CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901
Tel 610 878 4000

CSL Behring

October 17, 2016

Dear Patient Advocate:

This letter provides additional clarification around the recent announcement from CVS/Caremark regarding Helixate® FS, Antihemophilic Factor (Recombinant). Effective January 1, 2017, a limited number of Helixate FS patients will no longer have access to the product as part of their prescription benefits. Please note that the decision by CVS/Caremark impacts only those patients who participate in the Advanced Control Formulary; it:

- does not affect Helixate FS patients covered by other Caremark PBM (pharmacy benefit manager) plans; and
- does not affect access to Helixate FS via the CVS Specialty Pharmacy.

For questions regarding how the decision by CVS/Caremark may impact your access to Helixate FS, **please contact CSL Behring My Source® at 1-800-676-4266.** For patients enrolled in the CSL Behring Assurance℠ program, credit earned for Helixate FS will be honored for AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, the first and only single-chain recombinant Factor VIII that delivers proven, long-lasting bleed protection with twice-weekly dosing available. Please speak with your doctor to see if AFSTYLA is right for you.

CSL Behring remains committed to providing products and support services to meet the needs of hemophilia patients and their caregivers. Please contact CSL Behring My Source at 1-800-676-4266 for additional information regarding Helixate FS, AFSTYLA, or any other CSL Behring products for bleeding disorders.

Sincerely,
CSL Behring

AFSTYLA Important Safety Information

AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, is indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Routine prophylaxis to reduce frequency of bleeding episodes
- Perioperative management of bleeding

AFSTYLA is not indicated for the treatment of von Willebrand disease.

CSL Behring

AFSTYLA is contraindicated in patients who have had life-threatening hypersensitivity reactions to AFSTYLA or its excipients, or to hamster proteins.

AFSTYLA is for intravenous use only. AFSTYLA can be self-administered or administered by a caregiver with training and approval from a healthcare provider or hemophilia treatment center. Higher and/or more frequent dosing may be needed for patients under 12 years of age.

Hypersensitivity reactions, including anaphylaxis, are possible. Advise patients to immediately report symptoms of a hypersensitivity reaction. If symptoms occur, discontinue AFSTYLA and administer appropriate treatment.

Development of Factor VIII (FVIII) neutralizing antibodies (inhibitors) can occur. If expected FVIII activity levels are not attained or bleeding is not controlled with appropriate dose, perform an assay to measure FVIII inhibitor concentration.

Monitor plasma FVIII activity using a chromogenic assay or one-stage clotting assay. **If one-stage clotting assay is used, multiply result by a conversion factor of 2 to determine FVIII activity level.**

The most common adverse reactions reported in clinical trials (>0.5%) were dizziness and hypersensitivity.

Please see full prescribing information for AFSTYLA including patient product information.

Helixate FS Important Safety Information

HELIXATE® FS, Antihemophilic Factor (Recombinant), is a recombinant Factor VIII indicated for:

- Control and prevention of bleeding episodes in adults and children with hemophilia A
- Surgical prophylaxis in adults and children with hemophilia A
- Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage
- Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A

HELIXATE FS is not indicated for the treatment of von Willebrand disease.

CSL Behring

HELIXATE FS is contraindicated in patients who have life-threatening hypersensitivity reactions, including anaphylaxis to mouse or hamster protein or other constituents of the product.

Hypersensitivity reactions, including anaphylaxis have been reported with HELIXATE FS. Reported symptoms included facial swelling, flushing, hives, decrease in blood pressure, nausea, rash, restlessness, shortness of breath, tachycardia, tightness of the chest, tingling, urticaria, and vomiting. Discontinue HELIXATE FS if symptoms occur and seek immediate emergency treatment.

Neutralizing antibodies (inhibitors) have been reported following administration of HELIXATE FS predominately in previously untreated patients. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures Factor VIII inhibitor concentration.

Hemophilic patients with cardiovascular risk factors or diseases may be at the same risk to develop cardiovascular events as non-hemophilic patients when clotting has been normalized by treatment with Factor VIII.

Serious adverse reactions seen with HELIXATE FS are systemic hypersensitivity reactions including bronchospastic reactions and/or hypotension and anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to Factor VIII.

The most common adverse reactions (≥4%) observed in clinical trials were inhibitor formation in previously untreated and minimally treated patients, skin-related hypersensitivity reactions, infusion site reactions, and central venous access device (CVAD) associated infections.

Please see full prescribing information for HELIXATE FS including patient product information.