CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

ALEFACEPT RESUBMISSION
(Amevive® – Astellas Pharma 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 approved for treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy or systemic therapy.

Dosage Forms:
15 mg vial for intramuscular injection. Alefacept is administered once a week for 12 weeks followed by a minimum of 12 weeks off therapy.

Recommendation:
The Canadian Expert Drug Advisory Committee had previously recommended that alefacept not be listed (see Notice of CEDAC Final Recommendation on alefacept issued on May 26, 2005). Two new randomized controlled trials (RCTs) were the basis for the alefacept resubmission. The Committee maintains its recommendation that alefacept not be listed.

Reasons for the Recommendation:
1. In addition to the information considered in the previous alefacept submission, the Committee considered two additional RCTs in patients with moderate to severe plaque psoriasis. As one of these RCTs only enrolled 20 patients, the focus of the review was a new placebo controlled RCT in 195 patients for whom three or more other therapies had either failed or were inappropriate. Two weeks after the final dose of one 12 week course of therapy, significantly more patients treated with alefacept had achieved a ≥ 50% reduction in the Psoriasis Area Severity Index (PASI) score (24% of alefacept vs 11% of placebo) but there was no statistically significant difference in the number of patients who achieved a ≥ 75% reduction in the PASI score (9% of alefacept vs 5% of placebo patients). There was also no statistically significant difference in quality of life between the alefacept and placebo groups.

2. The cost of a 12 week course of alefacept is $15,000 and the annual cost of continued treatment with alefacept can be as much as $30,000 per patient. The Committee did not feel that these costs were justified in view of the relatively low response rates and lack of demonstrated effect on quality of life in patients who had failed other therapies.

Of Note:

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 Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

2. A number of biologic agents are now approved for use in severe psoriasis. Drug plans should consider a drug class review of these agents to assess their relative effectiveness, harms, cost and place in therapy and, the role of registries for these drugs.