2024 Ig Transition FAQ:
Updated IVIg and SCIg Transition Guidance, Product Availability, and RFP Process and Results

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. The choice of a specific IVIg product for an individual patient may be guided by other factors especially previous adverse reactions to specific products. **Given the clinical equivalency of IVIg products, brand switches can be safely undertaken if required due to product supply availability.**"

  and

  "There is no evidence to support that any specific SCIg brand has superior efficacy over another as an immunoglobulin replacement product or in other clinical indications where SCIg is indicated as a therapeutic strategy. However, a specific SCIg product may be selected or required for an individual patient guided by other clinical factors including previous adverse reactions to specific products or issues related to product administration. **Given the clinical equivalency of SCIg products, brand switches can be safely undertaken if required due to product supply availability**."

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

[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

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 are no longer 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 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.

TRANSITION GUIDANCE

Transitions off Octagam and Cutaquig are now required as remaining inventory of both products is close to being depleted.

What is the plan for transitioning Octagam patients?

- Effective April 1, 2023, Octagam was no longer listed on the PPRP Formulary. Hospital customers, Ig clinics, and patients supported the best use of remaining inventory by continuing to use Octagam up to this point.
- Octagam inventory will be available until approximately April 30, 2024 (based on current demand level), so it is now time for patients currently taking Octagam to be transitioned to another IVIg product. Choice of new product is at the discretion of the patient and treating physician.
- Patients may be transitioned to any other product currently on formulary without restrictions (Gammagard Liquid®, Gammagard S/D, Gamunex, Privigen).
- Octagam patients can be transitioned at any time while inventory remains available. and this product will remain on Canadian Blood Services' order form and online ordering portal until inventory is depleted.

What is the plan for transitioning Cutaquig patients?

- Effective April 1, 2023, Cutaquig was no longer listed on the PPRP Formulary. Hospital customers, Ig clinics, and patients supported the best use of remaining inventory by continuing to use Cutaquig up to this point.
- Cutaquig inventory will be available until approximately July 31, 2024 (based on current demand level), so it is now time for patients currently taking Cutaquig to begin transitioning to another SCIg product. Choice of new product is at the discretion of the patient and treating physician.
- Patients may be transitioned to any other product currently on formulary without restrictions (Cuvitru, Hizentra, HyQvia).
- Cutaquig patients can be transitioned at any time while inventory remains available.

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

- Canadian Blood Services is committed to providing ample time to transition patients, so this notice is being provided with significant lead ti me remaining.
- Octagam inventory will be available until approximately April 30, 2024, and Cutaquig inventory will be available until approximately July 31, 2024 (based on current demand levels respectively).
- Monthly IVIg share split reporting will continue to be updated to reflect targets across available products and when Octagam inventory is fully depleted.

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.
- There is not currently any need for SCIg share split management and so no corresponding SCIg share split report is provided.

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).

RFP RESULTS

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

- All current IVIg products remained on formulary with no restrictions except for Octagam and Panzyga. Octagam and Panzyga are no longer be listed on the formulary as of April 1 2023.
- All current SCIg products will be on formulary with no restrictions except for Cutaquig. Cutaquig will no longer be listed on the formulary as of April 1 2023.
- 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).

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.

What are the impacts of changing the product mix?

As a result of the RFP, some patient transitions are required, but they are limited. Patients receiving Octagam, Panzyga and Cutaquig, are required to transition to an alternate product. Previous guidance on next steps for transitioning away from Panzyga (now complete) can be found in a Customer Letter here:

https://www.blood.ca/sites/default/files/FAQ_-_IVIg_Transition_Apr_2023.pdf

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.

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.