A Positive Impact on Provincial Utilization

Saskatchewan Immune Globulin Stewardship Program

2025 Saskatchewan Transfusion Medicine Symposium Tuesday September 16, 2025

Presented by:
Jan Newby-Hempel, RN
Melissa Greene, RN
Sarah Selinger, RN

Healthy People, Healthy Saskatchewan

The Saskatchewan Health Authority works in the spirit of truth and reconciliation, acknowledging Saskatchewan as the traditional territory of First Nations and Métis People.





Disclosure of Conflict of Interest

IG Stewardship Program Nurse Navigators

Speaker: Jan Newby-Hempel, RN

- Nothing to Declare
- Paid employee of the Saskatchewan Health Authority

Speaker: Melissa Greene, RN

- Other: 2025 Canadian Society of Transfusion Medicine (CSTM) Nursing Bursary
- Paid employee of the Saskatchewan Health Authority

Speaker: Sarah Selinger, RN

- Nothing to Declare
- Paid employee of the Saskatchewan Health Authority





Introduction to Immune Globulins

What are Immune Globulins?

How are they administered?







Introduction to Immune Globulins

Immune Globulin

- Immune Globulin (Ig) is a human sourced blood product derived from the plasma of thousands of donors, and it contains thousands of different antibodies. Ig has many uses including:
 - Provides a boost of antibodies in the event of immunodeficiency which helps fight infection
 - Impedes the progress of an autoimmune disorder through anti-inflammatory mechanisms
- Global supply of this product is limited due to the rising demand for this therapeutic treatment.
- ➤ Given the potential risk of supply disruptions, Canadian Blood Services has emphasized the need for responsible utilization of Ig products, including both intravenous Ig (IVIG) and subcutaneous Ig (SCIG).
- Annual healthcare dollars spent on IG continues to rise.





Methods of Administration

Intravenous IG

- Induction or Maintenance schedules weekly to monthly
- Hospital or infusion clinic settings
- Doses range from 0.2 to 2 grams/Kg

Subcutaneous IG

- Once to twice weekly or monthly
- Administered in patient's home by patient
- Weekly doses typically 0.1 0.4g/Kg
- Monthly doses can be up to 2g/kg

Intramuscular IG

- Not commonly used and tends to be specific one-time dose
- Used for short term prevention of specific infectious diseases

The IG Stewardship Program currently only screens IVIG orders





Introduction to the Saskatchewan IG Stewardship Program





2020 IG forecast – Canadian Blood Services

In 2020 Canadian Blood Services identified the possible disruption of the IG supply and released recommendations to prepare for the potential shortage of IG. Part of this recommendation was to:



Ensure the utilization of Ig products follows best practices and provincial / territorial guidelines (indications, optimal use guides, modality of administration, and doses). A dose calculator based on adjusted body weight should be used for adult patients. Body weight adjustments for dosing and titration to lowest effective dose are considered best practices.



2020 IG forecast – Government of Canada

"Demand for IG continues to increase steadily in Canada (6-10% per year) and globally. Canada is now the 2nd highest global user per capita of IG."

"Due to the usage of IG in Canada, a number of audits were performed to understand the utilization of this product and the results showed a significant proportion of IG was being utilized outside established criteria and guidelines."

- Government of Canada: Protecting Access to Immune Globulins for Canadians





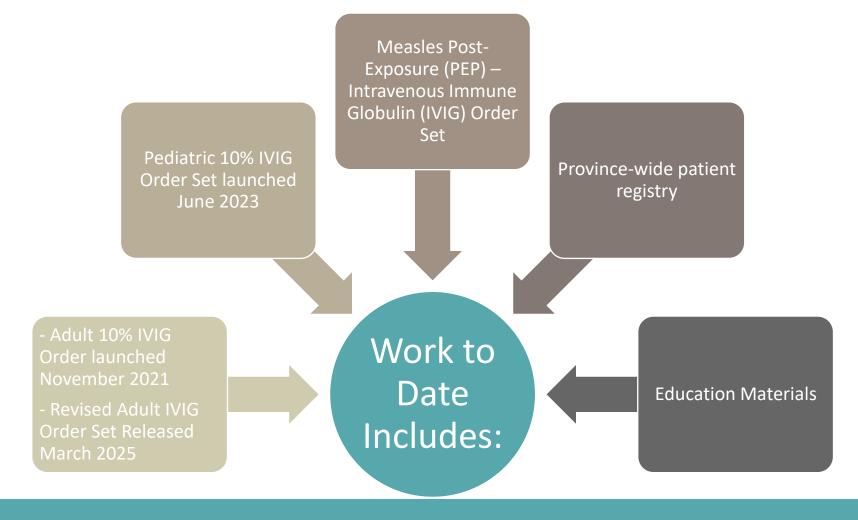
IG Stewardship Creation

- The IG Stewardship Program was initiated to monitor and ensure appropriate use of IVIG.
 - Dedicated funding from the Government of Saskatchewan is provided to the SHA for program delivery.
- Launched in November 2021 to ensure utilization of Ig products follow best practice by:
 - ABW dosing
 - The Criteria for the Clinical Use of Immune Globulin
- Our goal is to optimize IG therapy by implementing a comprehensive screening process that ensures patients receive the most effective, efficient and clinically appropriate IVIG dose.





IG Stewardship Work to Date







IG Stewardship Program Team

- IG Stewardship Program Team
- Nurse Navigators





IG Stewardship Program Team

Leadership

Brandi Keller – Executive Director Laboratory Medicine
Angela McTaggart – Director Laboratory Medicine Provincial Support
Kimberly Goodwill – Manager, Transfusion Safety/PBM North
Amanda Zylak – Manager, Transfusion Safety/PBM South

IG Stewardship Program Consultant Physicians

- Dr. Ardyth Milne, MD FRCPC
 - Division Lead Rheumatology, Regina Assistant Professor, Department of Medicine, College of Medicine, University of Saskatchewan
- Dr. Oksana Prokopchuk-Gauk, MD FRCPC DRCPSC
 - Transfusion Medicine Discipline Committee Clinical Lead, Saskatchewan Health Authority Clinical Hematologist, Saskatchewan Bleeding Disorders Program Assistant Professor, Department of Pathology and Lab Medicine, College of Medicine, University of Saskatchewan





IG Nurse Navigators Roles Screening and Approving Outpatient **Order Sets Education and** Maintain the Document **IG Patient** Development Registry Nurse **Navigator** Renewal Consent Letters for Renewal

Letters for

Outpatients

Outpatient

IVIG Order

Sets





Screening and Approval Of Intravenous Immune Globulin Orders

- Process Maps
- Criteria for the Clinical Use of Immune Globulin
- Alberta Health Services Adjusted Body Weight Calculator



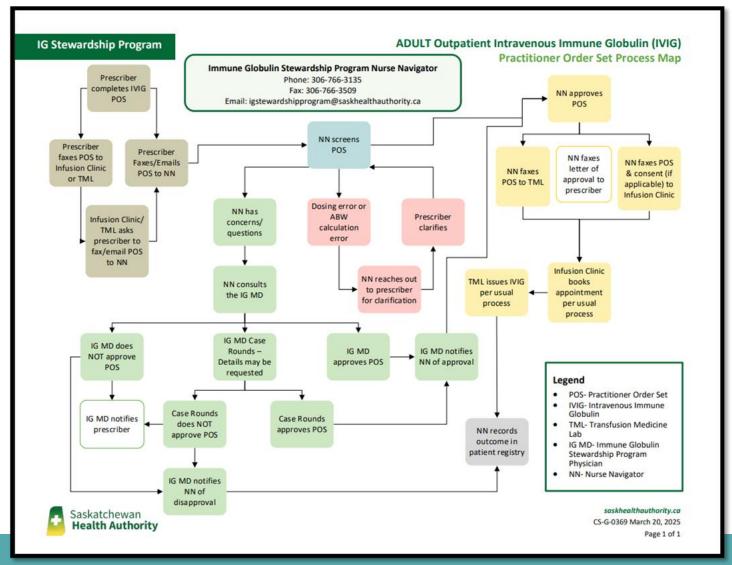


Screening Process of IVIG Orders - Outpatient

ADULT Outpatient IVIG Process Map

Outpatient IVIG POS Process

- Prescriber completes POS and obtains a valid Blood Consent Form.
- * All orders require a clinic note prior to approval *





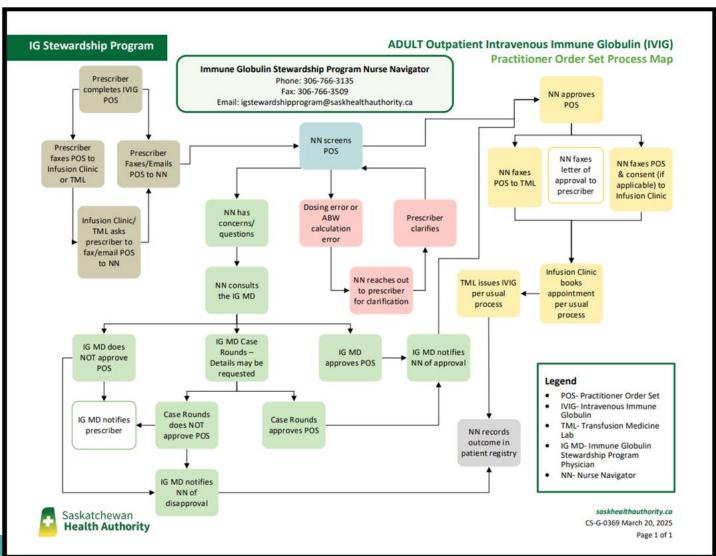


Screening Process of IVIG Orders - Inpatient

ADULT Inpatient and Urgent Outpatient IVIG Process Map

Inpatient and UrgentOutpatient IVIG Process

- Prescriber completes POS and faxes to the local Transfusion Medicine Lab for Screening and Approval
- A Transfusion Medicine Physician for Saskatchewan is on call 24 hr/7days







Screening IVIG Orders

'Criteria for the Clinical Use of Immune Globulin Second Edition, February 2022'

All orders in Saskatchewan are Screened against the Tri-Provincial Document: Criteria for the Clinical Use of Immune Globulin, Second Edition, February 2022.







Criteria for the Clinical Use of Immune Globulin

Second Edition

February 2022



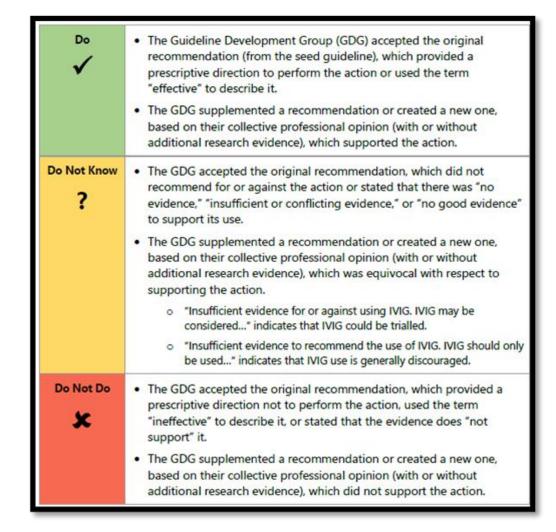


Criteria for the Clinical Use of Immune Globulin 2nd Edition

How it works

Diagnosis/Indications are broken down by Specialty:

- Dermatology Indications
- Hematology Indications
- Immunology Indications
- Infectious Disease Indications
- Transplant Medicine Indications (including infectious diseases in transplant recipients)
- Neurology and Neuromuscular Indications
- Rheumatology Indications
- Other Indications





Examples

Green Indication

✓ Myopathies, inflammatory – adult: dermatomyositis, polymyositis, necrotizing autoimmune myopathy				
See separate entries for <u>dermatomyositis – pediatric, inclusion body myositis</u> , and <u>polymyositis – pediatric</u> .				
Do Recommendation	IVIG may be used for patients with severe forms of disease when first-line therapies are ineffective or contraindicated. In severe or life-threatening situations, e.g., dysphagia or severe weakness, IVIG may be part of first-line therapy.			
Dose	2 g/kg adjusted body weight divided over 2 days, every 4 weeks. Once the patient's condition has stabilized, consider titrating the dose and/or the treatment interval to the lowest dose necessary to maintain clinical effectiveness.			
Review Criteria	Continued use of IVIG should be based on objective measures of effectiveness established at the outset of treatment. These measures should be assessed no later than 6 months after initiation of treatment and at least annually thereafter. If clinical effectiveness has not been achieved, IVIG should be discontinued.			
Evidence Source	SR (G1); EO (GDG-RCT)			

Myopathies, inflammatory – adult: dermatomyositis, polymyositis, necrotizing autoimmune myopathy:

- > Green Indication: Do Recommend
- Dose: 2g/kg ABW divided over 2 days every 4 weeks; along with titrating the dose and/or treatment interval to the lowest dose necessary to maintain clinical effectiveness.
- ➤ Review Criteria: Objective Measures of effectiveness established at the outset of treatment.





Examples

Yellow Indication

? Chronic idiopathic urticaria					
Do Not Know Recommendation	There is insufficient evidence for or against using IVIG. IVIG may be considered as a last resort in patients with severe disease when conventional therapies are ineffective or contraindicated.				
? Chronic id	? Chronic idiopathic urticaria				
Dose	2 g/kg adjusted body weight divided over 2 to 5 days. IVIG should be administered every 4 weeks initially. If clinical response is good, based on objective measures of effectiveness established at the outset of treatment, the interval between infusions can be gradually increased. IVIG should be administered for 3 to 6 months to assess efficacy. Some patients do not show a definitive sustained response until they have undergone up to 6 treatment cycles. In rare instances when longer term treatment is required (e.g., when disease recurs after withdrawal of IVIG and no other treat options are available), regular washout periods should be attempted.				
Qualifying Criteria	Patients must meet both of the following criteria: Contraindications or no response to high dose antihistamines; AND Contraindications or no response to omalizumab (if covered).				
Review Criteria	If clinical effectiveness has not been achieved after 6 treatment cycles, IVIG should be discontinued. Continued use of IVIG should be based on objective measures of effectiveness established at the outset of treatment. These measures should be assessed no later than 6 months after initiation of long-term treatment and at least annually thereafter. If clinical effectiveness has not been achieved or sustained, IVIG should be discontinued.				
Evidence Source	NR (G8); EO (GDG)				

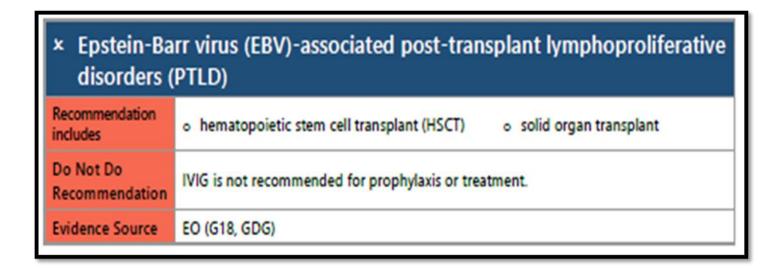
Chronic idiopathic urticaria:

- Yellow Indication: Do Not Know Recommendation
- ➤ Dose: 2g/kg ABW divided over 2 to 5 days.
 - Objective measures of effectiveness established at the outset of treatment to assess efficacy.
- Qualifying Criteria: Contraindications or no response to high dose antihistamines AND Contraindications or no response to omalizumab (if covered)
- ➤ Review Criteria: If Clinical effectiveness has not been achieved after 6 treatment cycles, IVIG should be discontinued.



Examples

Red Indication



Epstein-Barr virus (EBV)-associated posttransplant lymphoproliferative disorders (PTLD):

- Red Indication
- Do Not Do Recommendation: IVIG is not recommended for prophylaxis or treatment.



Adjusted Body Weight (Dosing Weight)

- Adjusted Body Weight (Dosing Weight) is a calculated weight based on gender, actual height in cm and weight in kg for obese and overweight patients.
- Its use is supported by the National Advisory Committee (NAC) on Blood and Blood Products and Canadian Blood Services.









Adjusted Body Weight (Dosing Weight)

Calculator Criteria

Adjusted Body Weight Dosing Criteria:

- Weight over 20 kg
- Height over 152.4 cm
 - Note: for ADULT patients <152.4 cm, calculate the ABW using the minimum height of 152.4 cm and the current weight



Exceptions:

- Pregnancy
- Under Ideal Body Weight
- Pediatrics

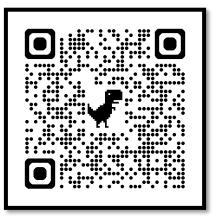


Adjusted Body Weight (Dosing Weight)

Alberta Health Services Calculator

Saskatchewan has adopted the Alberta Health Services Calculator: IVIG Dosing based upon Adjusted Body Weight Calculator

https://www.albertahealthservices.ca/webapps/labservices/IVIG Dosing Calculator.htm



IVIG Body Weight Calculator	IVIG Dose Calculator		
Enter Sex, Height & Weight, then click "Calculate".	Select Dosing, then click "Calculate".		
Sex: Male 🕶	Dosing: 1 v gram/kg		
Height: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	Calculate using Dosing Weight		
Calculate	IVIG Dose = g		
Ideal Body Weight = kg			
Dosing Weight	IVIG Dose Rounded to Nearest 5 grams		
(for obese or overweight patients) = —— kg	Rounded Dose = g		



Hospital Transitions

Maintenance Patients Only

Inpatient Orders cannot be used at Outpatient Clinics

Inpatient
Maintenance
Order Approved

Patient
Discharged

New Outpatient
Maintenance
Orders Required

Outpatient Orders are not be used while Inpatient

Outpatient
Maintenance
Order
Approved

New Inpatient
Maintenance
Orders
Required





IG Stewardship Program Registry

Brief Overview

Top Five Indications

Top five IVIG Indications that Utilize the most IVIG





Saskatchewan IG Stewardship Registry

Brief Overview

Patient Data

- PatientIdentification
- ABO
- Consent
- Weight changes
- Transfusion Adverse Events

Order Data

- Treatment Start Date
- Indication for IVIG
- Height/Weight for ABW
- Induction or Maintenance
- Renewal

Renewals

- 1st Renewal Letter sent 6 weeks before the next anticipated start date.
- 2nd Renewal Letter send 4 weeks after the first renewal letter/2 after final dose of the current order set.

Consents

- Consent Expiry Date
- 1st Renewal Letter 6 weeks before Expiry
- 2nd Renewal Letter 2 weeks before Expiry

Adverse Reaction

- Indicates if Further Follow-Up is required
- Notifies NN a transfusion reaction has occurred





Saskatchewan IG Stewardship Registry

Current Data – September 15, 2025

Total Patients

• 1437

Screened Orders

- 385 in 2025
- 3655 since inception of program

Active Maintenance

• 219





Saskatchewan IG Data

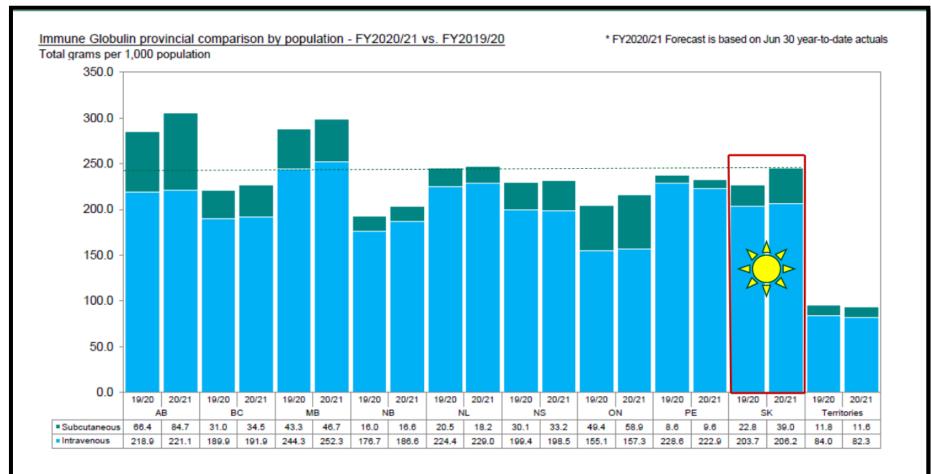
- Increased Demand for IG 2019-2020
- Q1 impact November 1, 2021-April 30, 2022
- Adjusted Body Weight Impact
- Canadian Blood Services Ig Brand Shares March 2025 to August 2025





Increased Demand for Ig noted Prior to Program

FY2020/21 vs. FY2019/20



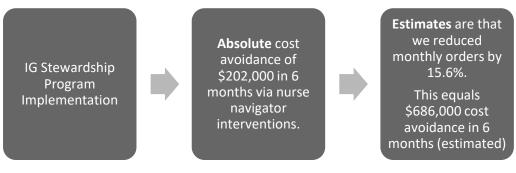
- Data from 2019/2020 indicates SK is using 226.5 grams of IVIG per 1,000 population
- Forecasted Data for 2020/2021 predicted a total use of 245.2 grams of IVIG per 1,000 population
- Quebec not included in CBS data as Héma Québec supplies
- ➤ 4th highest IG user in the country!

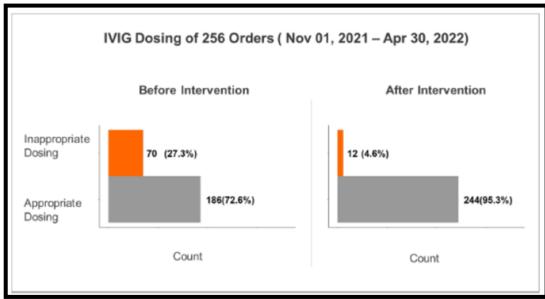


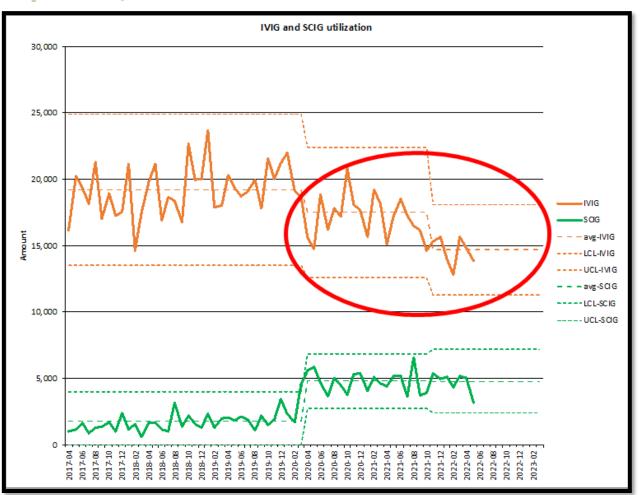


Immune Globulin Stewardship Program Initial Impact

Q1 Spotlight from November 1, 2021 – April 30, 2022





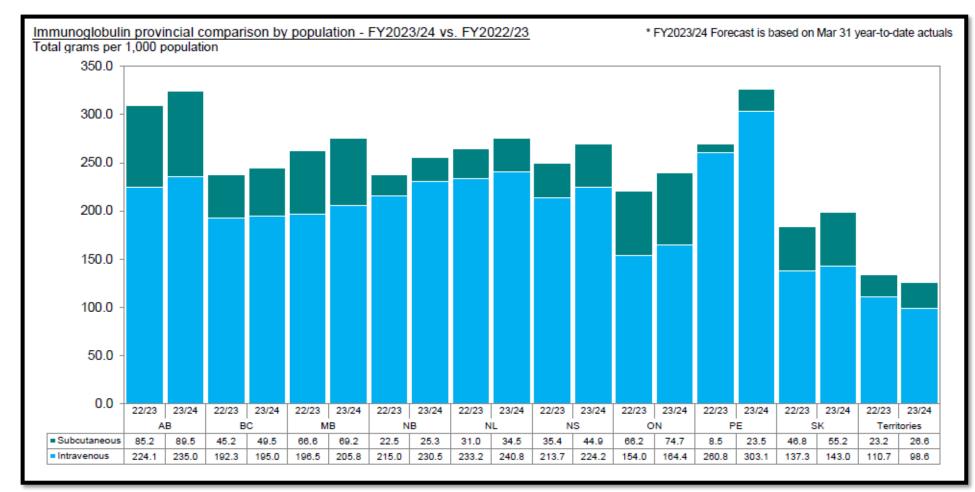






Immunoglobulin provincial comparison

FY2023/24 vs. FY2022/23



- Data from 2022/23 indicates SK is using 184.1 grams of IVIG per 1,000 population
- Forecasted Data for 2023/24 predicted a total use of grams of 198.2 grams of IVIG per 1,000 population
- Quebec not included in CBS data as Héma Québec supplies
- ➤ 2nd Lowest IG user nationally!

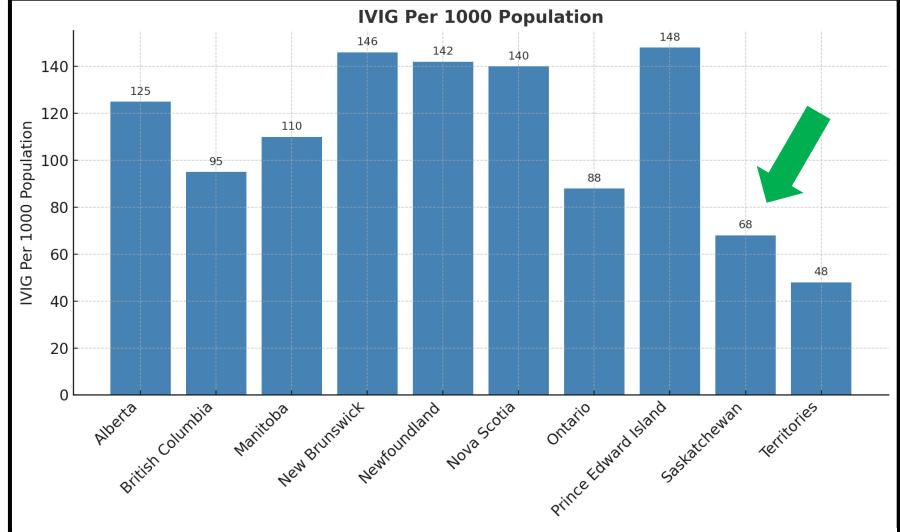




Canadian Blood Services

March 2025 - Aug 2025

- Quebec excluded (Héma Québec supplies)
- ➤ Saskatchewan is the 2nd lowest user nationally



Source: Canadian Blood Services (CBS) data; Population estimates from Statistics Canada, Quarterly Estimates.





IG Stewardship Program

Induction Order: Nurse Navigator/TML interventions

Induction Orders with Nurse Navigator/TML Interventions

	Total Number of Orders	IVIG in grams	Monetary Value
Total Induction Orders with Intervention	526		
Total Induction Orders with increased dose	176	1810 g	\$121,277
Total Induction Orders with decreased dose	350	12,220 g	\$818,707
Total Value saved			\$697,430





IG Stewardship Program

Maintenance Order Nurse Navigator/TML interventions

Maintenance Orders with Nurse Navigator/TML Interventions

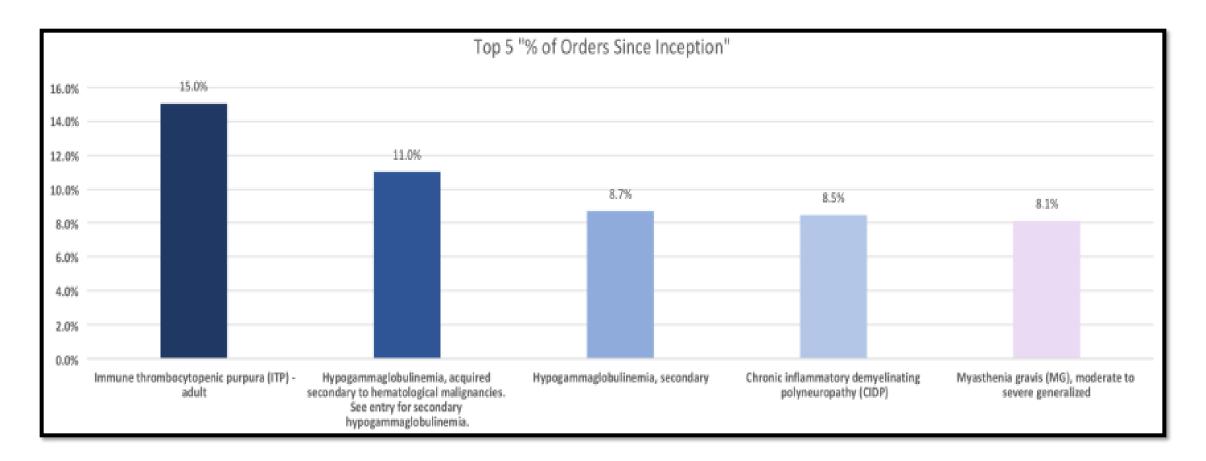
	Total Number of Orders	IVIG in grams	Monetary Value
Total Maintenance Orders with Intervention	329		
Total Maintenance Orders with increased dose	99	2117 g	\$141,832
Total Maintenance Orders with decreased dose	230	17,250 g	\$1,155,747
Total Value saved			\$1,013,915





Saskatchewan IG Stewardship Registry

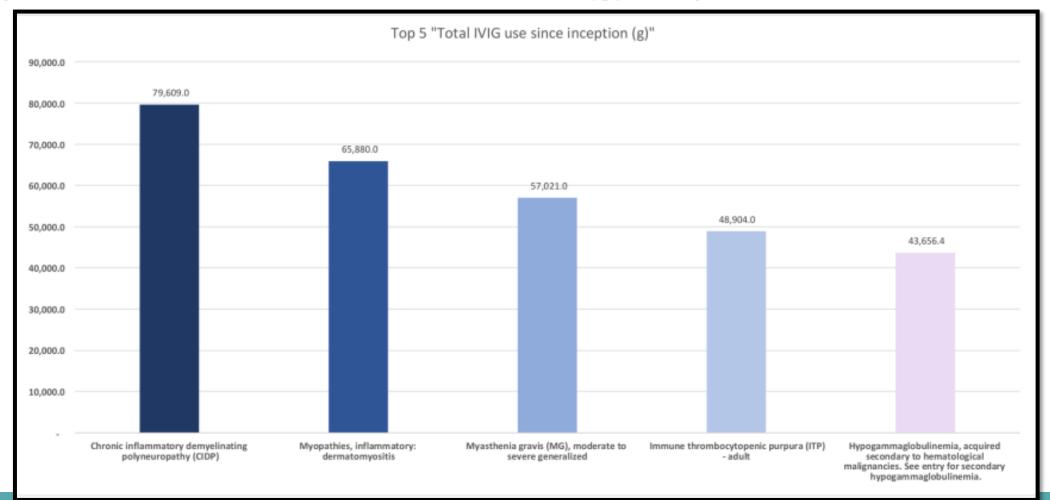
Top Five IVIG Indications Based on Orders (%) - Nov 2021 to June 2025





Saskatchewan IG Stewardship Program

Top Five Indications Based on IVIG Volume (g) - September 2021 - June 2025







The National Plan for Management of Shortages of Immunoglobulins (Ig) Products

National Ig Shortage Plan

National Ig Shortage Simulation Exercise





The National Plan for Management of Shortages of Immunoglobulins (Ig) Products

Launched May 30, 2024

- Canadian Blood Services Provincial/Territorial Blood Liaison Committee (CBS-PTBLC) worked collaboratively with the National Advisory Committee on Blood and Blood Products (NAC) to developed the 'The National Plan for Management of Shortages of Immunoglobulin (Ig) Products'
- Launched May 30, 2024

The National Plan for Management of Shortages of Immunoglobulin (Iq) Products May 30, 2024 National Advisory Committee | Comité consultatif national sur on Blood and Blood Products le sang et les produits sanguins





The National Plan for Management of Shortages of Immunoglobulins (Ig) Products

Green Phase = Normal inventory of IVIG/SCIG, supply generally meets demand

Green Phase Advisory

• Typically when Ig inventory is low or there is a potential supply disruption being forecasted.

Amber Phase

• Implies Ig inventory levels are insufficient to continue with routine practice.

Red Phase

 Implies Ig inventory levels are insufficient to ensure to ensure that patients identified as having critical need will receive the required products.

Recovery Phase

 Implies that Ig inventory have begun to increase and are expected to maintain at a level that would enable hospitals to move from Red to Amber to Green Advisory and subsequently to Green Phase The National Plan for Management of Shortages of Immunoglobulin (Ig) Products

May 30, 2024

National Advisory Committee | Comité consultatif national sur on Blood and Blood Products | le sang et les produits sanguins







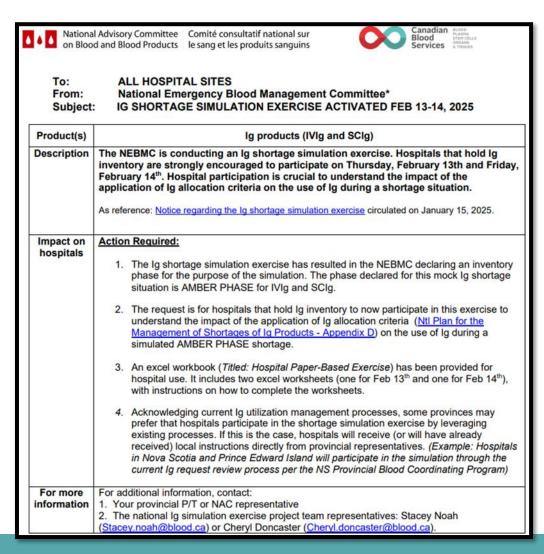
Planned National IG Shortage Simulation Activity

February 13-14, 2025

- To test 'The National Plan for Management of Shortages of Immunoglobulins (Ig) Products' the National Emergency Blood Management Committee arranged and IG shortages Simulation Exercise Activity for February 13-14, 2025.
- An Amber Phase Advisory was declared:

Amber Phase

- Implies Ig inventory levels are insufficient to continue with routine practice.
- Paper-based exercise ran from February 13, 2025 at 0800 to February 14, 2025 at 1600.
- No direct impact to patient care.
- Excel Spreadsheets titled 'Hospital Paper-Based Exercise' were provided to all hospitals that hold Ig Inventory.







National Immune Globulin (IG) Shortage Simulation: Saskatchewan Participation Summary

Report Prepared July 2025

Report Includes:

- Saskatchewan Response
- Potential Impact of an Amber Shortage
- Key Learnings
- Successes
- Challenges

Available on SaskBlood



National Immune Globulin (IG) Shortage Simulation: Saskatchewan Participation Summary

February 13-14, 2025

Report prepared July 2025

By the Saskatchewan IG Stewardship Program

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IG Resources

SaskBlood

https://saskblood.ca/programs/sk-ivig-program/

- > IVIG Resources
- Provincial IG Order Sets
- > SHA Blood Products: Monographs & Resources
- SHA Patient Information and Education (PIER) Resources for IG
- ➤ Job Aides, Posters and Work Standards
- Process Maps
- Memos
- > Links





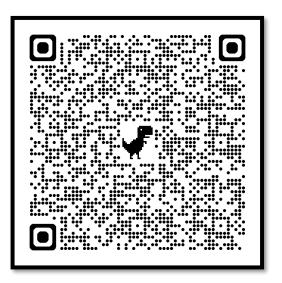


Additional Resources

SHA Resources

Intravenous Immune Globulin (IVIG) Home Page

https://www.saskhealthauthority.ca/intranet/health-provider-resources/clinical-resources/z-list-clinical-resources/transfusion-resources/intravenous-immune-globulin-ivig-clinical-resources







The END!

Please do not hesitate to reach out to the IG Stewardship Program, Monday to Friday 0800 - 1630 excluding statutory holidays, with any questions or concerns:

- Phone: (306) 766-3135
- Fax: (306) 766-3509
- Email: <u>igstewardshipprogram@saskhealthauthority.ca</u>



