Clinical Policy Title:	natalizumab
Policy Number:	RxA.532
Drug(s) Applied:	Tysabri®
Original Policy Date:	04/18/2022
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting multiple sclerosis;
   c. Secondary progressive multiple sclerosis;
2. Prescribed by or in consultation with a neurologist;
3. Trial and failure of at least one (1) preferred disease modifying therapies (Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, or Kesimpta®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization may be required for disease modifying therapies for MS

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Crohn's Disease (must meet all)**:**

1. Diagnosis of Crohn's Disease (CD);
2. Prescribed by or in consultation with a gastroenterologist;
3. Member meets one of the following (a or b):
   a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;
      *Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required;
4. Trial and failure of at least one (1) of the following agents: Cimzia®, Humira® unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed December 18, 2023.
2. 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. Full guideline available at: https://cdn-links.lww.com/permalink/wnl/a/wnl_2018_04_19_raegrant_neurology2017835181r1_sdc3.pdf. Accessed December 18, 2023.
3. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705. Available at: https://www.gastrojournal.org/article/S0016-5085(14)00918-4/fulltext?referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F. Accessed December 18, 2023.
4. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45. Available at: https://pubmed.ncbi.nlm.nih.gov/10636100/. Accessed December 18, 2023.
5. Feuerstein JD, Ho EY, Shmidt E, et al. Aga clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing crohn's disease. Gastroenterology. 2021;160(7):2496-2508. Available at: https://www.gastrojournal.org/article/S0016-5085(21)00645-4/fulltext?referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F. Accessed December 18, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy updated. 1. Initial approval criteria to include "Trial and failure of at least 2 preferred disease modifying therapies, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced." 2. Approval duration for all lines of business updated. 3. Approval duration for all lines of business	08/27/2020	09/14/2020
Policy updated. 1. Policy title updated 2. Policy was updated to all lines of business. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…".	09/14/2020	12/07/2020

1. Policy was reviewed and retired as it was already a part of RxA.592.Biologic_DMARDs.	09/29/2021	12/07/2021
1. RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Tysabri was created based on RxA.592.Biologic_DMARDs 1. Initial Approval Criteria, I.B.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 2. Initial Approval Criteria, I.B.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following for ≥ 3 months: Humira®, Cimzia®, Inflectra®, Renflexis™, Stelara®, unless contraindicated or clinically significant adverse effects are experienced". 3. Initial Approval Criteria, I.B.5: Updated to include new trial and failure Trial and failure of at least one (1) of the following agents: Cimzia®, Humira®, Stelara®, unless contraindicated or clinically significant adverse effects are experienced. 4. Initial Approval Criteria I.B.7: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 300 mg (1 vial) every 4 weeks. *Enter quantity limit for the dose of the indication consistent with FDA approved labelling. 5. Continued Therapy Approval Criteria, II.A.3.b: Updated to include Tysabri® is not prescribed concurrently with immunosuppressants (e.g., azathioprine, cyclosporine, 6-MP, MTX) or TNF-α inhibitors (note: aminosalicylates may be continued) for crohn's disease. 6. References were reviewed and updated.	02/17/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	01/19/2023	04/13/2023
Policy was reviewed: 1. Removed prior age criteria. 2. Removed requirement of prescribers registered in the MS TOUCH® Prescribing Program to prescribe Tysabri® for multiple sclerosis 3. Removed requirement of not using Tysabri in concurrent criteria with disease modifying	12/18/2023	01/01/2024

therapies for MS. 4. Removed prior dosing criteria. 5. Updated approval duration. 6. Removed requirement of not using Tysabri in combination with immunosuppresants (e.g., azathioprine, cyclosporine, 6MP, MTX) OR TNFα inhibitors for Crohn's Disease. 7. Removed reauthorization requirement for positive response to therapy. 8. References were reviewed and updated.		