Regimen Monograph

A - Regimen Name

ALDE(Intralesional) Regimen

Aldesleukin

Disease Site	Skin - Melanoma
Intent	Palliative Curative
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 in-transit metastases from melanoma in patients who have failed or are not candidates for surgery or other treatments. This recommendation is based on phase II studies that showed improvements in complete response; an overall survival benefit has not be demonstrated.
Supplementary Public Funding	**aldesleukin** New Drug Funding Program (Aldesleukin (interleukin-2) - In-Transit Metastases from Melanoma) (NDFP Website)

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B - Drug Regimen

The amount injected depends on the number and size of in-transit metastases. Doses should not exceed 1 vial (22 million IU) per cycle.

aldesleukin	up to 22 million IU	Intralesional

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C - Cycle Frequency

REPEAT EVERY 7 TO 14 DAYS

Curative: For a total of 8 cycles

Palliative: Until disease progression or lesion regression

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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E - Dose Modifications

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

Dosage with toxicity

Aldesleukin is generally well-tolerated. In one study, the drug was discontinued if lesions were enlarging despite injection or if there was no visible response by the fourth injection (Boyd et al. 2011).

Hepatic Impairment

Hold until recovery if any signs of hepatic failure are present.

Renal Impairment

Do not start treatment if serum creatinine > 130 µmol/L.

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F - Adverse Effects

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

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Injection-site reaction • Flu-like symptoms (fever, fatigue) • Nausea, vomiting	• Arrhythmia • Hypersensitivity

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G - Interactions

Refer to aldesleukin drug monograph(s) for additional details

Glucocorticoids may reduce the anti-tumour effect of aldesleukin.

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H - Drug Administration and Special Precautions

Refer to aldesleukin drug monograph(s) for additional details

Administration

- Reconstitute vial with 1.2 mL of SWFI and swirl gently to mix. DO NOT shake.

- Dilute with D5W to desired concentration.
- Withdraw into syringes for intralesional administration per local protocol.
- Store reconstituted drug between 2 to 8^{o}C for up to 48 hours. DO NOT freeze.

Contraindications

- hypersensitivity to aldesleukin, interleukin-2, or any other components of the product

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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

- CBC; baseline and as clinically indicated
- CT scan of brain to exclude CNS metastases; baseline
- Electrolytes; baseline and as clinically indicated
- Liver and renal function tests; baseline and as clinically indicated
- Clinical toxicity assessment for flu-like symptoms, injection site reactions, hypersensitivity; at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Pharmacy Workload (average time per visit) 47.350 minutes

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K - References

Aldesleukin drug monograph, Cancer Care Ontario.

Boyd KU, Wehrli BM, Temple CL. Intra-lesional interleukin-2 for the treatment of in-transit melanoma. J Surg Oncol. 2011 Dec;104(7):711-7.

Hassan S, Petrella TM, Zhang T, et al. Pathologic complete response to intralesional interleukin-2 therapy associated with improved survival in melanoma patients with in-transit disease. Ann Surg Oncol 2015;22(6):1950-8.

pCODR Expert review committee final recommendation. Aldesleukin for in-transit melanoma. May 2015.

Weide B, Derhovanessian E, Pflugfelder A, et al. High response rate after intratumoral treatment with interleukin-2: results from a phase 2 study in 51 patients with metastasized melanoma. Cancer. 2010 Sep 1;116(17):4139-46.

May 2019 Updated emetic risk category

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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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