National Ig Shortages Management Plan: Project Overview

Project Objective and Deliverables

Through the support of Health Canada and provincial and territorial ministries of health, this project will develop an evidence-based and stakeholder-informed National Ig Shortages Management Plan. Building upon the National Plan for Management of Shortages of Immunoglobulin Products – Interim Guidance (Interim Guidance) that received approval from provincial and territorial ministries of health in September 2020, the National Ig Shortages Management Plan will provide the necessary framework and guidance for appropriate allocation of Ig products to patients in the setting of short-term or more prolonged shortage situations.

Representatives of the National Advisory Committee on Blood and Blood Products (NAC), Health Canada, Canadian Blood Services, and the Provincial / Territorial Blood Liaison Committee (PTBLC) will provide subject matter expertise, advice on approach, strategic level issues and risks, as well as clinical and governmental perspectives. Upon completion, the National Ig Shortages Management Plan will be submitted to the provincial and territorial ministries of health for approval.

The following deliverables are expected by March 31, 2024:

• **Ethical framework:** outline key principles to guide deliberations and inform decisions about the triage and adjudication of Ig products during times of shortage.

• **Alternative therapy recommendations:** Access to alternative therapies is crucial for mitigating an increased shortage of inventory and to preserve Ig products for patients for whom there are no alternative therapies. To promote a consistent approach to alternative therapies across jurisdictions, recommendations for appropriate alternative therapies will be provided along with an overview of access to these alternative therapies across the country.

• **Triage and adjudication criteria:** Clear, evidence-based, and stakeholder informed guidelines for how Ig should be triaged during times of shortage will be developed, including prioritization of patients within and across clinical specialties.

• **Triage and adjudication process / operationalization plan:** To ensure the National Ig Shortages Management Plan is effectively operationalized, the project will establish roles and responsibilities of all stakeholders; develop a process and mechanism by which stakeholders can share data; create plans for communicating during times of shortage; and identify appropriate tools for use to document triage and adjudication decisions.

Existing guidance available provincially and nationally, including the Interim Guidance, will be leveraged as much as possible to minimize the potential for any duplication of effort.
Project Schedule

The following is a high-level overview of the project schedule.

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Stakeholders

Similar to the development of the Interim Guidance, a broad range of multidisciplinary perspectives will be solicited throughout the project. This includes, but is not limited to:

- Immunoglobulin prescribers and clinicians: immunology, neurology, rheumatology, hematology, oncology, dermatology, solid organ transplant, stem cell transplantation, infectious diseases
- Clinical nurse specialists
- Hospital transfusion medicine supervisors, medical leads, and technologists
- National Advisory Committee on Blood and Blood Products
- Canadian Blood Services
- Provincial/Territorial Blood Liaison Committee
- Provincial Emergency Blood Management Committee representation
- Health Canada (drug shortage process and procedures)
- Immunoglobulin product vendors/fractionators
- Blood coordinating offices/programs
- Provincial/territories
- Legal counsel
- Ethicists
• Patients
• Myasthenia Gravis (MG) Society of Canada
• Immunodeficiency Canada
• Immunity Canada (formerly Canadian Primary Immunodeficiency Organization (CIPO))
• Guillain-Barré Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy (GBS/CIDP) Foundation of Canada (includes Multifocal Motor neuropathy (MMN))
• Cell Therapy Transplant Canada (CTTC)
• Canadian Society of Allergy and Clinical Immunology (CSACI)
• Canadian Pediatric Society
• Canadian Society for Immunology
• Canadian Neurological Sciences Federation
• Canadian Hematology Society
• Canadian Dermatology Association
• Association of Medical Microbiology and Infectious Disease Canada
• Canadian Society of Transplantation (CST)
• Primary Immunodeficiency Nurses Network
• Canadian Association of Provincial Cancer Agencies
• Canadian Agency for Drugs and Technologies in Health (CADTH)
• Clinical Immunology Network Canada

For More Information
To find more information about this project to develop a National Ig Shortages Management Plan, please contact the NEBMC Secretariat (providing project management on behalf of CBS-PTBL and NAC): NEBMCSecretariat@blood.ca or Lindsay Wilson, Sr. Project Manager (lindsay.wilson@blood.ca), directly.