Regimen Monograph

 Regimen Name
 Drug Regimen
 Cycle Frequency
 Premedication and Supportive Measures
 Dose Modifications
 Adverse

 Effects
 Interactions
 Drug Administration and Special Precautions
 Recommended Clinical Monitoring
 Administrative

 Information
 References
 Other Notes
 Disclaimer

A - Regimen Name

LUSP Regimen

Luspatercept

- Disease Site Hematologic Myelodysplastic Syndrome (MDS)
- Intent Palliative

Regimen Evidence-informed :

Category

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.

This **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). 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.

Rationale and
UsesFor the treatment of transfusion-dependent anemia in patients with very low- to
intermediate-risk myelodysplastic syndromes (MDS) who have ring
sideroblasts, require at least two RBC units over 8 weeks, and have
progressed on or are not suitable for an erythropoietin stimulating agent

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Supplementary Public Funding	Iuspatercept Exceptional Access Program (luspatercept - For the treatment of red-blood cell (RBC) transfusion-dependent anemia associated with Myelodysplastic Syndromes (MDS), according to clinical criteria) (<u>EAP Website</u>)		
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B - Drug Regimen			
luspatercept ¹	1 mg /kg	Subcut	Day 1

¹ Starting dose. If a patient is not RBC transfusion-free, the dose may be increased stepwise according to the product monograph, to a maximum of 1.75 mg/kg or 168 mg (whichever is reached first).

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until a lack of meaningful response*, disease progression or unacceptable toxicity

*Luspatercept should be discontinued in patients who have not achieved a reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.75 mg/kg, in accordance with the product monograph.

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K - References

CADTH Reimbursement Recommendation: Luspatercept (Reblozyl). Canadian Journal of Health Technologies. Dec 2021.

Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in Patients with Lower-Risk Myelodysplastic Syndromes.N Engl J Med 2020;382:140-51. DOI: 10.1056/NEJMoa1908892

Product monograph: Luspatercept (Reblozyl®). October 2022.

March 2023 Modified Rationale/uses, Supplementary public funding, Drug regimen and Cycle frequency sections

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M - Disclaimer

Regimen Abstracts

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

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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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