Medical Coverage Criteria

Tysabri® (natalizumab) or Lemtrada® (alemtuzumab)

This document contains the most current medical coverage criteria using guidance from experts and approved by the Physicians Plus Pharmacy and Therapeutics Committee. This document remains dynamic and will be updated from time to time as new evidence becomes available reflecting substantive changes in care. The most recent version of the medical coverage criteria can be found at www.pplusic.com.

Boxed Warning for natalizumab (see full prescribing information for complete boxed warning)

1. Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic infection of the brain that usually leads to death or severe disability.
   a. Monitor patients, and withhold natalizumab immediately at the first sign or symptom suggestive of PML.

2. Natalizumab is available only through a special restricted distribution program called TOUCH® Prescribing Program and must be administered only to patients enrolled in this program.

FDA Indications for natalizumab (see full prescribing information for disease specific dosage and administration)

Multiple Sclerosis (MS)

- As monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. Natalizumab is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

Crohn’s Disease (CD)

- Inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn’s disease with evidence of inflammation who have had an inadequate response to, or unable to tolerate, conventional Crohn’s disease therapies and inhibitors of TNF-α.

Boxed Warning for alemtuzumab (see full prescribing information for complete boxed warning)

Autoimmune effects: Alemtuzumab causes serious, sometimes fatal, autoimmune conditions, such as immune thrombocytopenia and antiglomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of alemtuzumab.1

Infusion reactions: Alemtuzumab causes serious and life threatening infusion reactions. Alemtuzumab must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for 2 hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period.1

Malignancy: Alemtuzumab may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.1

REMS program: Because of the risk of autoimmunity, infusion reactions, and malignancies, Lemtrada is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) program. Call 1-855-676-6326 to enroll in the Lemtrada REMS program.1

FDA Indications for alemtuzumab (see full prescribing information for disease specific dosage and administration)

Multiple sclerosis, relapsing (Lemtrada): Treatment of patients with relapsing forms of multiple sclerosis (MS), generally who have had an inadequate response to 2 or more medications indicated for the treatment of MS.1
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Criteria
1.) Approvable for relapsing forms of multiple sclerosis (MS)
2.) Initial requests must be submitted by a board certified neurologist
3.) Requires prior use of formulary alternatives:
   a. Tecfidera
   b. Gilenya
   c. Avonex or Plegridy
   d. Copaxone
4.) Submit supporting clinic notes documenting reasons for the requested therapy (ex: discontinuation or contra-indications to formulary alternatives)
5.) Must be provided at a Physicians Plus Network location.
6.) Diagnosis of non-FDA approved indications require condition specific specialist referral and submission of institutional treatment guidelines and medical record documentation outlying the treatment and follow-up plan. Physicians Plus reserves the right to deny coverage when therapy is administered prior to an approved PA being obtained.

Choose Regimen

Sign/Date & Mail or Fax

Member Name: __________________________  Prescriber Name & Specialty: __________________________
Member Date of Birth: __________________  Prescriber Phone #: __________________
Member ID #: _________________________  Prescriber Phone #: __________________
Member PCP Name & Address: __________________________  Name & Location of Infusion Center:

1. Primary indication being treated: __________________________
   a. ICD-9 or ICD-10 code: __________________________

2. Requested medication: __________________________

3. Current status of patient therapy (check all that apply)
   □ New to requested therapy (Anticipated start date: ________________)
   □ Continuing requested therapy
   Start date: __________________________
   Date of last dose: __________________________
   Anticipated next dose: __________________________

4. □ No contraindications to the requested therapy

5. □ Pertinent lab tests/MRI prior to therapy initiation and/or ongoing have been performed (see package insert to specific medication);

Tysabri (natalizumab)
Requested dose: __________________________
Dosing frequency: __________________________
Requested duration: __________________________

Lemtrada (alemtuzumab)
Requested dose: __________________________
Dosing frequency: __________________________
Requested duration: __________________________

Prescriber Signature: __________________________  Date: __________________________

Physicians Plus Pharmacy Services Fax: (608) 327-0324
Prior Authorization Questions? (608) 260-7803 or (800) 545-5015
www.pplusic.com/providers

Physicians Plus Insurance Corporation
Attn: Pharmacy Services
P.O. Box 2078
Madison WI 53701-2078

P+6027-1508
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Condition Specific Criteria
(complete and submit this page, too)

Step 1:
Choose primary condition being treated

Step 2:
Select condition criteria that apply

Step 3:
Check all treatment criteria that apply

□ Must be prescribed by neurologist
□ Natalizumab used as monotherapy
□ Alemotuzumab used as monotherapy
(follow package insert recommendations)

□ Must have used formulary alternatives:
□ Copaxone □ Avonex
□ Plegridy □ Tecfidera
□ Gilenya
□ Other agents used (check all that apply)
□ Rebif □ Betaseron □ Glatopa
□ Extavia □ Aubagio

□ Multiple Sclerosis
□ Other:____________________

□ Crohn’s Disease
□ Other:____________________

□ Must be prescribed by gastroenterologist
□ Natalizumab not used together with TNF-α agents

□ Moderate to severe active CD
□ Other:____________________

□ Failed at least two of the following:
□ Prednisone □ Budesonide
□ Azathioprine □ 6-MP
□ Infliximab □ Adalimumab
□ Certolizumab
□ Other:____________________

Additional medical record documentation may be attached or describe the nature of why the preferred formulary options are not being used:

Remember to sign and date request form before submitting