

# RAPTIVA® UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Systemic Antipsoriatic Agents

**DRUG NAME:** Raptiva® (efalizumab)

## FDA INDICATIONS:

Raptiva, is an immunosuppressive agent that works by preventing activation and proliferation of T-cells. It is indicated for the following treatment:

- Chronic moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

**ICD-9 CODES:** Plaque Psoriasis 696.1

## BENEFIT DESIGN:

Coverage is provided immediately (without generating a coverage review process) for the treatment of plaque psoriasis in the presence of a prescription within the previous 18 months for any of the following drugs and if the prescribing physician is a dermatologist:

- Methoxsalen (Oxsoralen®)
- Methotrexate
- Cyclosporine
- Acitretin (Soriatane®)
- Etanercept (Enbrel®)
- Efalizumab (Raptiva®)

In situations where the above does not apply, coverage for Raptiva, is determined through the coverage authorization criteria.

## COVERAGE AUTHORIZATION CRITERIA:

Coverage is provided if the following criteria has been met:

- Member is being managed by a dermatologist

**AND**

- Diagnosis of Plaque Psoriasis, Pustular Psoriasis, or Erythrodermic Psoriasis

**AND**

- Body Surface Area (BSA) involvement of at least 5%

**OR**

- Involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment

**AND**

- Failure of systemic therapy (methotrexate, cyclosporine, Soriatane®) or patient has contraindication to these treatments

## BLACK BOX WARNINGS:

None

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## RATIONALE:

- Conventional therapy for moderate to severe psoriasis includes phototherapy and/or oral medications such as methotrexate and cyclosporine. Due to the potential for serious side effects, the cost impact, and the monitoring requirements, Raptiva® is considered second-line therapy after topical treatment, phototherapy, and other systemic medications currently used for psoriasis (i.e. methotrexate, cyclosporine, Soriatane®).

## DOSAGE AND ADMINISTRATION:

- **Dose** = 0.7mg/kg SC conditioning dose followed by weekly SC doses of 1mg/kg (maximum single dose not to exceed a total of 200mg)
- **Administration** = Raptiva® is intended for use under the guidance and supervision of a physician. If it is determined to be appropriate, patients may self-inject the medication after proper training in the preparation and injection technique and with medical follow-up.

## MONITORING

- Physicians should monitor patients for signs and symptoms of thrombocytopenia. Assessment of platelet counts is recommended upon initiating and periodically while receiving treatment. It is recommended that assessments be more frequent when initiating therapy (e.g. monthly) and may decrease in frequency with continued treatment (e.g. every 3 months).

## ADVERSE REACTIONS

- The most common adverse events during the clinical trials were headache, fever, chills, nausea, and myalgia. These were all first dose reactions that occurred within two days following the first two injections. The most serious adverse reactions were serious infection, malignancies, thrombocytopenia, and psoriasis worsening.

## RISK FACTORS/CONTRAINDICATIONS:

- **Serious Infections:** Raptiva® is an immunosuppressant agent and has the potential to increase the risk of infection and reactive, latent, chronic infections. As a result, this agent should not be administered to patients with clinically important infections, and caution should be exercised in patients with chronic infection or history of recurrent infections.
- **Malignancies:** Many immunosuppressive agents have the potential to increase the risk of malignancy. Caution should be exercised in these patients.

## DRUG INTERACTIONS:

- No drug interaction studies have been conducted. However, patients should not receive Raptiva® in conjunction with other immunosuppressive agents or live, live-attenuated, or acellular vaccines.

## REFERENCES:

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2. New Drug: Raptiva. Pharmacist's Letter 2003;19(12):1912-13.
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4. National Psoriasis Foundation website. Psoriasis treatment. [http://www.psoriasis.org/medical/advocacy/2003\\_systemicsdiagram.php](http://www.psoriasis.org/medical/advocacy/2003_systemicsdiagram.php)
5. Raptiva for the Treatment of Psoriasis. The Medical Letter. December 8,2003;(1171) pp. 97-98.
6. Rangioletti F, Borenstein M, Krisner R, Kerdel F. Erythrodermic recalcitrant psoriasis: clinical resolution of infliximab. J Dermatolog Treat. 2003 Dec;14(4): 222-5.
7. Barland C, Kerdel FA. Addition of low-dose methotrexate to infliximab in the treatment of a patient with severe, recalcitrant pustular psoriasis. Arch Dermatol. 2003 Jul; 139(7): 949-50.