Effective Date: 06/19/2015



NHS MEDICAL POLICY

Harvoni (ledipasvir/sofosbuvir) Medicine 2015-001

Treatment with Harvoni (ledipasvir/sofosbuvir) may be indicated when ALL the following are present:

The member has one of the following diagnoses: chronic hepatitis C virus (HCV) genotype 1 infection with a detectable HCV viral level over a six-month period co-infection with chronic hepatitis C (as above) and HIV co-infection with chronic hepatitis C (as above) and hepatitis B chronic hepatitis C (as above) with advanced fibrosis (Metavir score 2) chronic hepatitis C (as above) with an extra hepatic manifestation of hepatitis C (e.g., symptomatic cryoglobulinemia, porphyria cutanea tarda, Proteinuria, nephrotic syndrome, membranoproliferative glomerulonephritis) chronic hepatitis C (as above) chronic hepatitis C status post liver transplantation The member does NOT have worsening jaundice, active upper gastrointestinal bleeding, worsening ascites, or hepatic encephalopathy. 3 The medication was prescribed by or in consultation with a hepatologist or gastroenterologist. IF the member has eGFR < 30 mL/min/1.73 m2, the medication was prescribed by or in consultation with a nephrologist. Patient will not use another HCV protease inhibitor (e.g., Victrelis, Olysio) or nucleotide analog polymerase inhibitor (i.e. Sovaldi) in combination with Harvoni (ledipasvir/sofosbuvir). The member does not have a limited life expectancy (less than 12 months) due to non-liver related co-morbid conditions.

SOURCES

- 1. http://www.hcvguidelines.org/ was accessed Apr 6, 2015. American Association for the Study of Liver Diseases and Infectious Diseases Society of America.
- 2. www.UpToDate.com was accessed Apr 6, 2015: Cirrhosis in adults: Etiologies, clinical manifestations, and diagnosis

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

J8499

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
06/16/2016	Annual review and approval by UM Committee
06/14/2017	Annual review and approval by UM Committee
06/13/2018	Annual review and approval by UM Committee
06/12/2019	Annual review and approval by UM Committee
06/11/2020	Annual review and approval by UM Committee
06/11/2021	Annual review and approval by UM Committee
06/10/2022	Annual review and approval by UM Committee
05/26/2023	Annual review and approval by UM/QM Committee
05/20/2024	Annual review and approval by UM/QM Committee
03/24/2025	Annual review and approval by UM/QM Committee