Formulary listing recommendation report:

emicizumab (Hemlibra®)

Canadian Blood Services' plasma protein and related products (PPRP) formulary

Canadian Blood Services is a not-for-profit organization that operates independently from government. Working 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 manages 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.

CADTH-Canadian Blood Services interim plasma protein product (PPP) 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 seeking public reimbursement 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 or through a different assessment process, such as CADTH's Common Drug Review (CDR).

Once it is confirmed that the product will be assessed through the interim PPP review process, CADTH and Canadian Blood Services conduct assessments on the product to incorporate clinical, pharmacoeconomic, and ethical considerations before making a recommendation. Final recommendations are submitted to Provincial and Territorial Ministries of Health for a decision on whether the product will be carried under Canadian Blood Services' formulary.

* Submissions from manufacturers for new brands of products which fall under an already approved category are assessed by Canadian Blood Services through an open and competitive procurement process.

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

Submission summary

Brand name: Hemlibra®

Chemical name: emicizumab

Route of administration: Subcutaneous injection

Supplier: Hoffmann-La Roche Ltd.

Health Canada indication: Hemophilia A (congenital factor VIII deficiency) patients with or without factor VIII inhibitors as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes.

Reimbursement request (from supplier): For hemophilia A (congenital factor VIII deficiency) severe patients without factor VIII inhibitors as per HAVEN 3 trial patient eligibility, and including:

- Patients who have limited ability to receive regular IV therapy due to other underlying factors such as venous access challenges or geographical treatment access restrictions despite being candidates for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes with factor VIII.
- Patients who are at a significant risk for increased bleeding rates due to factors that lead to poor adherence or persistence despite being candidates for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes with factor VIII.

Review type: Interim Plasma Protein Product Review

CADTH recommendation

Recommendation: CADTH recommended listing emicizumab with criteria.

For more details, see the CADTH Reimbursement Recommendation on the CADTH website.

CADTH RECOMMENDATION
Date of recommendation: December 23, 2020 **Recommendation:** The CADTH Canadian Plasma Protein Product Expert Committee (CPEC) recommends that emicizumab be reimbursed for the treatment of patients with hemophilia A (congenital factor VIII deficiency) without factor VIII (FVIII) inhibitors only if the following conditions are met. **Conditions for Reimbursement:** Initiation criteria 1. Patients with severe hemophilia A (intrinsic FVIII level < 1%) who are candidates for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes. Prescribing conditions 1. The patients must be under the care of a hematologist with experience in the diagnosis and management of hemophilia A. Pricing conditions 1. The public payer cost of emicizumab should not exceed the public payer cost of treatment with the least costly FVIII replacement that is being reimbursed for the prophylactic treatment of patients with hemophilia A without FVIII inhibitors.

Canadian Blood Services recommendation

CANADIAN BLOOD SERVICES RECOMMENDATION
Date of recommendation: May 21, 2021 **Recommendation:** Canadian Blood Services recommends that emicizumab be listed with the following criteria: • Patients with severe hemophilia A (intrinsic FVIII level < 1%) who are candidates for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes. **Notes:** • This recommendation is aligned with the CADTH recommendation. • Exceptional cases would be reviewed through the Special Authorization process.

This new listing criteria is in addition to the current listing of emicizumab for patients with congenital hemophilia A with FVIII inhibitors.