

Policy #: 062

Posted: 10/1/09

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Title

Natalizumab (Tysabri®)

This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.

When services are covered

We cover Tysabri® (Natalizumab) when used as a monotherapy for¹:

Adults (18 years and older) with relapsing forms of Multiple Sclerosis (ICD-9 CM 340) when all of the following criteria are met:

- Treatment failure with or contraindication to one of the following: Avonex®, Betaseron®, Copaxone® or Rebif® within the past 6 months
- The drug is prescribed by a board-certified or board eligible neurologist

Adults (18 years and older) with moderately to severely active Crohn's Disease (ICD-9-CM diagnosis code range 555.0-555.9) when all of the following criteria are met:

- Treatment failure with or contraindication to one Tumor Necrosis Factor (TNF) blocking agent (i.e. Cimzia®, Enbrel®, Humira® or Remicade®).
- The drug is prescribed by a board-certified or board gastroenterologist.

When services are not covered

We do not cover the above drugs for other conditions not listed above.

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of individual patient, **physicians** may send relevant clinical information to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Operations
25 Technology Place
Hingham, MA 02043
Tel: (800) 366-7778
Fax: (888) 641-5355

Managed care guidelines

- Prior authorization is required for all outpatient sites of service

Indemnity and PPO guidelines

- Prior authorization **is** required when these medications are processed under the home infusion therapy benefit.

- Prior authorization **is not** required when these drugs are purchased by the physician and administered in the office in accordance with this medical policy.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

For physicians:

- Use HCPCS Level II code – J2323, injection, natalizumab, 1 mg. (Tysabri) with diagnosis codes:
- ICD-9 CM 340, multiple sclerosis
- ICD-9 CM diagnosis code range 555.0-555.9, moderate to severe active Crohn's disease

Other information

TYSABRI[®] is only:

- Prescribed by doctors who are enrolled in the TOUCH[™] Prescribing Program
- Infused at an infusion center that is enrolled in the TOUCH[™] Prescribing Program
- Given to patients who are enrolled in the TOUCH[™] Prescribing Program

Policy update history

Policy developed 1/09. Updated 10/09 to reflect UM requirements.

Scientific background, Rationale and References

¹Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 05/13/08.

References:

1. Tysabri [package insert]. San Diego, CA: Biogen Idec, Inc.; January 2008
2. Natalizumab (marketed as Tysabri) information. U.S. Food and Drug Administration. Updated June 14, 2006.
3. Kappos L, Hartung HP, Havrdova E, et al. Natalizumab treatment for multiple sclerosis: recommendations for patient selection and monitoring. *Lancet Neurol.* 2007;6:431-441
4. Polman CH, O'Connor, PW, Havrdova E, et al, for the AFFIRM Investigators. A randomized placebo controlled trial of natalizumab for relapsing multiple sclerosis. *N Engl J Med.* 2006;354:899-910
5. Rudick RA, Stuart WH, Calabresi PA et al, for the SENTINEL Investigators. Natalizumab plus interferon beta-1a for relapsing multiple sclerosis. *N Engl J Med.* 2006; 354:911-923.
6. Expert Opinion Paper. National Clinical Advisory Board of the National Multiple Sclerosis Society. Disease Management Consensus Statement. 2007. Accessed on January 16, 2008. Available at: http://www.nationalmssociety.org/docs/HOM/Exp_Consensus.pdf
7. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MD council for Clinical Practice Guidelines. *Neurology.* 2002; 58:169-178.
8. Sanborn WJ, Colombel JF, Enns R, et al, for the International Efficacy of Natalizumab as Active Crohn's Therapy (ENACT-1) and the Evolution of Natalizumab as Continuous Therapy (ENACT-2) Trial Group. Natalizumab induction and maintenance therapy for Crohn's Disease. *N Engl J Med.* 2004; 353:1912-1925.
9. Hanauer SB, Sandborn W; Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2001; 96:635-643.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Natalizumab (Tysabri®)
Outpatient Medical Prior Authorization Form
 Please complete and fax to: (888) 641-5355
 Please contact Pharmacy Operations with questions at
 (800)366-7778

If the patient is a BCBSMA employee, please fax the form to:
 (617)246-0134

For Home Infusion Authorization:

Company Name:		Contact:	
Telephone:		Provider #:	
Fax:			
Patient Name:		Patient Address:	
Patient BCBSMA ID#:		Patient DOB:	
Physician Name:		Physician Telephone:	
Physician Address:		Physician Fax:	

For Outpatient Administration:

Servicing Provider:	Name: NPI #:	Requesting Provider	Name: NPI #:
Phone:		Phone:	
Fax:		Fax:	
Contact Person:		Contact Person:	
Patient Name:		Patient Address:	
Patient BCBSMA ID#:		Patient DOB:	

Required Clinical Information

Drug: _____ **Dose:** _____ **Frequency:** _____

Route of administration: _____ **Dates of Service:** ___/___/___ to ___/___/___

Diagnosis: _____ **ICD-9 code:** _____

Please indicate treatment failure with or contraindication to one or more of the medications listed below

- Avonex®
- Betaseron®
- Copaxone®
- Rebif®
- Cimzia®
- Enbrel®
- Humira®
- Remicade®
- Other Please list: _____

Physician Signature: _____

Copy of a signed prescription is required for all Home Infusion requests