



NHS MEDICAL POLICY

Harvoni (ledipasvir/sofosbuvir) Medicine 2015-001

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

1	<p>The member has one of the following diagnoses:</p> <ul style="list-style-type: none"> • 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
2	<p>The member does NOT have worsening jaundice, active upper gastrointestinal bleeding, worsening ascites, or hepatic encephalopathy.</p>
3	<p>The medication was prescribed by or in consultation with a hepatologist or gastroenterologist.</p>
4	<p>IF the member has eGFR < 30 mL/min/1.73 m², the medication was prescribed by or in consultation with a nephrologist.</p>
5	<p>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).</p>
6	<p>The member does not have a limited life expectancy (less than 12 months) due to non-liver related co-morbid conditions.</p>

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