

Origination Date: 8/07	Revision Date(s): 8/08, 3/11
Developed By: Medical Criteria Committee	

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Approved: Robert Neal Mills, MD

Date: 03/04/11

ODS RX ^{1.0} <input type="checkbox"/>	ODS RX ^{2.0} <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

PURPOSE: To ensure the appropriate and safe use of Amevive for FDA approved indications.

DESCRIPTION: T-cell inhibitors block multiple T-cell mediated responses involved in the pathogenesis of psoriatic plaques. Activated T-cells secrete a number of inflammatory mediators which are involved in psoriasis.

INDICATIONS:

- Plaque psoriasis:
 - Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

PRODUCT AVAILABILITY:

Amevive (alefacept): 15mg injection, solution reconstituted

QUANTITY LIMITS:

Amevive (alefacept): 15mg – 4 vials per 30-day supply

GUIDELINES FOR USE:

- 1) Is the drug being prescribed by a dermatologist?
 - a) If yes, go to #2
 - b) If no, forward to clinical
- 2) Does the patient have documented chronic (≥ 12 months) plaque psoriasis which covers $\geq 10\%$ of the body surface area or involves areas of the face, ears, hands, feet or genitalia?
 - a) If yes, go to #3
 - b) If no, forward to clinical
- 3) Is the patient at least 18 years of age?
 - a) If yes, go to #4
 - b) If no, forward to clinical
- 4) Is the patient a candidate for systemic therapy and/or phototherapy?
 - a) If yes, go to #5
 - b) If no, forward to clinical

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- 5) **Does the patient have a clinically important active infection?**
- If yes, forward to clinical** (Note: It is relatively contraindicated for patients with a chronic or recurrent infection to receive therapy. Therapy may place patients at greater risk for developing serious infections.)
 - If no, go to #6**
- 6) **Does the patient have one of the following?**
- Patient with a CD₄ count < 250 cell/ μ L**
 - Patient with HIV infection**
 - Patient with unknown HIV status who is at a high risk of HIV infection**
- If yes, forward to clinical** (Note: Amevive should not be administered to patients diagnosed with HIV. Amevive reduces CD₄+ T lymphocyte counts, which might accelerate disease progression or increase complications of disease in these patients.)
 - If no, go to #7**
- 7) **Has the patient been previously treated with Amevive?**
- If yes and prescribing Amevive, go to #10**
 - If no, go to #8**
- 8) **Will the patient be using the prescribed agent in combination with Enbrel or Remicade?**
- If yes, forward to clinical**
 - If no, go to #9**
- 9) **Does the patient have documented relative contraindication to or failure/intolerance of optimal dosing/adequate duration of systemic therapy (i.e. methotrexate, cyclosporine, acitretin) and/or phototherapy (i.e. PUVA, UVB)?**
- If yes, approve for 12 weeks initial therapy per the above quantity limitations**
 - If no, forward to clinical**

RENEWAL CRITERIA:

- 10) **How long has the patient been on Amevive?**
- If patient has received previously only one cycle of 12 weeks of therapy, go to # 11**
 - If patient has received a total of 24 weeks of Amevive therapy in the past, forward to clinical**
- 11) **Did the patient receive clinical benefit on the therapy as measured by PASI improvement (\geq 50% improvement in PASI score) or a significant improvement in Quality of Life observed by the physician and patient (i.e. Dermatology Life Quality Index)?**
- If yes, go to 12**
 - If no, forward to clinical**
- 12) **Has the patient been off Amevive for at least 12 weeks?**
- If yes, approve for 12 weeks per the above quantity limitations (ONE TIME RENEWAL ONLY, 24 weeks total therapy)**
 - If no, forward to clinical**

Special Instructions:

Approval lengths:

- Initial induction -- 12 weeks
- Maintenance -- 12 weeks for Amevive (one time renewal only, a total of 24 weeks of therapy)

Clinical Information:

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- **Dosing**

- ◊ Amevive- 7.5mg once weekly IV bolus for 12 weeks (seldom used) or 15mg once weekly IM injection for 12 weeks, a second course of treatment may be initiated at least 12 weeks after completion of the initial course of treatment

- **Pregnancy Category: B**

- Amevive therapy has a high risk of lymphopenia. The CD₄ and CD₈ count should be monitored every 2 weeks during the 12 weeks of therapy.
- Serious infections, sepsis and fatalities have been reported with the use of these agents. These medications should not be initiated in patients with clinically important, active infections.