Regimen Monograph

A - Regimen Name

LANR Regimen

Lanreotide

Disease Site

Gastrointestinal
- Neuroendocrine (GI)

Lung
- Neuroendocrine (Lung)

Intent

Palliative

Regimen Category

Evidence-Informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses

- For the treatment of enteropancreatic neuroendocrine tumours in adult patients with grade 1 or a subset of grade 2 (equivalent to Ki67 < 10%) unresectable, locally advanced or metastatic disease to slow progression. No survival benefit was seen; there are few data on patients with hindgut tumours.
- Treatment of lung neuroendocrine tumours
- Treatment of adult patients with carcinoid syndrome; when used, lanreotide reduces the administration frequency of short-acting somatostatin analog rescue therapy

Supplementary **lanreotide**
Public Funding ODB - General Benefit (lanreotide) (ODB Formulary)

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B - Drug Regimen

lanreotide	120 mg	Subcut	Day 1

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

If patients are being treated with lanreotide for enteropancreatic NETs, do not give an additional dose for the treatment of carcinoid syndrome.

Dosage with toxicity

No dosage adjustment required. The drug should be discontinued in the case of disease progression or severe adverse events.

Hepatic Impairment

In acromegaly patients, lanreotide clearance is reduced by 30% in patients with moderate to severe hepatic impairment. Patients with neuroendocrine tumours or carcinoid tumours and hepatic impairment have not been studied.

Suggested dosage adjustment:

Hepatic impairment	**Lanreotide starting dose (mg)**
Mild (Child-Pugh A)	Use with caution as no data
Moderate to severe (Child-Pugh B or C)	Use with caution as no data*

*in acromegaly, a dose of 60 mg is recommended.

Renal Impairment

Lanreotide clearance was not affected in patients with neuroendocrine tumours and mild or moderate renal impairment. Patients with carcinoid syndrome and renal impairment have not been studied.

Suggested dosage adjustment:

Renal impairment (CrCl in ml/min)	**Enteropancreatic NET starting dose (mg)**	**Carcinoid syndrome starting dose (mg)**
Mild to moderate (CrCl ≥ 30)	120	Use with caution as no data
Severe (CrCl < 30)	Use with caution as no data*	Use with caution as no data*

*in acromegaly, a dose of 60mg is recommended.

Dosage in the Elderly

Increases in half-life and mean residence time were observed in healthy subjects over 65 years of age, with no change in either AUC or Cmax. No effect of age on clearance and volume of

distribution was observed in pharmacokinetics analysis with NET patients aged 65-85 years. Clinical studies did not include sufficient patients to evaluate the impact of age.

Dosage adjustment is not necessary.

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F - Adverse Effects

Refer to lanreotide drug monograph(s) for additional details of adverse effects

Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Abdominal pain • Nausea, vomiting • Headache • Cholelithiasis • Hypertension • Musculoskeletal pain	• Hyper / hypoglycemia • Bradycardia • Hypersensitivity • Hepatic failure • Pancreatic insufficiency • Pancreatitis • Cholecystitis

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G - Interactions

Refer to lanreotide drug monograph(s) for additional details

- Lanreotide is extensively metabolized in the GI tract after biliary excretion and may reduce intestinal absorption of co-administered drugs.
- Intestinal absorption of oral cyclosporine may be delayed; monitor cyclosporine levels and adjust the dose as required or switch to IV cyclosporine.
- Bromocriptine absorption may be altered; caution and monitor for bromocriptine toxicity.
- Caution & monitor with hypoglycemic agents; adjust dose of hypoglycemic agent as required.
- Increased risk of bradycardia when used with drugs that may decrease heart rate (e.g. beta blockers); dose adjustment of concomitant drugs may be necessary.

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H - Drug Administration and Special Precautions

Refer to lanreotide drug monograph(s) for additional details

Administration:

- Lanreotide should be injected by deep subcutaneous route in the superior external quadrant of the buttock
- In the case of self-administration (with appropriate training), the injection may be given in the upper outer thigh
- The injection site should be alternated between right and left sides
- If a dose is missed, the next dose should be administered as soon as possible
- The drug should be stored under refrigeration (2-8^{o}C) in its original package

Contraindications:

- Patients who are hypersensitive to this drug or any ingredients in the formulation
- Patients who are hypersensitive to somatostatin or related peptides
- Patients with complicated, untreated lithiasis of the bile ducts

Warnings/precautions:

- Use with caution and monitor blood glucose closely in patients with diabetes.
- Exercise caution when driving or operating machinery while on treatment, as headache and dizziness were most commonly reported.

Pregnancy & lactation:

- Lanreotide is not recommended for use in pregnancy given limited clinical experience. Adequate contraception should be used by both sexes during treatment, and for at least 6 months after the last dose.
- Breastfeeding is not recommended.

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Blood glucose; Baseline and at each visit; more frequent in diabetic patients
- Gallbladder ultrasound; Baseline and periodic

- Heart rate; Baseline and at each visit; more frequent in patients with cardiac disorders
- Thyroid function tests; as clinically indicated
- Clinical toxicity assessment for GI effects, injection site reactions, CNS effects, hypertension; at each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Outpatient prescription; drug administration at Cancer Centre or physician's office

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K - References

Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. N Engl J Med 2014;371:224-33.

Fisher GA Jr., Wolin EM, Liyanage N, et al. Patient-Reported Symptom Control of Diarrhea and Flushing in Patients with Neuroendocrine Tumors Treated with Lanreotide Depot/Autogel: Results from a Randomized, Placebo-Controlled, Double-Blind and 32-Week Open-Label Study. Oncologist. 2018 Jan;23(1):16-24.

Vinik AI, Wolin EM, Liyanage N, et al. Evaluation of Lanreotide Depot/Autogel efficacy and safety as a carcinoid syndrome treatment (ELECT): a randomized, double-bind, placebo-controlled trial. Endocr Pract. 2016 Sep;22(9):1068-80.

Lanreotide drug monograph, Cancer Care Ontario.

PEBC Advice Documents or Guidelines

- Systemic Therapy of Incurable Gastroenteropancreatic Neuroendocrine Tumours

September 2022 Added Neuroendocrine(Lung) as a disease site

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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