CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

OFFICE CANADIEN DE COORDINATION DE L'ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

ALEFACEPT
(Amevive® – Biogen Idec Canada Inc.)

Description:
Alefacept is a recombinant human fusion protein that inhibits the activation and proliferation of T cells which play a role in the inflammatory pathogenesis of psoriatic lesions. Alefacept is indicated for treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy or systemic therapy.

Recommendation:
The Canadian Expert Drug Advisory Committee recommends that alefacept not be listed.

Reasons for the Recommendation:

1. The Committee considered 3 randomized double-blind placebo controlled trials in patients with moderate to severe plaque psoriasis. Alefacept has only been compared directly against placebo, and not alternative therapies. A significantly greater portion of patients treated with alefacept had an efficacious response versus placebo patients. However, the lack of comparison of alefacept to alternative therapies prevents determining alefacept's place in therapy for patients with severe chronic plaque psoriasis.

2. There are no controlled studies of alefacept beyond two 12-week treatment cycles. The evidence to date has only evaluated alefacept in relation to placebo and as a short-term therapy for a chronic condition.

3. In the short trials submitted, serious infection and malignancy were more frequent in the alefacept-treated than placebo groups. Although the difference was not statistically significant, these adverse events are a concern because of this product's mechanism of action.

4. Alefacept is administered once a week for 12 weeks followed by a minimum of 12 weeks off therapy. Considered on a weekly or yearly basis, alefacept is more expensive than the other therapeutic options that are approved in Canada for the same indication. Since it has only been compared to placebo, the higher cost in relation to other therapies for the same indication has not been justified.

Of Note:

1. For some patients, none of the current treatment options for moderate to severe plaque psoriasis achieve adequate remission. However, there is insufficient evidence that alefacept should be used for patients refractory to currently available therapeutic options.

2. CD4+ cell counts must be monitored biweekly during therapy. The cost of CD4+ monitoring (~$100/test) should be considered when calculating the overall cost of alefacept therapy.

3. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.