Canadian Blood Services
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

INFORMATION ONLY

Launch of Hemlibra (emicizumab injection)

Customer Letter # 2019-17

2019-08-02

Dear Colleagues:

Canadian Blood Services is very pleased to announce the upcoming availability of Roche's Hemlibra [emicizumab Injection] for treating patients with FVIII hemophilia with inhibitors. Canadian Blood Services is making initial purchases during the week of August 6 and therefore product could be available as early as August 12. Additional correspondence will be provided to the Association of Hemophilia Clinic Directors of Canada clinics when timings are finalized. Please refer to the attached letter from Roche for further details regarding the product.

The named patient program as described in Customer Letters #2018-34 and #2019-12 will be followed when requesting Hemlibra. For new patients, please complete the **Patient Designated Plasma Protein Products Request form (**sample attached). This form must accompany the order form for all new patients and for any changes in dosage or duration of treatment. Contracts will have a duration of 12 months or less. When placing an order for an existing eligible patient, please use the Factor Concentrate and Other Plasma Protein Products Order Form which must include the patient ID number and linked contract number provided by Canadian Blood Services. These numbers should be recorded in the comments section near the top of the order form.

Each jurisdiction may implement additional ordering requirements, which will be managed by the jurisdiction itself.

Specific criteria as listed below in *italic* and indicated on the **Patient Designated Plasma Protein Products Request form** must be met for Hemlibra patient use.

Congenital hemophilia A (factor VIII deficiency) with inhibitor (antibodies) to factor VIII (> 0.6 Bethesda Units/mL) confirmed on more than one occasion by an appropriate assay.

And

Prescribed by a physician associated with a Hemophilia Treatment Centre.

No exceptions to the listed criteria will be allowed. Prior to expanding product use within the category to FVIII patients without inhibitors, a CADTH review of all monoclonal antibody treatment products for FVIII hemophilia in comparison to recombinant and plasma-derived FVIII treatment products is required.

Key product highlights:

- Vial Sizes: 30mg/1mL, 60mg/0.4mL, 105mg/0.7mL, 150mg/1mL
- Administration: Subcutaneous

Additionally, the attached hospital product fact sheet may be used as a tool for customers.

Revisions have been made to the following and can be found at www.blood.ca in the "Hospital" section

- Factor Concentrates and Other Plasma Protein Products Order Form
- Plasma Protein Products – Customer Table of Information
- Manufacturer Contact List

CBS will be reporting quarterly to provinces and territories on Hemlibra expenditures and volumes. Provinces and territories also retain the right to cap funding if expenditures and volumes exceed product usage by FVIII hemophilia patients with inhibitors.

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

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

Sincerely,

Isra Levy, MB BCh, MSc, FRCPC
Vice President, Medical Affairs and Innovation