



Commercial/Healthcare Exchange PA Criteria Effective: November 2, 2016

Prior Authorization: Epclusa

Products Affected: Epclusa (sofosbuvir/velpatasvir) 400 mg/100 mg tablets, 200 mg/50 mg tablets, Epclusa (sofosbuvir/velpatasvir) pellets

Medication Description:

Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV). Hepatitis C is a blood-borne virus. Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs. For some people, hepatitis C is a short-term illness but for 70%–85% of people who become infected with Hepatitis C, it becomes a long-term, chronic infection. Chronic Hepatitis C is a serious disease that can result in long-term health problems, even death. The majority of infected persons might not be aware of their infection because they are not clinically ill. There is no vaccine for Hepatitis C. The best way to prevent Hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs. 3.5 million (Range 2.5 million-4.7 million) people are estimated to be currently infected with hepatitis C, according to a study in 2015. This figure was derived from the 2003-2010 National Health and Nutrition Examination Survey (NHANES).

EPCLUSA is a fixed-dose combination tablet containing sofosbuvir and velpatasvir for oral administration. Sofosbuvir is a nucleotide analog HCV NS5B polymerase inhibitor and velpatasvir is an NS5A inhibitor.

Covered Uses:

1. Chronic Hepatitis C Virus (HCV)

Exclusion Criteria:

Epclusa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. Previous treatment with Epclusa
2. Epclusa and ribavirin combination regimen is contraindicated in patients for whom ribavirin is contraindicated.

Required Medical Information:

1. Current HCV viral load (documentation required)
2. HCV genotype (documentation required)
3. Previous treatment regimens
4. Dose and frequency
5. For patients with cirrhosis, documented by FibroScan, FibroSure, liver biopsy, or radiological imaging

Age Restrictions: 3 years of age and older





Prescriber Restrictions: Must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, infectious disease specialist, liver transplant physician, healthcare practitioner experienced and trained in the treatment of Hepatitis C Virus, or healthcare practitioner under the direct supervision of one of the above listed specialists

Coverage Duration: Coverage duration will be in accordance with FDA-approved prescribing information

Other Criteria:

1. Chronic Hepatitis C Virus (HCV)

- A. The patient has a current viral load; **AND**
- B. The viral load is post-treatment in previously treated patients; **AND**
- C. Patient has genotype 1, 2, 3, 4, 5, or 6; **AND**
- D. Patient is without cirrhosis or with compensated cirrhosis; **OR**
- E. Patients with decompensated cirrhosis for use in combination with ribavirin.

References:

1. Eplclusa [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; October 2020.
2. "Hepatitis C FAQs for Health Professionals." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, 08 Jan. 2016. Web. 06 Oct. 2016.
3. Manns, M P, H Wedemeyer, and M Cornberg. "Treating Viral Hepatitis C: Efficacy, Side Effects, and Complications." *Gut* 55.9 (2006): 1350–1359. *PMC*. Web. 06 Oct. 2016.
4. AASLD-IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. Available at: <http://www.hcvguidelines.org>. Accessed October 6, 2016.
5. Product Information: EPCLUSA(R) oral tablets, oral pellets, sofosbuvir velpatasvir oral tablets, oral pellets. Gilead Sciences Inc (per manufacturer), Foster City, CA, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/06/2016
2	Criteria change	For genotypes 1, 4, 5, 6 patients need to have tried Harvoni	Other Criteria	01/01/2017
3	Policy Update	Remove required trial of Harvoni in patients with genotype 1, 4, 5, 6	Other Criteria	12/31/2019

Last Res. July 2022



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.

4	Update	CCI to adopt EH Policy & Template CCI P&T Review History: 2/16, 5/16, 11/16, 2/17, 11/17, 1/18 CCI Revision Record: 2/16, 5/16,	All	12/31/2019
5	Update	Updated Covered Indications, Other Criteria	Updated Covered Indications, Other Criteria	03/27/2020
5	Policy Update	Added Epclusa Pellets to Products Affected, Updated Age Restrictions from 6 years and older to 3 years and older	Products Affected, Age Restrictions	7/8/2022