

2023 IVIg Transition FAQ:

Product Availability, RFP Process and Results, and Transition Guidance

Q&As

IMMUNOGLOBULIN TRANSITIONS

Is it safe to transition between immunoglobulin (Ig) products?

- Yes, it is possible to safely transition between different Ig products. The National Advisory Committee on Blood and Blood Products (NAC) has published a statement on the clinical equivalency of intravenous immunoglobulin (IVIg) products and subcutaneous immunoglobulin (SCIg) products. In part, it [says](#)¹:

“Currently, all IVIg products are considered clinically equivalent and, therefore, interchangeable with respect to clinical efficacy for all indications.”

“Currently, all SCIg products are considered clinically equivalent and, therefore, interchangeable with respect to clinical efficacy for all indications.”

- The NAC has also provided clinical practice considerations for IVIg brand switches which can be found [here](#)².

Why is transition required?

Canadian Blood Services conducts periodic Request for Proposals (RFP) for Plasma Protein and Related Products (PPRP) as part of the required cycle of product procurement. As a result of the most recent RFP, some brands of Ig will no longer be carried on the formulary. More details on this process and the specific products are included below, but it is important to know that limiting the number of resulting patient transitions was a key consideration of the process.

Is there a national shortage of immunoglobulins?

No. It is important to note that today's rapidly shifting global market for Ig necessitates a proactive and ongoing approach to ensure an adequate supply of Ig for the Canadian healthcare system, but there is no national shortage of immunoglobulins. Canadian Blood

¹ <https://nacblood.ca/en/resource/nac-statement-clinical-equivalency-select-fractionated-plasma-protein-products>

² https://nacblood.ca/sites/default/files/2021-09/NAC%20IVIg%20Brand%20Switching%20Guidance%20Feb%2023%202021_Final.pdf

Services works to protect an appropriate stockpile of Ig, and these changes will sometimes have an impact on the system and require patient transition. Canadian Blood Services appreciates hospitals' and patients' ongoing understanding, assistance, and cooperation to protect the availability of Ig for patients across the country.

RFP PROCESS

Why does Canadian Blood Services issue requests for proposals (RFPs) for products such as immunoglobulins?

- An RFP process allows organizations to solicit proposals from qualified suppliers and choose the most appropriate vendor(s) to provide products and services that align with the RFP's objectives.
- Canadian Blood Services issues RFPs for various PPRP every three to five years, depending on the terms of each contract.
- In April 2022, Canadian Blood Services issued an RFP for a variety of PPRP which included intravenous and subcutaneous immunoglobulin products.
- Canadian Blood Services' overall goal of the PPRP RFP process is to maximize value for both patients and healthcare systems. By way of design, the RFP process requires proponents to submit competitive pricing, while also demonstrating the safety and efficacy of their products. Although price is important, it is not the only consideration when determining a product's value. Considerations such as security of their supply chain, patient choice, and product characteristics are also important components of value.

What products were included in this RFP?

In April 2022, Canadian Blood Services issued an RFP for PPRP including immunoglobulins, C1-esterase inhibitors, clotting factors, albumin, and others. Recombinant products like Factor VIIa (rFVIIa), Factor VIII (rFVIII), etc. were excluded as they were recently procured through a separate RFP.

How did Canadian Blood Services decide on the product mix?

- In March 2022, Canadian Blood Services invited companies to submit proposals for products included in this RFP.

- The proposals were reviewed by a Selection Committee comprised of Canadian Blood Services staff and external parties (including representatives from patient groups and clinical specialties).
- For product categories where there was more than one choice (like IVIg and SCIg), products were evaluated against predetermined criteria. Ultimately, Canadian Blood Services selected a product mix that balances the needs of patients and the system by minimizing patient transitions and workload on hospital clinics and transfusion services, while resulting in cost avoidance. Other aspects, such as security of supply and impacts on inventory, were also considered.

RFP RESULTS

What are the results from the 2022 plasma protein and related products RFP?

- All current IVIg products will be on formulary with no restrictions except for Octagam and Panzyga. Octagam and Panzyga will no longer be listed on the formulary. These products will continue to be available for ordering until inventory is depleted.
- All current SCIg products will be on formulary with no restrictions except for Cutaquig. Cutaquig will no longer be listed on the formulary. It will continue to be available for ordering until inventory is depleted.
- All other plasma-derived products will remain on formulary with no changes except for Cinryze (a C1-esterase inhibitor product) and Octalbin (an albumin product).

What is the duration of the contracts?

Generally, products renewed through the 2022 RFP are under contract for a minimum of three years (until March 2026) with the possibility of two one-year extensions.

What are the impacts of changing the product mix?

As a result of the RFP, there will be some need for patient transitions, but they should be limited. Patients receiving Octagam, Panzyga and Cutaquig, will be required to transition to an alternate product. Guidance on next steps for transitioning away from Octagam, Panzyga and Cutaquig can be found in a Customer Letter here:

https://www.blood.ca/sites/default/files/2023-03/CL_2023-05.pdf.

TRANSITION GUIDANCE

Panzyga is the only Ig product for which a transition is currently required. All other Ig products, even if they will no longer be listed on formulary, will continue to be available for ordering until inventory is depleted.

What is the plan for transitioning Panzyga patients?

- Effective April 1, 2023, Panzyga will no longer be listed on the PPRP Formulary. To help support hospital clinics and their patients who are making transitions, Panzyga inventory will still be available until approximately June 30, 2023 (based on current demand level) and remain on Canadian Blood Services' order form until inventory is depleted.
- Given this change, patients currently taking Panzyga will need to be transitioned to another IVIg product. Choice of new product is at the discretion of the patient and treating physician.
- Panzyga patients are encouraged to transition to Privigen if possible, but may be transitioned to another product currently on formulary without restrictions (Gammagard Liquid®, Gammagard S/D, Gamunex) if required.
- Panzyga patients can be transitioned at any time while inventory remains available.

When will patients taking Cutaquig or Octagam be required to transition?

- While Cutaquig and Octagam will no longer be listed on the PPRP Formulary effective April 1st, inventory of these products is estimated to last until the end of 2023 or even into 2024 and will be available for ordering until inventory is depleted. To avoid product wastage and additional patient transitions, hospital customers should pay close attention to their monthly reporting provided by Canadian Blood Services and adhere to it as closely as possible.
- Canadian Blood Services is committed to providing ample time to transition patients and will provide further updates as those transition periods approach.

What monthly reporting is provided by Canadian Blood Services?

IVIg share split reports outline the target usage (as a percentage of the total usage) for each product, and the current usage for each hospital customer. This reporting helps to ensure that the mix of products available from Canadian Blood Services matches usage by hospital customers and that no wastage or shortage occurs.

Who distributes the latest Ig share splits, and who reviews them?

- IVIg share splits are provided to hospital customers and provincial blood coordinators through regular reports received from their respective Hospital Liaison Specialist or Canadian Blood Services contact. These reports show the most recent target share splits, along with current share splits viewable by single site, by multiple sites, by province, or nationally (excluding Quebec).
- SCIg share splits are not currently required.

QUESTIONS**Who should we contact if we have questions?**

Patients receiving treatment should connect with their own clinician or care team.

Hospital customers should reach out to their Hospital Liaison Specialist with any questions or feedback.

Clinical societies and patient organizations should reach out to the PPRP Formulary Team at: pprpformularyprogram@blood.ca.