MASAC Recommendation Regarding the Use of Bypassing Agents in Patients with Hemophilia A or B and Inhibitors

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on April 22, 2006, and adopted by the NHF Board of Directors on June 3, 2006.

Patients with hemophilia A or B who develop inhibitors to factor VIII or IX may no longer respond to clotting factor VIII or IX concentrates to prevent or control bleeding episodes.

Lack of an effective clotting factor product to prevent or treat bleeding episodes has resulted in increased mortality and morbidity in these patients. These individuals have not been able to have necessary surgery performed and have developed severe, crippling joint disease as a result of recurrent, uncontrolled bleeding into joints and muscles.

Recombinant factor VIIa (NovoSeven) is a recombinant clotting factor that bypasses the need for factor VIII or IX, allowing clotting to occur. FEIBA, an activated prothrombin complex concentrate that is plasma-derived, has also been demonstrated to bypass the need for FVIII or FIX, resulting in hemostasis. Numerous pre and post licensure studies have shown that both are effective in preventing and controlling bleeding episodes in inhibitor patients, including in the surgical setting. These products have allowed inhibitor patients to have much needed surgery including joint replacement. Postoperative care for these patients may include many months of physical therapy, which could result in repeated bleeding into joints and a poor outcome from the surgery unless treatment with bypassing agents (currently FEIBA, NovoSeven) is continued. The mechanism of action is different for these two products and may be synergistic; therefore both agents may be required for the same patient.

Therefore MASAC recommends that bypassing agents be used in patients with hemophilia A or B with inhibitors to prevent or control bleeding in settings in which clotting factor VIII or IX would otherwise be used, including before and after surgery and physical therapy. These recommendations are consistent with MASAC Document #153.

This material is provided for your general information only. NHF does not give medical advice or engage in the practice of medicine. NHF under no circumstances recommends particular treatment for specific individuals and in all cases recommends that you consult your physician or local treatment center before pursuing any course of treatment.

Copyright 2006 National Hemophilia Foundation. To facilitate the dissemination of these medical recommendations, reproduction of any material in this publication in whole or in part will be permitted provided: 1) a specific reference to the MASAC recommendation number and title is included and 2) the reproduction is not intended for use in connection with the marketing, sale or promotion of any product or service. NHF reserves the right to make the final determination of compliance with this policy. For questions or to obtain a copy of the most recent recommendations, please contact the NHF Director of Communications at 1-800-42-HANDI or visit the NHF website at www.hemophilia.org.