in Multiple Sclerosis. This policy is intended for the use of Tysabri® in Crohn's disease :)

- I. Patient has a diagnosis of moderate to severe Crohn's disease and criterion A thru B is met.
 - a. Documentation of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
 - b. Documentation of trial and failure of least two preferred biologics indicated for Crohn's disease after the induction period, except if not tolerated due to clinical side effects.
- II. Minimum age requirement: 18 years old.
- III. Prescriber is a gastroenterologist.

EXCLUSION CRITERIA

- Active or history of progressive multifocal leukoencephalopathy (PML).
- Co-administration with TNF blockers (adalimumab, infliximab or certolizumab).

OTHER CRITERIA

- Not to be used in combination with other immunosuppressants (e.g. 6-mercaptopurine, azathioprine, cyclosporine or methotrexate).
- If patient is using corticosteroids must taper off within 6 months of therapy.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 300 mg IV every 4 weeks.

APPROVAL LENGTH

- **Authorization:** 1year.

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://www.tysabri.com/content/dam/commercial/multiple-sclerosis/tysabri/pat/en_us/pdfs/tysabri_prescribing_information.pdf.
2. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambria/Program_Summaries/dru111reg.pdf.
3. Medispan

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
Click or tap to enter a date.	1.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.