

PHARMACY POLICY STATEMENT

Ohio Medicaid

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| DRUG NAME | Amevive (alefacept) |
| BILLING CODE | J0215 (1 unit = 0.5 mg) |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Outpatient Hospital/Office |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Humira, Enbrel 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 (PP)

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 PP 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 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
 - b) At least 12 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 of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretnin) for at least 12 weeks; AND
8. Member has tried and failed treatment with both Enbrel and Humira.
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. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- 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. |

References:

1. Amevive [package insert]. Astellas Pharma US, Inc: Deerfield, IL; May, 2011.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. Journal of the American Academy of Dermatology, Volume 65, Issue 1, 137 – 174.
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.

Effective date: 08/09/2017
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