



Canadian Hemophilia Society
Help Stop the Bleeding
Société canadienne de l'hémophilie
Arrêtons l'hémorragie

CBS announces factor concentrate contracts for 2018-2020

OTTAWA – November 1, 2017 – Canadian Blood Services (CBS) has announced the Request for Proposals (RFP) results for clotting factor concentrates for the period of April 1, 2018 to March 31, 2020 with the possibility of two one-year extensions.

The results of two other RFP processes, one for the fractionation of CBS plasma and the other for the commercial supply of Immunoglobulins and albumin, were also announced this week.

Hemophilia A

The three standard half-life recombinant factor VIII (rFVIII) products currently distributed by CBS—Kovaltry (Bayer), Nuwiq (Octapharma) and Xyntha (Pfizer) will continue to be available. The mean half-life of these products is reported to be 12 to 14 hours.* ADYNOVATE (Shire), a pegylated form of ADVATE with a reported half-life of 16 hours, will be added to the portfolio.

No specific criteria will restrict access to any of the four products named above.

Eloctate (Bioverativ, reported half-life of 19 hours) will be available on a named-patient basis to minimally treated young patients currently using Eloctate up to a maximum of 100 exposure days. An exposure day is defined as a day during which FVIII was infused. They will then be required to switch to one of the other four rFVIII products. Pediatric and adult patients currently receiving Eloctate for immune tolerance induction (ITI) to eliminate an inhibitor will be able to continue using Eloctate to the end of their ITI protocols, again on a named-patient basis.

Note that the use of ADYNOVATE in children under the age of 12 is dependent on its approval for this age group by Health Canada. That decision is expected in the coming months.

Hemophilia B

The standard half-life recombinant factor IX product, Benefix (Pfizer, reported half-life of 19 hours), will continue to be available. Rebinyn (Novo Nordisk), a pegylated rFIX with a reported half-life of 114 hours, will be added to the portfolio. No specific criteria will restrict access to either of the two products named above.

Alprolix (Bioverativ, reported half-life of 82 hours) will be phased out.

The introduction of Rebinyn is dependent on its receiving a Notice of Compliance (license to market) from Health Canada. This, too, is anticipated in the coming months.

Other coagulation products

The availability of other coagulation products will remain unchanged. These include Humate P (CSL Behring) and Wilate (Octapharma) for the treatment of VWD and hemophilia A, inhibitor bypassing agents NiaStase (Novo Nordisk) and FEIBA (Shire), and factor concentrates for rare factor deficiencies.

Transition

Exact details of the timing of transition for those patients changing products have not yet been worked out. While switches will not begin to take place for several months, patients/caregivers should address any questions they have to their comprehensive care teams.

Conclusion

The Selection Advisory Committee included, in addition to CBS staff, two representatives from the Canadian Hemophilia Society, two representatives from the Association of Hemophilia Clinic Directors of Canada and one representative from the Canadian Association of Nurses in Hemophilia Care. Their involvement allowed patient needs and specialized medical expertise to be considered by the Committee. The role of the Selection Advisory Committee was to review the submissions, and provide guidance and recommendations to the CBS Executive Management Team and the Board of Directors, who had final responsibility for decisions. The five-month RFP process was considered rigorous and fair.

This latest RFP process has resulted in maintenance of product choice—four rFVIII products and two rFIX products—and access to at least one extended half-life product in each category.

The cost reduction as a result of the three RFPs, taking into account all fractionated and recombinant products, is estimated by CBS at \$125 million in 2018-19 and \$190 million in 2019-2020.

- * Half-life is the time for 50 per cent of the factor to be eliminated from the bloodstream. Half-lives quoted in this article are the means (averages) reported in the product monographs for adolescents and adults. The ways of measuring half-life can vary from company to company. Half-life can also vary significantly from person to person, and is typically shorter in children.