Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 12, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Natalizumab – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Natalizumab submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Natalizumab will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Natalizumab to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Natalizumab to add the following to the requests for renewal of the prior authorization section:

- A guideline that the prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

*01-25- 21	09-25-21	27-25-21	33-25-21
02-25-21	11-25-21	30-25-21	
03-25-21	14-25-21	31-25-21	
08-25-22	24-25-21	32-25-21	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- A guideline that the requested natalizumab product is prescribed by or in consultation with an appropriate specialist.
- A guideline related to requests for a non-preferred natalizumab product with an interchangeable biosimilar or brand or unbranded biologic that is preferred on the Preferred Drug List.

There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of prescriptions for Natalizumab were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Natalizumab are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Natalizumab) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Natalizumab

A. Prescriptions That Require Prior Authorization

All prescriptions for a natalizumab product must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a natalizumab product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested drug by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease); **AND**

5. Does not have a contraindication to the requested drug; **AND**

6. Is not receiving chronic immunosuppressant or immunomodulator therapy; **AND**

7. For treatment of Crohn's disease, **both** of the following:

    a. **One** of the following:

        i. For a diagnosis of moderate to severe Crohn's disease, **one** of the following:

            a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids

            b) **One** of the following:

                (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines[1]

[1] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

(ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,[1]

ii. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),[2]

iii. **Both** of the following:

a) Has achieved remission with the requested drug
b) Will be using the requested drug as maintenance therapy to maintain remission

b. **One** of the following:

i. **All** of the following:

a) **One** of the following:

(i) Has a history of therapeutic failure of at least one tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
(ii) Has a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn's disease,

b) Has a history of therapeutic failure of or a contraindication or an intolerance to ustekinumab,

c) Has a history of therapeutic failure of or a contraindication or an intolerance to vedolizumab

ii. Has a current history (within the past 90 days) of being prescribed a natalizumab product;

AND

8. For a non-preferred natalizumab product, **one** of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred natalizumab product(s) approved or medically accepted for the beneficiary's diagnosis
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred natalizumab product (does not apply to non-preferred brands when the interchangeable biosimilar or unbranded biologic is preferred or to non-preferred

[2] Examples of high-risk or poor prognostic features in patients with Crohn's disease include: initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, and laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, and high fecal calprotectin levels (AGA 2014; ECCO 2017; CAG 2019; AGA 2021).

interchangeable biosimilars or unbranded biologics when the therapeutically equivalent interchangeable brand or brand biologic is preferred).

See the Preferred Drug List (PDL) for the list of preferred natalizumab products at: https://papdl.com/preferred-drug-list;

AND

9. If a prescription for the requested drug is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A NATALIZUMAB PRODUCT: The determination of medical necessity of a request for renewal of a prior authorization for a natalizumab product that was previously approved will take into account whether the beneficiary:

1. For a diagnosis of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**

2. For a diagnosis of Crohn's disease, **both** of the following:

   a. **One** of the following:

      i. Has documentation of therapeutic benefit within three months of starting therapy
      ii. Was able to discontinue concomitant corticosteroid use within six months of starting therapy

   b. Did not require additional steroid use for disease control for more than three months in a calendar year;

   AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested drug by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease); **AND**

5. For a non-preferred natalizumab product with a therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that would not be expected to occur with the requested drug.

   See the PDL for the list of preferred natalizumab products at: https://papdl.com/preferred-drug-list;

   AND

6. If a prescription for the requested drug is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a natalizumab product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of a natalizumab product will be approved as follows:

1. For a diagnosis of multiple sclerosis:

   a. Initial requests will be approved for up to six months.
   b. Renewal requests will be approved for up to 12 months.

2. For a diagnosis of Crohn’s disease:

   a. If the beneficiary is not taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to three months.

b. If the beneficiary is taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to six months to allow tapering of the corticosteroids.
c. Renewal requests will be approved for up to 12 months.

E. References

1. Tysabri Package Insert. Cambridge, MA: Biogen Inc., June 2020.
2. Goodin DS et.al. Assessment: the use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2008;71;766-773.
3. Goodin DS et.al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan 22;58(2):169-78.
4. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated July 10, 2020. Accessed July 28, 2020.
5. Rae-Grant A 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 Apr 24; 90:777. doi.org/10.1212/WNL.0000000000005347.
6. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113(4):481-517.
7. Gomollón F, Dignass A, Annese V, et al. 3rd European evidence-based consensus on the diagnosis and management of Crohn's disease 2016: part 1: diagnosis and medical management. J Crohns Colitis. 2017;11(1):3-25.
8. Gionchetti P, Dignass A, Danese S, et al. 3rd European evidence-based consensus on the diagnosis and management of Crohn's disease 2016: part 2: surgical management and special situations. 2017;11(2):135-149.
9. Nelson SM, Nguyen TM, McDonald JW, MacDonald JK. Natalizumab for induction of remission Crohn's disease. Cochrane Database Syst Rev. 2018;8:CD006097.
10. Torres J, Bonovas S, Doherty G, et al. ECCO guidelines on therapeutics in Crohn's disease: medical treatment. J Crohns Colitis. 2020;14(1):4-22.
11. 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;160:2496-2508.
12. Torres J, Bonovas S, Doherty G, et al. ECCO guidelines on therapeutics in Crohn's disease: medical treatment. J Crohns Colitis. 2020;14(1):4-22.