

MASAC Document #159

MASAC RECOMMENDATION REGARDING FACTOR CONCENTRATE PRESCRIPTIONS AND FORMULARY DEVELOPMENT AND RESTRICTIONS

The following recommendations were approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation on February 12, 2005, and adopted by the NHF Board of Directors on March 12, 2005.

Persons with bleeding disorders require treatment with clotting factor concentrates for prevention and treatment of bleeding.

Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal & inactivation processes, potential immunogenicity, and other attributes. The characteristics of each product and the resultant product choice for an individual patient require a complex decision making process with the ultimate product being agreed upon by the patient and their respective healthcare provider. It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed.

MASAC supports continued availability and reimbursement of the full range of all prescribed replacement therapies for treatment of bleeding disorders. Prescriptions for clotting factor therapies should be written as non-generic to assure that the product prescribed is appropriately dispensed and reimbursed. Reimbursement for clotting factor replacement therapies should continue to be based upon methodologies appropriate to each specific product. The benefit of limiting products to one within a class, such as one recombinant factor VIII concentrate, solely for the purpose of cost containment is not supported by present clinical practice or by published data.

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 2005 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.

116 West 32nd Street • 11th Floor New York, NY 10001
(800) 42-HANDI • (212) 328-3700 • fax (212) 328-3777 www.hemophilia.org • info@hemophilia.org