Formulary Listing Recommendation Report:

Zemaira® (alpha1-proteinase inhibitor (human))

Canadian Blood Services' Plasma Protein and Related Products Formulary

Canadian Blood Services is an independent not-for-profit organization, operating independently of government. Operating within a broader national network of health-care systems, we are responsible for providing blood and blood products, as well as transfusion and stem cell registry services, on behalf of all provincial and territorial governments except Quebec.

As part of our work, Canadian Blood Services manage a pan-Canadian formulary of plasma protein and related products (PPRP) which are accessible to clinicians in Canada for use in caring for their patients. The formulary is fully integrated with the national blood system, as we also manage the procurement, inventory management, and distribution of PPRP.

For more information about the PPRP program and formulary, please visit Plasma protein and related products (blood.ca).

CADTH-Canadian Blood Services Interim Plasma Protein and Related Product Review Process

In November 2019, CADTH and Canadian Blood Services established a new interim process for the review of PPRP.

Applications from manufacturers for PPRP which are new in Canada are submitted to the Canadian Agency for Drugs and Technologies in Health (CADTH) and Canadian Blood Services for consideration.

Provincial and Territorial Ministries of Health make an initial decision on whether the new product will be assessed through the interim PPRP review process.

Once confirmed, CADTH and Canadian Blood Services conduct assessments on the product to incorporate clinical, pharmacoeconomic, and ethical considerations before a final recommendation is submitted to Provincial and Territorial Ministries of Health for a decision on whether the product will be carried under Canadian Blood Services' formulary.

*In the case of procurement of new brands of existing products on Canadian Blood Services' formulary, Canadian Blood Services makes the final decision.

This formulary listing recommendation report provides details on CADTH's and Canadian Blood Services' recommendations for Zemaira®, supporting notes, and key milestones of the review.

Submission Summary

Brand name: Zemaira®

Chemical name: Alpha1-Proteinase Inhibitor (Human)

Dosage form: IV infusion

Supplier: CSL Behring Canada

Health Canada indication:

Zemaira (Alpha1-Proteinase Inhibitor (Human)) is indicated for maintenance treatment in adults with severe A1-PI deficiency (e.g. genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ) and clinical evidence of emphysema.

Patients are to be under optimal pharmacologic and non-pharmacologic treatment and show evidence of progressive lung disease (e.g., lower forced expiratory volume per second (FEV1) predicted, lower diffusion capacity, impaired walking capacity or increased number of exacerbations) as evaluated by a healthcare professional experienced in the treatment of A1-PI deficiency.

Reimbursement request (from supplier):

Same as above (i.e., Health Canada approved indication)

Review type: Interim Plasma Protein and Related Products Review

Final listing decision: Eligible for listing

CADTH recommendation

Date recommendation issued: May 02, 2022

Recommendation: CADTH CPEC recommended to list with criteria. Visit the CADTH website for more details.

https://www.cadth.ca/sites/default/files/DRR/2022/ST0702 Zemaira - CADTH Final Rec Final.pdf

CADTH recommendation □ List x List with conditions. □ Do not list.	Initiation conditions 1. Zemaira should be reimbursed in adults with severe A1-PI deficiency (e.g., genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ) and clinical evidence of emphysema. 2. Patients must be nonsmokers for at least 6 months. Discontinuation condition 3. Reimbursement of Zemaira should be discontinued in patients who receive a lung transplant. Prescribing conditions 4. Patient should be under the care of a respirologist. Pricing conditions 5. A reduction in price. Feasibility of adoption 6. The feasibility of adoption of Zemaira must be addressed.

Canadian Blood Services recommendation

Date of recommendation: Sept. 26, 2022

Recommendation:

Canadian Blood Services recommends that Zemaira® be eligible to be listed for adults with severe A1-PI deficiency and clinical evidence of emphysema on condition of a lower price being achieved.

Notes

- Negotiations with the vendor for Zemaira® through the interim PPRP review were not able to address the concerns identified by CADTH and Canadian Blood Services with respect to cost-effectiveness and value for money. To achieve the best value for money, Canadian Blood Services will issue a Request for Proposals for all Health Canada approved A1-PI products.
- If a lower price is achieved, Canadian Blood Services would proceed with listing the selected A1-PI product with following criteria:
  - Prescribing criteria:
    - Respirologist has confirmed the diagnosis of severe A1-PI deficiency and clinical evidence of emphysema and indicated that patient would benefit from treatment with A1-PI product.
  - Eligibility criteria:
    - A1-PI deficiency, defined as serum A1-PI levels <11 µM/L or < 80 mg/dL before start of the treatment, and
    - Clinical evidence of emphysema (FEV1 <80%), and
    - Patients must be nonsmokers for at least 6 months.
  - Discontinuation criteria:
    - Discontinuation for patients who receive a lung transplant.