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

Csaba Mera MD

Approved: Csaba Mera, MD Date: 8/8/08

Description:

Amevive is a biological agent used for the treatment of moderate-to-severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It is a fusion protein that prevents the activation of T lymphocytes involved in the pathogenesis of psoriasis. Amevive can be administered intravenously (IV) or via intramuscular injection (IM). Treatment is given weekly over a 12 week course.

Criteria:

- I. ODS will cover 12 weeks of treatment with Amevive to plan limitations when **all** of the following criteria are met:
 - a. Patient is an adult, age 18 or older; and
 - b. Amevive is being ordered by a dermatologist who has experience using Amevive; and
 - c. At least 10% of the body surface area is affected by plaque psoriasis; and
 - d. Patient has been treated with one or more topical or systemic antipsoriatic agents (e.g. topical corticosteroids, topical coal tar products, tazarotene, cyclosporine, methoxasalen, anthralin, calcipotriene, methotrexate, or acetretin);
 - e. Patient is a candidate for systemic therapy or phototherapy; and
 - f. Patient has a normal CD4 lymphocyte count (250 cells/ μ L or greater)

- II. ODS may cover a 2nd 12 week course of Amevive if **all** of the following criteria are met:
 - a. A minimum of 12 weeks has passed since the end of the previous course of Amevive therapy; and
 - b. Previous treatment with Amevive resulted in remission of the disease or improvement in the severity of symptoms; and
 - c. The patient has a normal CD4 lymphocyte count (250 cells/ μ L or greater)

Information to be Submitted with Pre-Authorization Request:

Chart notes from the treating physician documenting the following:

- Moderate-to-severe plaque psoriasis
- BSA affected by plaque psoriasis
- Previous treatment tried
- CD4 lymphocyte count

References:

- Amevive product information. Accessed August 16, 2007. Available at URL address: <http://www.amevive.com>
- FDA approves new therapy for psoriasis. Hayes Alert. February 1, 2003.
- New psoriasis therapy endorsed by FDA advisory panel. Hayes Alert. July 2003. V(7).
- Langley RG, Ho V, Lynde C, et al. Recommendations for incorporating biologicals into management of moderate to severe plaque psoriasis: individualized patient approaches. J Cutan Med Surg. 2006;9 Suppl 1:18-25.
- Rich SJ, Bello-Quintero CE. Advancements in the treatment of psoriasis: role of biologic agents. J Manag Care Pharm. 2004 Jul-Aug;10(4):318-25.

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- Kruegger GG. Clinical response to alefacept: results of a phase 3 study of intravenous administration of alefacept in patients with chronic plaque psoriasis. *J Eur Acad Dermatol Venereol.* 2003 Jul;17 Suppl2:17-24.
- Scheinfeld N. Alefacept: its safety profile, off-label uses, and potential as part of combination therapies for psoriasis. *J Dermatolog Treat.* 2007;18(4):197-208.
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