Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Amevive (alefacept)
BILLING CODE	J0215 (1 unit = 0.5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Cimzia, Cosentyx, Enbrel, Otezla, and Siliq QUANTITY LIMIT— 60 mg per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Amevive (alefacept) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by a rheumatologist or dermatologist; AND
3. Member's CD4 count is documented in chart notes, and it is greater than 250 cells/microliter; AND
4. Member has moderate to severe chronic PsO for one year or over, and it involves 10% or more of the body surface area (BSA); AND
5. Member's baseline of Psoriasis Area and Severity Index (PASI) score documented in chart notes; AND
6. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 4 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 4 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments; tanning beds emit mostly UVA light and therefore would not meet this criteria);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 4 weeks; AND
8. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least for 30 days of therapy with each drug.
9. **Dosage allowed:** IV: 7.5 mg once weekly for 12 weeks; IM: 15 mg once weekly for 12 weeks.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improving signs and symptoms of disease; AND
3. Member's CD4 count is greater than 250 cells/microliter; AND

4. PASI score improvement of 50% from baseline documented in chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for additional 12 months.

CareSource considers Amevive (alefacept) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Psoriatic arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
07/18/2017	New policy for Amevive created.
02/26/2019	Humira trial removed from criteria; Cimzia, Cosentyx, Otezla and Siliq added to trial agents list. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies.

References:

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3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
4. Amevive. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 24, 2017.

5. Krueger GG, Papp KA, Stough DB, 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. J Am Acad Dermatol 2002;47:821-833.
6. Lebwohl M, Christophers E, Langley R, et al. An international, randomized, double-blind, placebo controlled phase 3 trial of intramuscular alefacept in patients with chronic plaque psoriasis. Arch Dermatol 2003;139(6):791-793.
7. Gottlieb AB, et al. Safety observations in 12095 patients with psoriasis enrolled in an international registry (PSOLAR): experience with infliximab and other systemic and biologic therapies. J Drugs Dermatol. 2014 Dec;13(12):1441-8.
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10. Smith CH, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017;177(3):628.

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