

FACT SHEET: Canadian Immunoglobulin (Ig) Supply and Intravenous Immunoglobulin (IVIg) Brand Switching

What is the current state of Ig supply globally?

 Canada is part of a global supply chain and the supply of immunoglobulins (Ig) is tight. Internationally, demand for these products exceeds the available supply. Since late 2018, plasma collections worldwide have not been able to keep up with a growing patient demand for plasma-derived medications, particularly Ig. The COVID-19 pandemic has made this situation worse due to supply chain disruptions and decreased plasma collections world-wide.

What is the impact of the tightening of Ig supply on IVIg distributed by Canadian Blood Services?

• Canadian Blood Services buys IVIg from several different manufacturers. In late 2020, they were informed that some of these manufacturers could not provide their promised volumes. This means that based on current demand, there some IVIg brands and vial sizes will be in short supply, at least until spring 2022.

What steps have been taken to try prevent a shortage of IVIg?

- To help prevent a shortage, Canadian Blood Services approached all IVIg manufacturers and have been able to arrange for additional supply of IVIg. It is important to understand that this additional supply of IVIg does <u>not</u> guarantee prevention of a national IVIg shortage. The global situation is very dynamic and unexpected supply disruptions may trigger a shortage without much lead time.
- The national IVIg supply is being closely monitored by Canadian Blood Services and transfusion medicine (blood bank) leaders. Healthcare jurisdictions are also in the process of establishing programs to review IVIg product requests for appropriateness and track the proprtions of different IVIg brands used by hospitals. Minimization of patient impact is a priority.

What is the is the expected impact of changes to available IVIg brands on hospitals and patients?

- The relative proportion of the different brands and vials sizes that Canadian Blood Services has available for distribution in 2021 and 2022 has changed. Hospital blood banks are now prepared to accept all vial sizes and brands of IVIg provided by Canadian Blood Services. Some patients on chronic IVIg therapies be transitioned to a different brand of IVIg because Canadian Blood Services was not able to secure extra inventory for all current product brands.
- Hospitals are encouraged to select IVIg brands for patients with acute IVIg needs carefully to help with balancing IVIg brand percentages. The availability of brands may fluctuate on a frequent basis.

Are all IVIg brands similar in terms of effectiveness and adverse reactions?

• There are no known differences in the clinical effectiveness of the different IVIG for different medical conditions, despite slight differences in the licensed indications among different IVIg products. Adverse reactions are seen with all IVIg products. Canadian hemovigilance data

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does not suggest the rates of specific adverse reactions are different between products. However, individual patients may have adverse reactions to specific IVIg brand products, but tolerate product of a different brand.

Should all patients be considered for brand switches of IVIg?

 Due to an immediate need to rebalance IVIg brand use nationally, patients receiving certain brands of IVIg for chronic treatment may need to switch to a different IVIg brand. IVIg brand switching may not be an option for some patients. Many factors are important in deciding if a brand switch of IVIg is appropriate, including a history of previous serious reactions to a specific IVIg brand. The decision regarding IVIg brand switching in specific patient cases will be made by local transfusion medicine experts, together with physician prescribers.

Will patients be involved in the IVIg brand switching decision?

• IVIg prescribers may contact patients in some cases to discuss IVIg brand switching. However, due to IVIg supply limitations, the decision to proceed with IVIg brand switching may be made at the discretion of the physician prescriber without involving the patient in discussion.

Who will be notified if a patient IVIg brand switch is needed and how will this happen?

In situations where an IVIg brand switch is necessary for a patient, a written communication
must be sent from the hospital transfusion medicine (blood bank) service to the prescribing
physician. The transfusion medicine physician and/or the prescribing physician is responsible for
notifying the patient and IVIg infusion clinic in writing, as per local policy. Communications must
emphasize the potential impact to the IVIg infusion duration for the first exposure to a new IVIg
brand.

What is the impact to the patient if an IVIg brand switch is needed?

 The manufacturers of all IVIg brands recommend that the first infusion take place at a slower maximum rate. This means that patients who are used to receiving IVIg will have a longer infusion time at their first infusion of a different IVIg brand. It is important that patients and infusion clinics take this time into account when preparing for administration of a different IVIg brand to a patient on chronic IVIg therapy. To minimize patient and healthcare impacts, switching IVIg brands more than once is discouraged, unless absolutely necessary.

If an IVIg shortage does occur, how with will this be handled in Canada?

- In the event of a shortage, planning to safeguard the supply of blood and blood products is led by the National Emergency Blood Management Committee (NEBMC), which includes representation from provincial and territorial health systems, the National Advisory Committee on Blood and Blood Products and Canadian Blood Services. It is expected that provincial jurisdictions and hospitals impement actions that are complementary and congruent to national recommentations.
- For further information, please refer to the <u>National Plan for the Management of Shortages of</u> <u>Immunoglobulin (Ig) Products – Interim Guidance</u>.