VENTURA COUNTY
HEALTH CARE PLAN

# FORMULARY EXCEPTION POLICY

**POLICY:** Harvoni® (sofosbuvir/ledipasvir tablets low dose tablets [45 mg/200 mg] and oral pellets – Gilead)

**DATE CREATED:** 10/03/2019

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**CRITERIA**

1. **Chronic Hepatitis C Virus (HCV) Genotype 1.** Approve Harvoni low-dose tablets (45 mg/200 mg) or oral pellets for the specified duration below if patients meet all of the following criteria (A, B, and C):
   - **A)** The patient is ≥ 3 to < 12 years of age; AND
   - **B)** Harvoni low-dose tablets (45 mg/200 mg) or oral pellets are prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient meets ONE of the following criteria (i, ii or iii):
     - **i. Approve for 8 weeks** in patients who meet all of the following (a, b, c, d, and e):
       - **a)** The patient is treatment-naïve; AND
       - **b)** The patient does not have cirrhosis; AND
       - **c)** The patient does not have human immunodeficiency virus (HIV)[2] (patients with HIV should be reviewed the same as patients without HIV using *Criteria ii or iii below*); AND
       - **d)** The patient is not awaiting liver transplantation (patients awaiting liver transplantation should be reviewed using *Criteria ii or iii below*); AND
       - **e)** Baseline hepatitis C virus (HCV) RNA is < 6 million IU/mL; OR
     - **ii. Approve for 12 weeks** in patients who meet ONE the following (a, b, or c):
       - **a)** The patient is treatment-naïve AND does not meet criterion *Ci* above (Note: this would include patients with or without HIV who are treatment-naïve with compensated [Child-Pugh A] cirrhosis regardless of baseline HCV RNA, or treatment-naïve patients with or without HIV without cirrhosis and baseline HCV RNA ≥ 6 million IU/mL. This would also include treatment-naïve patients awaiting transplant with compensated [Child-Pugh A] cirrhosis regardless of baseline HCV RNA or treatment-naïve patients awaiting transplant without cirrhosis and baseline HCV RNA ≥ 6 million IU/mL); OR
       - **b)** The patient has previously been treated for hepatitis C virus (HCV) and does not have cirrhosis (for patients with compensated cirrhosis [Child-Pugh A] see criterion *Ciii* below, for patients with decompensated cirrhosis [Child-Pugh B or C] see criterion *Ciic* below); OR
       - **c)** The patient is treatment-naïve or has previously been treated for hepatitis C virus (HCV) and meets both of the following criteria ([1] and [2]):
         - **(1)** The patient has decompensated (Child-Pugh B or C) cirrhosis; AND
         - **(2)** The patient is ribavirin eligible (for ribavirin ineligible patients with decompensated cirrhosis, see criterion *Ciiib* below) AND Harvoni (brand or generic) will be prescribed **in combination with ribavirin**.
     - **iii. Approve for 24 weeks** in patients who meet ONE of the following (a or b):
       - **a)** The patient has previously been treated for hepatitis C virus (HCV) and has compensated (Child-Pugh A) cirrhosis. OR

**b)** The patient is treatment-naïve or has previously been treated for hepatitis C virus (HCV) and the patient meets both of the following criteria ([1] and [2]):
**(1)** The patient has decompensated (Child-Pugh B or C) cirrhosis; AND
**(2)** The patient is ribavirin ineligible, according to the prescribing physician.

2. **Chronic Hepatitis C Virus (HCV) – Genotype 4, 5, OR 6.** Approve Harvoni low-dose tablets (45 mg/200 mg) or oral pellets for **12 weeks** in patients who meet the following criteria (A and B):
**A)** The patient is ≥ 3 to < 12 years of age; AND
**B)** Harvoni low-dose tablets (45 mg/200 mg) or oral pellets are prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

3. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotypes 1 OR 4.** Approve Harvoni low-dose tablets (45 mg/200 mg) or oral pellets for **12 weeks** in patients who meet the following criteria (A, B, C and D):
**A)** The patient is ≥ 3 to < 12 years of age; AND
**B)** The patient has recurrent hepatitis C virus (HCV) after a liver transplantation; AND
**C)** Harvoni low-dose tablets (45 mg/200 mg) or oral pellets are prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center[2]: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
**D)** Harvoni low-dose tablets (45 mg/200 mg) or oral pellets will be prescribed **in combination with ribavirin**.

4. **Patient Has Been Started on Harvoni.** Approve Harvoni low dose-tablets (45 mg/200 mg) or oral pellets for an indication or condition above. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

[**]*Note: Treatment-naïve includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy have not been treated for HCV. Treatment-naïve also includes patients who have not started HCV therapy and have never previously been treated for HCV.*

## HISTORY

| Type of Revision | Summary of Changes* | Effective Date |
|---|---|---|
| New Policy | -- | 10/03/2019 |