Policies Repository

Independence Blue Cross

Policy Title	Efalizumab (Raptiva®)
Policy Number	FS.CLIN.54

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy	**Efalizumab (Raptiva®) is** indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Policy Description	**Efalizumab (Raptiva®)** is an immunosuppressive recombinant humanized IgG1 kappa isotype monoclonal antibody that binds to human CD11a, the α subunit of leukocyte function antigen-1 (LFA-1), which is expressed on all leukocytes, and decreases cell surface expression of CD11a. Efalizumab (Raptiva®) inhibits the binding of LFA-1 to intercellular adhesion molecule-1 (ICAM-1), thereby inhibiting the adhesion of leukocytes to other cell types. Interaction between LFA-1 and ICAM-1 contributes to the initiation and maintenance of multiple processes, including activation of T lymphocytes, adhesion of T lymphocytes to endothelial cells, and migration of T lymphocytes to sites of inflammation including psoriatic skin. Lymphocyte activation and trafficking to skin play a role in the pathophysiology of chronic plaque psoriasis. In psoriatic skin, ICAM-1 cell surface expression is upregulated on endothelium and keratinocytes. CD11a is also expressed on the surface of B lymphocytes, monocytes, neutrophils, natural killer cells, and other leukocytes. Therefore, the potential exists for Efalizumab (Raptiva®) to affect the activation, adhesion, migration, and numbers of cells other than T lymphocytes.
Policy Guideline Inclusion	**Efalizumab (Raptiva®)** is approved when the following inclusion criterion is met: • Documented diagnosis of moderate to severe chronic plaque psoriasis and ALL of the following:

- Patient is an adult (≥ 18 years)
- Medication is being recommended and prescribed by a dermatologist
- Patient had at least a 30-day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
  - Topical calcipotriene containing products
  - Topical anthralin
  - Topical steroids
  - Topical immunomodulators (Elidel®, Protopic®)
  - Topical retinoids
  - Topical fluorouracil (Efudex®)
  - Adalimumab (Humira®)
  - Etanercept (Enbrel®)
- Patient does not have concurrent immunosuppressive therapy
- Patient does not have active infection
- Patient does not have active malignancy

Policy Guideline Exclusion

Efalizumab (Raptiva®) is denied when **any** of the following exclusion criteria is present:

- No documented diagnosis of moderate to severe chronic plaque psoriasis
- Patient is less than 18 years of age
- Medication is not being recommended and prescribed by a dermatologist
- Patient does not have at least a 30-day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
  - Topical calcipotriene containing products
  - Topical anthralin
  - Topical steroids
  - Topical immunomodulators (Elidel®, Protopic®)
  - Topical retinoids
  - Topical fluorouracil (Efudex®)
  - Adalimumab (Humira®)
  - Etanercept (Enbrel®)
- Patient has concurrent immunosuppressive therapy
- Patient has active infection
- Patient has active malignancy

Policy List of Applicable Drugs

Brand Name	Generic Name
Raptiva	efalizumab

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Bos JD, Hagenaars C, Das PK, et al. Predominance of "memory" T cells (CD4+, CDw29+) over "naïve" T cells (CD4+, CD45R+) in both normal and diseased human skin. Arch Dermatology Res 1989; 281:24-30.

Ellis C, Krueger GG. Treatment of chronic plaque psoriasis by selective targeting of memory effector T lymphocytes. N Engl J Med 2001; 345:248-255.

Gartlehner G, Hansen RA, Thieda P, Jonas B, Lohr KN, Carey T. Drug Class Review on Targeted Immunemodulators [Final Report] January 2007. Oregon Health & Science University. Drug Effectiveness Review Project [available at http://www.ohsu.edu/drugeffectiveness/reports/final.cfm]

Gladman DD, Mease PJ, Cifaldi MA, et al: Adalimumab improves joint-related and skin-related functional impairment in patients with psoriatic arthritis: patient-reported outcomes of the Adalimumab Effectiveness in Psoriatic Arthritis Trial. Ann Rheum Dis 2007; 66(2):163-168.

Gordon KB, Langley RG, Leonardi C, et al: Clinical response to adalimumab treatment in patients with moderate to severe psoriasis: double-blind, randomized controlled trial and open-label extension study. J Am Acad Dermatology 2006; 55(4):598-606.

Iyer S, Yamauchi P, & Lowe NJ: Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy. Brit J Dermatology 2002; 146:118-121.

Leonardi CL, Powers JL, Matheson RT, et al: Etanercept as monotherapy in patients with posoriasis. N Engl J Med 2003; 349(21):2014-2022.

Mease PJ, Goffe BS, Metz J, et al: Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomized, trial. Lancet 2000; 356:385-390.

Raptiva® (Efalizumab) In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed September 13, 2008.

Raptiva® (Efalizumab) In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed September 13, 2008.

Raptiva® (Efalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; October 2008.

Werther WA, Gonzalez TN, O'Connor SJ, McCabe S, Chan B, Hotaling T, et al. Humanization of an anti-lymphocyte function-associated antigen (LFA)-1 monoclonal antibody and reengineering of the humanized antibody for binding to rhesus LFA-1. J Immunology 1996;157:4986-95.

Policy Link to Related Policies

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