

# Pharmacy Medical Necessity Guidelines

Injectable Drugs for the Treatment of Psoriasis: Amevive™ (alefacept), Raptiva™ (efalizumab), Enbrel® (etanercept), Humira® (adalimumab) and Remicade® (infliximab)

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Subject: Injectable Drugs for the Treatment of Psoriasis: Amevive (alefacept), Raptiva (efalizumab), Enbrel (etanercept), Humira (adalimumab) and Remicade (infliximab)

Effective Date: July 8, 2008

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX and MED	Administrative Process (Internal Use Only)	RN

**Note:** Background, applicable product and disclaimer information is located at the end of this document.

## Overview

Psoriasis is a chronic disease of the skin characterized by inflammation and patches of red skin covered with silvery scales. These patches, sometimes called plaques or lesions, occur when the cells in the skin reproduce faster than normal and build up on the surface of the skin. These plaques can appear on any part of the skin but mostly on elbows, knees, scalp, lower back, face, palms and soles of the feet. The cause of psoriasis has been determined to be due to a disorder of the immune system. T-cells of the immune system that normally protect the body from disease are releasing substances that trigger the inflammation and cause the plaque formation. Amevive (alefacept), Raptiva (efalizumab), Enbrel (etanercept), and Humira (adalimumab) have been approved by the FDA for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. Remicade (infliximab) has been approved by the FDA for the treatment of adult patients with chronic severe plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Amevive is an intravenous medication that blocks or eliminates T-cells in psoriasis plaques, which plays a role in chronic plaque psoriasis, thereby decreasing the severity of the psoriasis. Raptiva is a subcutaneous medication that inhibits the activation of T-cells and their trafficking to the dermis and epidermis, which plays a role in chronic plaque psoriasis, thereby decreasing the severity of the psoriasis. Enbrel is a subcutaneous medication with anti-tumor necrosis factor (TNF) activity. In patients with psoriasis, TNF causes inflammation, which can lead to the formation of psoriasis plaques. PUVA is a psoriasis treatment that combines phototherapy (UVA light) with a systemic psoralen medication. Remicade is an IV infusion therapy that targets TNF-alpha. By inhibiting TNF-alpha, Remicade slows down the production of skin cells and reduces the inflammation associated with psoriasis.

## Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of **Amevive** (alefacept), **Raptiva** (efalizumab), **Enbrel** (etanercept), **Humira** (adalimumab), and **Remicade** (infliximab) for adult Members 18 years of age or older when all of the following criteria are met:

1. The Member must have a definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis for Amevive (alefacept), Raptiva (efalizumab), and Enbrel (etanercept) or of severe chronic plaque psoriasis for Remicade (infliximab).
2. The Member has failed to respond to, or has been unable to tolerate phototherapy **and ONE** of the following therapeutically-similar medications:
  - Soriatane (acitretin)
  - Methotrexate
  - Cyclosporine

## Limitations

1. Coverage for Enbrel (etanercept) will be limited to a 28-day supply as follows:
  - Enbrel 25 mcg syringe – 16 syringes per 28 days (initial 12 weeks) then 8 syringes per 28 days thereafter.
  - Enbrel 50 mcg syringe – 8 syringes per 28 days (initial 12 weeks) then 4 syringes per 28 days thereafter.
2. Coverage for Humira (adalimumab) will be limited to a 28-day supply as follows:
  - Humira 40 mg syringe – 4 syringes per 28 days (initial 4 weeks) then 2 syringes per 28 days thereafter.

## Codes

The following HCPCS/CPT code(s) are:

Code	Description
J1745	Injection, infliximab, 10mg
J0215	Injection, alefacept, 0.5mg

## References

1. Amevive package insert, Biogen, 2003
2. Amevive Medical Information Dossier, Biogen, 2003
3. U.S. Department of Health and Human Services, 4-women.gov, Psoriasis, Published August 2002, <http://www.4woman.gov/faq/psoriasis.htm>
4. Krueger, Gerald G., et al., A randomized, double-blind, placebo-controlled phase III study evaluating efficacy and tolerability of 2 courses of alefacept in patients with chronic plaque psoriasis. Journal American Academy of Dermatology. December 2002, Vol 47, No. 6, 821-833
5. Remicade (infliximab) [package insert]. Malvern, PA: Centocor, Inc.; October 2006.
6. Centocor, Inc. Remicade and Psoriasis. URL: <http://www.remicade.com/psoriasis/index.jsp>. Available from Internet. Accessed 2006 October 30.
7. Humira package insert, Abbot Laboratories, 2008
8. National Psoriasis Foundation. Phototherapy: light treatment for psoriasis. 2006.

## Approval History

Reviewed by the Pharmacy and Therapeutics Committee in November 2003.

Subsequent Endorsement Date(s) and Changes Made:

1. June 14, 2005: No changes
2. May 9, 2006: Removed, "Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA) " and replaced with, "narrow band UVB"
3. November 14, 2006:
  - Added Remicade (infliximab) to title and pharmacy coverage guidelines.
  - Changed first guideline from "The Member must have a definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis" to "The Member must have a definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis for Amevive (alefacept), Raptiva (efalizumab), and Enbrel (etanercept) or of severe chronic plaque psoriasis for Remicade (infliximab)."
4. January 9, 2007:
  - Added Limitation:  
Coverage for Enbrel (etanercept) will be limited to a 28-day supply as follows:
    - Enbrel 25 mcg syringe – 16 syringes per 28 days (initial 12 weeks) then 8 syringes per 28 days thereafter.
    - Enbrel 50 mcg syringe – 8 syringes per 28 days (initial 12 weeks) then 4 syringes per 28 days thereafter.
5. January 15, 2008: No changes.
6. March 4, 2008:
  - Added Humira (adalimumab) to the title and pharmacy coverage guidelines
  - Added Limitation #2: Humira 40 mg syringe – 4 syringes per 28 days (initial 4 weeks) then 2 syringes per 28 days thereafter.
7. July 8, 2008:
  - Removed "narrow band UVB" from pharmacy coverage guideline #2 and replaced with "phototherapy."

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health Plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. However, for Tufts Health Plan Medicare Preferred Members, the Pharmacy Medical Necessity Guidelines only apply to Medicare Part D covered drugs. Tufts Medicare Preferred defers to Medicare coverage guidelines when reviewing Medicare Part B

covered drugs. Medicare's national and local coverage determinations for Part B covered drugs can be accessed via the CMS coverage database at <http://www.cms.hhs.gov/mcd/search.asp>. Medicare general coverage guidelines are located in Chapter 15 of the Medicare Benefit Policy Manual, which can be accessed at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>. Generally, Tufts Medicare Preferred requires prior authorization for the same drugs that require prior authorization for the fully insured Tufts Health Plan offerings. Check the applicable formulary in the Pharmacy section of our Web site at <http://www.tuftshealthplan.com/providers> to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink<sup>SM</sup> Members.

For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.