November 16, 2015

New Indications Approved for Harvoni

Gilead Sciences' hepatitis C drug, Harvoni® (ledipasvir/sofosbuvir) received approval from the U.S. Food and Drug Administration (FDA) for three additional indications on Nov. 12, 2015. It was approved as treatment for patients with genotypes 4, 5 and 6 chronic hepatitis C virus (HCV) infection. Although approximately 70% of Americans have genotype 1 HCV, other genotypes are more prevalent in African, Asian and Eastern European countries. Harvoni also was approved for patients who have HIV and HCV co-infection. About one-third of patients with HIV also have HCV. Additionally, a 12-week course of Harvoni treatment, in combination with ribavirin, was approved for patients previously treated for HCV who have genotype 1 HCV and liver cirrhosis. Harvoni is a once-daily tablet that was first approved by FDA on Oct. 10, 2014, for treating adults with HCV genotype 1. Updated prescribing information for Harvoni is at:


NOTICE: Although the information and recommendations set forth herein (hereafter “information”) are presented in good faith and believed to be correct as of the date hereof, neither Express Scripts Holding Company nor any of its subsidiaries or affiliates (collectively, “Express Scripts”), make any representations or warranties as to the completeness or accuracy thereof and assumes no obligation to update any of the information. In no event will Express Scripts be held responsible for damages of any nature whatsoever resulting from the use of or reliance upon any information or any product to which any information refers. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO ANY INFORMATION OR ANY PRODUCT TO WHICH ANY INFORMATION REFERS.

© 2015 Express Scripts Holding Company. All Rights Reserved. Express Scripts and “E” Logo are trademarks of Express Scripts Holding Company and/or its subsidiaries. Other trademarks are the property of their respective owners.