Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

LANREOTIDE ACETATE (Somatuline® Autogel® – Ipsen Limited)

Description:

Lanreotide acetate is a synthetic octapeptide analogue of natural somatostatin that is approved for use in the long-term treatment of patients with acromegaly due to pituitary tumours who have had inadequate response to or cannot be treated with surgery and/or radiotherapy; and for the relief of symptoms associated with acromegaly.

Dosage Forms:

60 mg, 90 mg and 120 mg pre-filled syringes. The recommended dose is 60, 90 or 120 mg given every four weeks by deep subcutaneous injection.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that lanreotide acetate (Somatuline® Autogel®) be listed with restrictions in a similar manner that drug plans currently list long acting octreotide acetate (Sandostatin® LAR®) for the treatment of acromegaly.

Reasons for the Recommendation:

1. Within the approved dosage ranges, the monthly costs of lanreotide acetate ($1,102 for 60 mg, $1,470 for 90 mg and $1,840 for 120 mg) are slightly less than the long acting formulation of octreotide acetate (Sandostatin® LAR® costs $1,183 for 10 mg, $1,578 for 20 mg and $1,976 for 30 mg).

Summary of Committee Considerations:

The Committee considered a systematic review of randomized controlled trials (RCTs) of lanreotide acetate in adult patients with acromegaly. Two RCTs met the inclusion criteria for the systematic review, one of which was a randomized cross-over study comparing lanreotide acetate with octreotide in only 12 patients. The focus of the review was a four week, double blind RCT in 108 patients that compared three doses of lanreotide acetate (60 mg, 90 mg, 120 mg, each given monthly) with placebo. After four weeks, patients who had received placebo were crossed-over to one of the three lanreotide acetate dose groups. Patients were followed for a total of 52 weeks and dose titration was permitted between week 20 and week 52 of the trial. After four weeks, statistically significantly more patients treated with lanreotide acetate 60 mg (30%) and 90 mg (30%) achieved normal levels of insulin-like growth factor-I (IGF-I) compared to placebo (4%). There was no statistically significant difference in the rate of normalization of IGF-I levels between lanreotide acetate 120 mg (17%) and placebo. Levels of growth hormone decreased

in all lanreotide acetate groups and increased in the placebo group and these differences were statistically significant. The effect of lanreotide on normalization of IGF-I and growth hormone were maintained for 52 weeks, as assessed during the open label, dose-ranging phase of the trial.

The most common adverse reactions associated with lanreotide acetate therapy are injection site reactions and gastrointestinal complaints, such as diarrhea and abdominal pain.

Of Note:

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

Background:

CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.