

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: AMEVIVE Policy

Drug(s): AMEVIVE (alefacept)

Covered Uses: AMEVIVE is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis, who are candidates for systemic therapy or phototherapy. All criteria in "other criteria" section must be met for coverage.

Required Medical Information: CD4+ count, %BSA involvement, previous and current therapies and responses, quality of life assessments at baseline and current, chart notes indicating relevant information

Age Restrictions: Restricted to 18 years of age and older.

Prescriber Restrictions: Restricted to dermatologists

Other Criteria: Treatment with these agents will be considered medically necessary when ALL of the following criteria are met:

- The medication must be ordered by or with consult of a plan participating dermatologist.
- Use of the biologic agents should be reserved for members with severe psoriasis or those with functional disability and/or intractable recalcitrant psoriasis which interferes with activities of daily living due to the affected areas (e.g. hands and/or feet).
- A diagnosis of severe chronic plaque psoriasis with 30% BSA (body surface area) involvement or involvement of the palms, soles of feet and scalp for at least one year.
- Topical corticosteroids are not effective or contraindicated.
- Treatment with other topical agents such as calcipotriene, tazarotene, salicyclates are not effective or contraindicated.
- Treatment with phototherapy or photochemotherapy was not effective or contraindicated.
- An appropriate treatment trial was not effective or contraindicated with at least two of the following agents: methotrexate, oral retinoids, or cyclosporine.
- And who have functional impairment related to symptomatology of psoriasis.

Initial authorization period will be allowed for up to a maximum of three months. Continuation of therapy will be allowed for up to a maximum of 6 months and will require documentation of improved patient status in the monitoring parameters of all of the following:

- At least a 50% improvement of clinical signs/symptoms of psoriasis (e.g. itching, redness, scaling, psoriatic body surface area coverage) at three months and 75% improvement at six months.
- Quality of life assessments - improved per patient and/or physician.
- The recommended regimen is a course of 12 weekly injections. A second cycle may be given provided the CDA+T lymphocyte count is greater than 250 cells per

microliter and 12 weeks has elapsed since the previous cycle. Data on retreatment beyond 2 cycles is limited. Since there is no safety data for continuous long-term administration, use of this agent is not considered medically necessary for first-line biologic therapy.

Exclusion Criteria: Coverage is excluded for:

- First-line biologic therapy or retreatment beyond 2 cycles.
- Members for whom these medications are contraindicated as listed in the Drug Prescribing Information.
- Members who have not had plaque psoriasis for more than one year.
- Members who have a clinically important infection or a history of chronic or recurrent infections.
- Members who are receiving concurrent treatment with immunosuppressive therapies or have a history of malignancy.
- Combination therapy with multiple biologics.
- Combination light therapy with biologics will be assessed for additional benefit over monotherapy alone.
- Members who have another form of psoriasis other than chronic plaque psoriasis (e.g. guttate, erythrodermic or pustular psoriasis as the sole or predominant form).
- Members who have a low CD4+ count less than 250 cells/ μ L prior to ordering alefacept

Coverage Duration: 12 weeks initial with one additional cycle of 12 weeks if appropriate.