FORMULARY EXCEPTION POLICY

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

DATE CREATED: 10/03/2019

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-naive 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: 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-naive 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-naive also includes patients who have not started HCV therapy and have never previously been treated for HCV.

### HISTORY

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<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>Effective Date</th>
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<td>New Policy</td>
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