



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders

MASAC Document #167

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.

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