Subject: Alefacept (“Amiveve”) Therapy for Psoriasis*

Effective Date: March 27, 2007

Department(s): Utilization Management

Policy: Alefacept is reimbursable for medically necessary indications delineated in this policy, under Plans administered by QualCare.

Note: Astellas Pharma US, Inc initiated a voluntary US market discontinuation of Alefacept (“Amiveve”) for business reasons on November 16, 2011

Objective: To assure proper and consistent reimbursement and to delineate the medically necessary indications for the coverage.

Procedure:

Eligible Members with benefit in place who have moderate to severe chronic plaque psoriasis, and who have received phototherapy or systemic therapy, are eligible for coverage of Alefacept therapy.

Psoriasis severity is categorized by body surface area (National Psoriasis Foundation) as:

- **Mild**: covers less than 2% of the body.
- **Moderate**: covers 2-10% of the body.
- **Severe**: covers more than 10% of the body.
- Psoriasis of the palms can be severe even though the percentage of the body surface area covered may be small.

1. Patients should be tried on topical and UVB therapies when deemed medically appropriate by the treating physician, and where available, have a medical contraindication to such therapies, or a basis for a reasonable medical expectation that these therapies would not be effective.

2. The treatment may be repeated if the initial course of therapy resulted in remission and a minimum of 24 weeks has elapsed since the completion of the previous treatment.
3. CD4+ lymphocyte counts must be drawn and available to the treating physician prior to the administration of each treatment and submitted to QualCare before authorization is given.

4. Other systemic treatments must have been considered by the physician and discussed with the patient, but are not required to have been tried.

**Alefacept will not be covered for the following:**

1. Alefacept is not indicated for treatment in patients who have forms of psoriasis other than chronic plaque psoriasis.

2. Alefacept is not FDA approved for combination therapies; therefore, it will only be covered when used as mono-therapy or when tapering off of a previous therapy.

3. Alefacept will be considered not reasonable or necessary in patients;
   - Who are receiving it in combination with phototherapy or other systemic therapies, as these uses are considered investigational (except while tapering the prior treatment during initiation of Alefacept therapy).
   - Who receive it as a second course of treatment after failure of an initial course of treatment.
   - In whom the CD4+ count is < 250 cells/ml at the time of administration, nor for subsequent doses in any patient in whom the CD4+ count is < 250 cells/ml for a month.
   - In whom the administration is contraindicated because of clinically significant infection, malignancy, and history of systemic malignancy or concurrent treatment with other immunosuppressive therapies (including phototherapy).

References:


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Approved By/Date: QM Committee 03/27/07
Revised By/Date: M. McNeil MD 03/02/11
Approved By/Date: QM Committee 03/22/11
Revised By/Date: M. McNeil, MD 02/12/13
Approved By/Date: QM Committee 02/26/13

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.