

Formulary Listing Recommendation Report:

Ondexxya® (Andexanet alfa)

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 healthcare 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 \(blood.ca\)](https://blood.ca/plasma-protein-and-related-products).

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.

Submission Summary

Brand name: Ondexxya®

Chemical name: Andexanet alfa

Dosage form: IV infusion

Supplier: AstraZeneca

Health Canada indication:

- Adult patients treated with FXa inhibitors (rivaroxaban or apixaban) when rapid reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Review type: Interim Plasma Protein and Related Products Review

Final review status: Closed. Following the CADTH Canadian Plasma Protein Product Expert Committee (CPEC) recommendation, CBS and the sponsor agreed to not pursue negotiations.

CADTH recommendation

Date recommendation issued: December 21, 2023

Recommendation: The CADTH Canadian Plasma Protein Product Expert Committee (CPEC) recommended that Ondexxya should not be reimbursed. Visit the CADTH website for more details.

<https://www.cadth.ca/andexanet-alfa>

<p>CADTH recommendation</p> <ul style="list-style-type: none"> <input type="checkbox"/> List <input type="checkbox"/> List with conditions <input checked="" type="checkbox"/> Do not list 	<p><u>Summary</u></p> <p>Based on the evidence (ANNEXA-4) reviewed, the CPEC was not convinced that treatment with Ondexxya would achieve outcomes (neurologic status and mortality) that are clinically important to patients or meet needs not already addressed by other available treatments.</p>
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Canadian Blood Services recommendation

Date of decision: March 20, 2024
Recommendation: N/A Review status: Closed
Notes <ul style="list-style-type: none">Based on the evidence reviewed and the negative recommendation from CPEC, after several engagements with the sponsor, it has been decided that the negotiation will not be pursued.