NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

MASAC Document #247
(Replaces Document #234)

MASAC RECOMMENDATIONS ON TREATMENT OF HEPATITIS C IN INDIVIDUALS WITH HEMOPHILIA AND OTHER BLEEDING DISORDERS

The following recommendations were approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) on October 23, 2016, and adopted by the NHF Board of Directors on November 3, 2016

Hepatitis C (HCV) is now the leading cause of mortality in individuals with hemophilia. The development and approval of direct-acting agents (DAAs) have revolutionized treatment. Recently the FDA has approved 2 all-oral agents that are 90-100% effective in some genotypes (GT 1, GT 2), producing a sustained virologic response (SVR) with minimal or no side effects. However, a 12- or 24-week course of treatment is expensive and therefore not approved by some insurance providers. Several new DAAs have come into the marketplace that may be effective in other genotypes (e.g. GT 3), may shorten the time for treatment, and thus reduce the cost of treatment.

Therefore MASAC recommends:

1. All individuals with hemophilia and other bleeding disorders who have received blood or plasma-derived products should be tested for HCV infection. These tests should include HCV genotype, HCV RNA viral load, and Fibrosure test for fibrosis.
2. All individuals with hemophilia and other bleeding disorders who are found to be HCV positive should be referred to a hepatologist or an infectious disease specialist for evaluation of extent of liver disease and indications for treatment.
3. Barriers to treatment with DAAs by insurance companies and third-party payers should be identified and efforts made to eliminate them.
4. All individuals with hemophilia and other bleeding disorders should be evaluated for HCV infection by December 31, 2016, and treated by December 31, 2017.
5. All patients considering HCV DAA therapy should be assessed for HBV coinfection with testing for HBs Ag, anti-HBs, and anti-HBc. A test for HBV DNA should be obtained prior to initiating DAA therapy in patients who are HBsAg positive.
6. Patients meeting criteria for treatment of active HBV infection should be started on therapy at the same time or before HCV DAA therapy is initiated. Patients with low or undetectable HBV DNA levels should be monitored at regular intervals (usually every 4 weeks) for HBV reactivation with HBV DNA, and those patients with HBV DNA levels meeting treatment criteria should initiate HBV therapy.
7. There are insufficient data to provide clear recommendations for the monitoring of patients testing positive either for anti-HBc alone (isolated anti-HBc) or for anti-HBs and anti-HBc. However, the possibility of HBV reactivation should be considered in these

7 Penn Plaza · Suite 1204
New York, NY · 10001
(800) 42.HANDI · (212) 328.3700 · fax (212) 328.3777
www.hemophilia.org · info@hemophilia.org

groups in the event of unexplained increases in liver enzymes during and/or after completion of DAA therapy.
8. HBV vaccination is recommended for all susceptible individuals with HCV.

REFERENCES

1. Jacobson IM et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. New Engl J Med 2013; 368(20): 1867-77.
2. Lawitz E et al. Sofosbuvir for previously untreated chronic hepatitis C infection. New Engl J Med 2013; 368(20): 1878-87.
3. Kowdley KV et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. New Engl J Med 2014; 370(20): 1879-88.
4. Afdhal N et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. New Engl J Med 2014; 370(20): 1889-98.
5. Zeuzem S et al. Sofosbuvir and ribavirin in HCV genotypes 2 and 3. New Engl J Med 2014; 370(21): 1993-2001.
6. Liang TJ, Ghany MG. Therapy of hepatitis C—back to the future. N Engl J Med. 2014; 370(21): 2043-7.
7. AASLD, ISDA. Recommendations for testing, managing, and treating Hepatitis C. Available at http://www.hcvguidelines.org/fullreport, accessed October 22, 2016.