Formulary Listing Recommendation Report:

HyQvia® (Immunoglobulin (human) 10% and recombinant human hyaluronidase)

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 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 (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 HyQvia®, supporting notes, and key milestones of the review.

Submission Summary

Brand name: HyQvia®

Chemical name: Immunoglobulin (human) 10% and recombinant human hyaluronidase

Dosage form: Subcutaneous injection

Supplier: Takeda Canada

Health Canada indication:

As replacement therapy for primary humoral immunodeficiency (PI) and secondary humoral immunodeficiency (SI) in adult patients.

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: List

CADTH recommendation

Date recommendation issued: July 04, 2022

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

Normal Immunoglobulin (Human) 10% and Recombinant Human Hyaluronidase (HyQvia) (cadth.ca)

CADTH recommendation □ List x List with conditions □ Do not list	Initiation condition 1. Eligibility for reimbursement of IgHy10 should be based on the criteria currently used for reimbursement of other immunoglobulin replacement therapies (IgRTs) for the treatment of primary humoral immunodeficiency and secondary humoral immunodeficiency. Renewal condition 2. Renewal criteria of IgHy10 should be based on the criteria currently used for other IgRTs currently reimbursed for the treatment of primary humoral immunodeficiency and secondary humoral immunodeficiency. Prescribing condition 3. IgHy10 should be prescribed by a specialist with appropriate knowledge and training in primary humoral immunodeficiency and secondary humoral immunodeficiency. Pricing condition 4. The price of IgHy10 should be negotiated so that it does not exceed the cost of treatment with the least costly IVIg or SCIg reimbursed for the treatment of primary humoral immunodeficiency and secondary humoral immunodeficiency. Feasibility of adoption 5. The feasibility of adoption of IgHy10 must be addressed.

Canadian Blood Services recommendation

Date of recommendation: Nov 29, 2022
Recommendation Canadian Blood Services recommends that HyQvia® be listed on the PPRP formulary without restrictions.
Notes ▪ This recommendation is to list HyQvia® in the same manner as other Ig products on the PPRP formulary. ▪ This recommendation reflects negotiations between Canadian Blood Services and the vendor for HyQvia®, as part of the interim PPRP review process, to confirm feasibility of adoption. ▪ This recommendation considers the expert feedback received from clinical and patient stakeholders on the potential impacts of the product's introduction, and on the implications of the CADTH conditions (above).