

May 7, 2019

Dear Blood Bank Director/Staff Member,

Since the launch of CUVITRU in April 2018, there has been an unprecedented growth in demand for Subcutaneous Immunoglobulins (SCIG). SCIG volumes have typically grown 20% per year. However, over the past year, the growth has been greater than 50%. In addition, due to a variety of reasons, demand for the 8g format of CUVITRU has been much higher than previous large formats of SCIG.

As a result of these significant changes in patient demand, Shire Pharma Canada ULC (now part of Takeda) will be increasing the supply of CUVITRU over and above original forecasts. Due to the complex and lengthy immunoglobulin manufacturing process, these increases are expected to be available in the second half of 2019.

Despite these significant increases in SCIG therapy demand, Takeda has sufficient supply to maintain patients currently on CUVITRU as well as patients currently enrolled in the OnePath patient support program.

However, enrolling new patients on CUVITRU at this time may be challenging from a supply perspective. As a result, physician and patient organizations who treat and support IG patients have established a working group who will be developing recommendations within the next two weeks to help effectively manage supply in the short term.

In addition, you may be required to substitute smaller format vials for larger format vials. For example, substituting 2 X 4g vials in place of 1 x 8g vial. We anticipate returning to normal supply levels during the second half of 2019 and will provide you with updates on a regular basis. We deeply regret any inconvenience or additional efforts that this may place on your personnel and thank you in advance for your understanding and collaboration.

Shire Pharma Canada ULC

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Shire is now part of Takeda

If you have any questions, please reach out to your Takeda representative for more information. If you wish to view a specific patient report for your blood bank, or discuss specific metrics, please call the OnePath program at +1-844-691-7284. You can call any time from Monday to Friday 8am – 8pm EST. For medical inquiries, please contact Takeda Medical Information at +1-800-268-2772.

Sincerely,

Ascher Essebag Franchise Head, HAE/Immunology Takeda Canada