



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders

MASAC Document # 203
(Replaces MASAC Doc # 200)

The following recommendations were approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation on May 1, 2011, and adopted by the NHF Board of Directors on May 22, 2011.

MASAC RECOMMENDATIONS FOR TREATMENT OF CHRONIC HCV INFECTION IN INDIVIDUALS WITH HEMOPHILIA AND OTHER BLEEDING DISORDERS

Given the high rate and long duration of hepatitis C (HCV) infection in individuals with hemophilia and other bleeding disorders, the availability of new drugs for treatment of HCV, including antiviral, protease inhibitor (PI), and other direct acting agents (DAA), is greatly anticipated. While recommendation regarding the use of such drugs is based on randomized trials in non-hemophilic individuals with HCV mono-infection and genotype 1, there may be insufficient data to address potential safety, bleeding, and drug interaction issues for those with hemophilia or with HIV co-infection, who may already use protease inhibitors as part of HIV treatment.

1. MASAC recommends as new anti-HCV drugs are initiated, there is a need for safety monitoring in individuals with hemophilia and other bleeding disorders, especially those with HIV coinfection who may use protease inhibitors as part of antiretroviral therapy for HIV infection. Special consideration should be made by patients and their providers to the potential safety issues, including bleeding risk, drug interactions, and drug resistance.
2. MASAC encourages the FDA to develop post-licensure surveillance of new anti-HCV drugs in collaboration with HTC's through UDC and WebTracker data collection, and manufacturers through post licensure marketing to assist in the recognition and reporting of adverse effects and to assure the collection of safety data.

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