BlueCross BlueShield of Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Amevive®

Policy Number: 5.01.502
Origination: 12/2003
Last Review: 01/2014
Next Review: 01/2015

Policy

Blue Cross and Blue Shield of Kansas City will provide coverage for Amevive® (alefacept) when it is determined to be medically necessary because the criteria shown below have been met.

When Policy Topic is covered

Use of alefacept will be considered medically necessary for the treatment of adults age 18 and older with chronic plaque psoriasis when the following criteria are met:

- Ten percent or more body surface area is affected by plaque psoriasis;
- Patient has documented functional impairment due to psoriasis;
- Treatment with at least 1 systemic agent approved for the treatment of psoriasis was not effective;
- Step therapy as defined by the National Psoriasis Foundation Guidelines for Treatment of Psoriasis has not been effective.

National Psoriasis Foundation Guidelines for Treatment of Psoriasis
Step 1: Topical therapy with steroids, coal tar, calcipotriene, tazarotene, anthralin, salicylates, or other topical agents (moisturizers, bath solutions, and over the counter medications).
Step 2: Phototherapy with sunlight, ultraviolet light B (UVB), psoralen plus ultraviolet light A (PUVA), or PUVA plus calciprotriene, topical steroids, or anthralin. Additionally, UVB, methotrexate, or oral retinoids can be used with PUVA to enhance response.
Step 3: Systemic therapy with methotrexate, oral retinoids, cyclosporine, or biologics. The National Psoriasis Foundation also lists under this category other agents not approved by the FDA for the treatment of psoriasis. These agents include hydroxyurea, mycophenolate mofetil (with cyclosporine), sulfasalazine, and 6-Thioguanine.

The recommended dose of alefacept is 7.5mg once weekly as an IV bolus or 15mg once weekly given intramuscularly. Alefacept should only be used under the guidance and supervision of a physician. This drug is considered a **medical benefit.**

When Policy Topic is not covered

Amevive® (alefacept) is considered not medically necessary if the criteria above are not met.

Considerations

Alefacept may reduce circulating CD4+ and CD8+ T-lymphocytes. Weekly CD4+ tests are required for monitoring prior to each injection. The CD4+ count must remain > 250 for continuation of therapy.

Initial therapy with alefacept may be authorized for a period of 12 weeks when criteria are met. An authorization for a second 12 week treatment course may be granted if it has been a minimum of 12 weeks since the completion of the first 12 week treatment course and CD4+ T lymphocyte counts are normal.

Treatment with alefacept is considered investigational for any condition other than chronic plaque psoriasis.

This Blue Cross and Blue Shield of Kansas City policy was developed using available resources such as, but not limited to Hayes Medical Technology Directory, Food and Drug Administrative (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Psoriasis is a chronic, immune-related disease of the skin that primarily affects adults. Plaque psoriasis is the most common form of psoriasis, characterized by relapsing scaling and inflammation. Certain biologic drugs treat plaque psoriasis by interacting with cellular components of the immune system that are thought to play significant roles in the disease process. Amevive® (alefacept) has been approved by the FDA for treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

Psoriasis severity is categorized by percentage of body surface area involved (National Psoriasis Foundation):
Mild: covers less than 2% of the body
Moderate: covers 2-10% of the body
Severe: covers more than 10% of the body

Note: Psoriasis of the palms can be severe, even though the percent of body area involved may be minimal.

Rationale

- Alefacept is approved for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.[1]

- There is no data available comparing the efficacy and safety of alefacept to other treatments for moderate to severe psoriasis, and alefacept has not been proven to have additional benefit over less expensive alternatives.

- A substantial number of treatments for psoriasis are effective and have known long-term safety profiles.

- The long-term safety profile of alefacept is unknown and published safety and efficacy data beyond two cycles of treatment are lacking.

- Inclusion criteria for the pivotal trials of alefacept allowed patients with chronic plaque psoriasis (diagnosed at least 12 months prior) with involvement of at least 10% of body surface area who had received previous systemic or phototherapy treatment. An additional criteria was that the patient must have CD4+ counts above the lower limit of normal.[2]

- Baseline demographics for patients evaluated in one of the pivotal clinical trials used to obtain FDA approval for alefacept had a median duration of psoriasis of 18 years and a median body surface area involvement of 22%.[2] These baseline demographics are similar to those of the other fully published pivotal trial used to obtain FDA approval.[3]

- Of the patients who had received prior systemic therapy (95% of patients), approximately 50% had received ultraviolet B therapy, approximately 35% had received methotrexate therapy, approximately 35% had received psoralen plus ultraviolet A therapy, and approximately 16% received retinoids.[2]

- Other treatment options for moderate to severe psoriasis include methotrexate, oral retinoids, cyclosporine, and phototherapy or photochemotherapy.[4]

- The American Academy of Dermatology lists maximum potency topical corticosteroids as having high effectiveness in the treatment of mild to moderate psoriasis.[4] Methotrexate and photochemotherapy are capable of inducting total clearing and long remission (months to years) in patients with psoriasis.

- There are only limited data (unpublished, unavailable, manufacturer data on file) evaluating the efficacy of retreatment beyond two cycles.

- The use of alefacept is limited by the risk of potential side effects and needs to be weighed against the risk/benefit ratio in using other therapeutic alternatives.

- Alefacept carries a bolded warning that states that it induces dose-dependent reductions in circulating CD4+and CD8+ T lymphocyte counts.[1] Alefacept therapy should not be initiated in patients with a CD4+ T lymphocyte count below normal. The CD4+ T lymphocytes counts of patients receiving alefacept should be monitored weekly throughout the course of the 12 week dosing regimen.

- Alefacept may increase the risk of malignancies and should not be administered to patients with a history of systemic malignancy.[1]

- Alefacept has the potential to increase the risk of infection and reactivate latent, chronic infections.[1] Alefacept should not be administered to patients with a clinically important infection.

- There are only limited data (unpublished, unavailable, manufacturer data on file) evaluating the safety of retreatment beyond two cycles.

References

1. Amevive prescribing information, Biogen, Inc., Cambridge, MA, August 2004.

2. Krueger GG, 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;47:821-33.

3. Ellis CN, et al. "Treatment of chronic plaque psoriasis by selective targeting of memory effector T lymphocytes." N Engl J Med 2001;345:248-55.

4. American Academy of Dermatology Association, Guidelines of Care for Psoriasis, http://www.aadassociation.org/Guidelines/psoriasis.html. 1993. Accessed May 15, 2003.

Billing Coding/Physician Documentation Information

J0215 Injection, alefacept, 0.5mg

Additional Policy Key Words

Policy Number 5.01.502

Related Topics

N/A

Policy Implementation/Update Information

12/2003 New Policy Titled Biologic Drugs for the Treatment of Psoriasis
12/2004 Revised – Enbrel® added to policy
01/2006 Revised – updated coding

01/2007 Revised – Remicade® added to policy
01/2008 Reviewed – no changes made.
01/2009 Revised – Changed policy name to Amevive and Raptiva. Removed references to Enbrel and Remicade as psoriasis guidelines are covered in their respective policies.
07/2009 Revised – Removed all references to Raptiva® (efalizumab) from the policy. Raptiva was voluntarily removed from the market in April, 2009.
01/2010 Reviewed – no changes made
01/2011 Reviewed – no changes made
01/2012 Reviewed – no changes made
01/2013 Reviewed – no changes made
01/2104 Reviewed – no changes made

This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.