natalizumab (Tysabri®) **natalizumab-sztn (Tyruko®)**	**Place of Service** **Infusion Center Administration** **Home Infusion Administration** **Office Administration** **Outpatient Facility Infusion Administration** **HCPCS** **Tysabri**: **J2323** per 1 mg **Tyruko**: **Q5134** per 1 mg

Conditions listed in policy (*see criteria for details*)

- Crohn's disease
- Multiple sclerosis, relapsing (RMS)

AHFS therapeutic class: Immunomodulatory Agents

Mechanism of action: recombinant humanized anti-α4-integrin monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for natalizumab must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Crohn's disease

1. Not taking in combination with immunosuppressants (e.g., azathioprine, 6-mercaptopurine, methotrexate, cyclosporine), a TNF-α inhibitor or anakinra (Kineret®), **AND**
2. Inadequate response or intolerable side effect with preferred infliximab product (Avsola, Inflectra, Renflexis) and adalilumab

Covered Doses
Up to 300 mg IV infusion every 4 weeks

Coverage Period
Initial approval: 12 weeks
Re-authorization: Indefinite (if patient had clinical benefit)

ICD-10:
K50.00-K50.119, K50.80-K50.919

Multiple sclerosis, relapsing (RMS)

1. Patient had an inadequate response, intolerance, or contraindication to at least one of the following therapies: Extavia®, Gilenya®, Tecfidera®, OR a glatiramer containing product (Glatopa, glatiramer), **AND**
2. Not being used in combination with another disease-modifying therapy to for MS (e.g., Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Rebif, Tecfidera, mitoxantrone, Ocrevus)

Covered Doses
Up to 300 mg IV infusion every 4 weeks

Coverage Period
Indefinitely

ICD-10:
G35

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for natalizumab must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
300 mg (Solution for dilution prior to infusion)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018 Apr;113(4):481-517.
- Havrdova E, Galetta S, Hutchinson M, et al. Effect of natalizumab on clinical and radiological disease activity in multiple sclerosis: a retrospective analysis of the Natalizumab Safety and Efficacy in Relapsing-Remitting Multiple Sclerosis (AFFIRM) study. Lancet Neurol. 2009 Mar;8(3):254-60.
- Hutchinson M, Kappos L, Calabresi PA, et al. The efficacy of natalizumab in patients with relapsing multiple sclerosis: subgroup analyses of AFFIRM and SENTINEL. J Neurol. 2009 Mar;256(3):405-15.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)

- Rae-grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788.
- Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-alpha biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology 2013;145:1459-63.
- Tyruko® (natalizumab-sztn) [Prescribing information). Princeton, NJ: Sandoz Inc.; 8/2023.
- Tysabri® (natalizumab) [Prescribing information). Cambridge, MA: Biogen Idec.; 4/2023.

(7) Policy Update

Date of last revision: 2Q2024

Date of next review: 4Q2024

Changes from previous policy version:

- Added natalizumab-sztn (Tyruko®), Q5134 per 1 mg

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee