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 (NETs) 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.
- For the treatment of lung NETs
- For the 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

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.

Hepatic Impairment	Lanreotide Dose
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 starting dose of 60 mg is recommended followed by dose adjustments.

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.

Renal Impairment (CrCl in mL/min)	Enteropancreatic NET Dose (mg)	Carcinoid Syndrome Dose (mg)
Mild (CrCl ≥ 60)	120	Use with caution as no data
Moderate (CrCl 30 to <60)	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 starting dose of 60 mg is recommended followed by dose adjustments.

Dosage in the Elderly

No specific dose adjustment has been recommended.

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 number of patients aged ≥ 65 years with carcinoid syndrome or enteropancreatic NETs to evaluate whether they respond differently from younger patients.

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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 • Injection site reaction • Anemia • Hearing impaired

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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; consider bromocriptine dose reduction.
- 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.
- Caution and monitor with CYP3A4 substrates that have a low therapeutic index; consider substrate dose reduction.

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H - Drug Administration and Special Precautions

Refer to lanreotide drug monograph(s) for additional details

Administration:

- The drug is for immediate and single use after first opening. No reconstitution is required.
- Lanreotide should be injected by deep subcutaneous route in the superior external quadrant of the buttock or upper outer thigh.
- In the case of self-administration (with appropriate training), the injection may be given in the upper outer thigh.
- The skin should be stretched prior to injection and the injection site should be alternated between right and left sides.
- Typically 20 seconds are needed to complete each injection.
- 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.
- The drug may be stored at room temperature for 30 minutes before administration. Keep pouch sealed until just prior to injection.

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:

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: May reduce fertility in females

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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
- Heart rate; Baseline and at each visit; more frequent in patients with cardiac disorders
- Gallbladder ultrasound; Baseline and periodic
- 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.

Lanreotide drug monograph, Ontario Health (Cancer Care Ontario).

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.

PEBC Advice Documents or Guidelines

- Systemic Therapy for Unresectable Advanced or Metastatic Pancreatic and Midgut Neuroendocrine Tumours

May 2024 Modified Dosage in hepatic impairment, Dosage in renal impairment, Dosage in the elderly, Interactions, Administration, and Pregnancy/lactation sections

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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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The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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