



INDIANA HEMOPHILIA & THROMBOSIS CENTER, INC.

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Indiana's only federally recognized comprehensive hemophilia center

Date: November 3, 2022

Re: Desmopressin Nasal Spray

To Whom It May Concern:

This letter is in support of the medical necessity for Desmopressin Acetate Nasal Spray 1.5 mg/ml by STAQ Pharma. This medication is a CGMP manufactured desmopressin acetate nasal spray. DESMOPRESSIN is a synthetic analogue of 8-arginine-vasopressin. This nasal spray contains 1.5 mg/mL of desmopressin acetate in an aqueous solution at a pH of approximately 5. Each actuation of the pump delivers 0.1 mL of solution, which is equivalent to 150 mcg of desmopressin acetate. This medication is supplied in an amber glass vial with a spray pump capable of delivering 6 treatment sprays of 150 mcg of desmopressin acetate.

In August 2020, we received notification that Stimate[®] (desmopressin acetate) had a nationwide recall with no estimated resolution date. Many patients with mild hemophilia, some forms of von Willebrand disease and platelet function disorders depend on Stimate[®] nasal spray to prevent or control bleeding. Many of these patients require Stimate[®] use prior to medical procedures, and some patients use it prophylactically to prevent bleeding. Once Stimate[®] was recalled, patients that previously used Stimate[®] were prescribed clotting factor. Clotting factor is very expensive and requires an IV infusion. Additionally, it is well recognized that in mild hemophilia A that use of clotting factor concentrate can be associated with inhibitor development, a complication that increases the complexity of management, cost of therapy and risk of poor outcomes. Stimate[®] nasal spray was much more affordable, easier to administer for patients in their homes, and is not associated with inhibitor development in hemophilia A.

The Hemophilia Alliance partnered with STAQ Pharma to develop desmopressin acetate (NDC 73177-0114-15); in September 2021, the IHTC started to obtain desmopressin acetate from STAQ-Pharma. In the past 13 months, the IHTC has dispensed 216 vials to 197 unique patients. During this time, we have not observed a difference in response to desmopressin acetate compounded by STAQ-Pharma as compared with Stimate[®]. Many patients have successfully undergone surgical interventions utilizing desmopressin acetate for hemostatic coverage. It is essential that these patient populations continue to have access to a safe and affordable nasal spray option for care. Please feel free to call my office with any questions or concerns.

Sincerely,

Amy Shapiro, MD
Medical Director and CEO

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