

Pharmacy Medical Necessity Guidelines

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

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

Effective Date: May 11, 2010

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: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

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), Enbrel (etanercept), Humira (adalimumab) and Stelara (ustekinumab) 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 (alefacept) 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.

Enbrel (etanercept) and Humira (adalimumab) are subcutaneous medications 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 (infliximab) 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.

Stelara (ustekinumab) is a human immunoglobulin G1 (IgG1) kappa monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. Stelara (ustekinumab) is a subcutaneous medication indicated for administration by a healthcare professional.

Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of **Amevive** (alefacept), **Enbrel** (etanercept), **Humira** (adalimumab), **Remicade** (infliximab) or **Stelara** (ustekinumab) 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), Humira (adalimumab), Enbrel (etanercept) and Stelara (ustekinumab) or of severe chronic plaque psoriasis for Remicade (infliximab).

AND

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.
3. Coverage of Stelara (ustekinumab) will be limited as follows:
 - Patient weight of 100 kg or less: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
 - Patient weight of more than 100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Codes

The following HCPCS/CPT code(s) are:

Code	Description
J0215	Injection, alefacept, 0.5mg
J1745	Injection, infliximab, 10mg
C9261	Injection, ustekinumab, 1 mg

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.
9. Amevive (alefacept) [package insert]. Deerfield, IL: Astellas Pharma US, Inc.; March 2009.
10. Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corporation; November 2009.
11. Humira (adalimumab) [package insert]. North Chicago, IL: Abbott Laboratories; November 2009.
12. Remicade (infliximab) [package insert]. Malvern, PA: Centocor Ortho Biotech Inc.; November 2009.
13. Stelara (ustekinumab) [package insert]. Horsham, PA: Centocor Ortho Biotech Inc.; December 2009.

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."
8. July 14, 2009:
 - Removed Raptiva™ (efalizumab) from Pharmacy Medical Necessity Guidelines due to market withdrawal.
9. January 1, 2010:
 - Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
10. May 11, 2010:
 - Added Stelara (ustekinumab) to Medical Necessity Guidelines.

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. 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 CareLinkSM 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.

For Tufts Medicare Preferred, please refer to Tufts Medicare Preferred Prior Authorization Criteria.

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.