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ACTION REQUIRED

Subcutaneous Immune Globulin Transition Update

Customer Letter # 2018-35

2018-08-23

Dear Colleagues:

We are writing regarding the change of available products on the Canadian Blood Services formulary for the care of patients requiring subcutaneous immune globulin (Ig) therapy. As the inventory of Hizentra® will soon be depleted, it is important that patients be transitioned to Cuvitru® as quickly as possible.

Thank you for the work you and your clinical team members have done to date following the decisions resulting from the request for proposal (RFP) process last fall. We recognize the increased workload and the challenges this transition may have created for you, your transfusion medicine laboratory, and your clinic staff; please know your cooperation and assistance is greatly appreciated. We also acknowledge that there have been many learnings from the conduct of this RFP and the implementation of the transition, and we are committed to making improvements. We look forward to continuing to collaborate with you, our hospital customers, and other stakeholders to provide a secure supply of plasma protein products for the patients who need them.

All patients who are currently receiving Hizentra® will need to transition to another Ig product. Cuvitru® has been chosen as the replacement subcutaneous Ig product. We acknowledge that the transition has been complicated by the need for a new patient care program (OnePath®), previous limitations on room temperature storage of the new product, and a different mix of available vial sizes. While we understand the transitioning of patients treated with subcutaneous Ig is proceeding at a steady pace, we believe patients remaining on a subcutaneous delivery system need to be transitioned to Cuvitru® more quickly to mitigate the chances of sudden product shortages. While recognizing that not all patients will need to be enrolled in Shire's patient support program (OnePath®), in early July, only about 60 per cent of affected patients across the country had registered for OnePath®, and only about 25 per cent of these patients had switched to Cuvitru®.

Canadian Blood Services anticipated that some supply of Hizentra® would need to be available to support patients though the transition period, which began on April 1, 2018. **Please note that these quantities will soon be depleted.** We predict that use of Hizentra® at current levels will fully deplete the remaining inventory by October 2018, with certain vial sizes (2 g and 4 g) expected to deplete earlier. We therefore request that all patients switching to Cuvitru®, be prepared to change from Hizentra® to Cuvitru® as soon as possible. If required, patients should be directed to register with OnePath® to assist in preparing for the change.

To further aid in managing the transition, we will share distribution data (Plasma Protein Products Transition Newsletter) for specific clinics where the rate of product transition appears to be lower than Canadian Blood Services' predictions of what should reasonably occur.

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Canadian Blood Services recognizes that there may be **extremely rare** cases in which patients may require ongoing, exceptional access to Hizentra® or other products for significant medical reasons. Upon receiving the appropriate documentation, these cases will be reviewed individually to determine whether there is an appropriate medical need for the non-formulary product. Requests may be submitted to the national plasma protein product team at Canadian Blood Services for consideration (csr@blood.ca).

We remain committed to providing regular supply updates and to assisting, where possible, in achieving a successful and timely transition of therapeutic products for you and your patients. If you would like to discuss ideas for how we can assist you in managing this transition, please contact me directly at isra.levy@blood.ca or the number below, or contact your local hospital liaison specialist.

Please share a copy of this customer letter with relevant physicians at your hospital who might be interested in this information. In particular, please distribute this letter to physicians who prescribe subcutaneous Ig therapy.

This customer letter can also be viewed at www.blood.ca in the "Hospitals" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Please also feel free to contact me directly if you would like to discuss any specific matters.

Sincerely,

Isra Levy, MD
Vice President, Medical Affairs and Innovation
613-739-2121