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17 April 2025

Expert Committee on the Selection and Use of Essential Medicines
Medicines Selection, IP and Affordability (MIA)
Department of Health Products Policy and Standards (HPS)
20 Avenue Appia
CH-1211 Geneva 27
Email: emlsecretariat@who.int

SUBJECT: **Cerus Corporation Support for WFH's Application "C.1 Changes to listings of cryoprecipitate, pathogen-reduced cryoprecipitate, and plasma-derived clotting factor concentrates"**

To the WHO Expert Committee on the Selection and Use of Essential Medicines:

Cerus Corporation is writing to express its strong support for the application submitted by the World Federation of Hemophilia (WFH) seeking revisions to the Essential medicines List (EML) and the Essential Medicines List for Children (EMLc) concerning the treatment of hemophilia A, hemophilia B, and von Willebrand Disease (VWD).

We commend the WFH for its comprehensive proposal aimed at aligning the EML with a higher standard of safety and efficacy in the treatment of bleeding disorders. Specifically, Cerus supports the WFH's recommendations for:

1. Removal of non-pathogen-reduced cryoprecipitate (Cryo) for all indications.

2. Limitation of the use of pathogen-reduced cryoprecipitate (PR Cryo) to evidence-based indications outside the treatment of hemophilia A and von Willebrand Disease (VWD).

3. Transfer of the listings of plasma-derived Factor VIII (FVIII) concentrates for the treatment of hemophilia A and VWD and Factor IX (FIX) concentrates for the treatment of hemophilia B from the Complimentary list to the Core list.

4. Removal of FIX complex as a therapeutic alternative to FIX concentrates for the treatment of hemophilia B.

During recent discussions with the WFH, Cerus addressed the pricing information for PR Cryo presented on page 11 of their application, specifically the derivation of the cost per IU of FVIII for INTERCEPT-treated PR Cryo. While cryoprecipitate prepared from INTERCEPT-treated plasma may be used for treatment of FVIII and VWD deficiency in regions outside of the United States, the pricing cited is based

on the expired New Technology Add-on Payment (NTAP) for the product Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT Fibrinogen Complex, IFC) set by the U.S. Centers for Medicare & Medicaid Services. In that U.S. context, IFC is indicated for fibrinogen replacement with extended room temperature shelf life and with no specific FVIII level requirement. Given the specific U.S. indication for fibrinogen replacement and the expired NTAP, this pricing is not representative of the cost of FVIII replacement with PR Cryo. The actual cost of the INTERCEPT kit(s) required to treat the plasma used to produce a pool of PR Cryo, which can vary in size, ranges from approximately $150 to $450. This estimate does not account for variations in blood center processing costs or the allocation of plasma acquisition expenses.

We appreciate the WFH's understanding of our position that this pricing data is not applicable in the context of Factor VIII costs and should therefore be disregarded.

Cerus Corporation believes, alongside the WFH, that the focus of the EML should be on ensuring access to the safest and most efficacious treatments for patients with hemophilia and VWD. While cost is a consideration, our primary concern is to advocate for treatment options that ensure patient dignity, improve quality of life, and minimize the risks associated with blood borne pathogens and unpredictable clotting factor levels. We believe the WFH's application strongly supports these goals.

We appreciate the opportunity to provide our input and fully support the WFH's efforts in this important endeavor.

Sincerely,

William M. Greenman
President and CEO
Cerus Corporation