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**Medicare Part D – 2016****Prior Authorization Group Description**

HARVONI

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D. For the treatment of hepatitis C virus genotype 4, 5 and 6. For the retreatment of persons in whom prior sofosbuvir-containing therapy has failed.

**Exclusion Criteria:****Required Medical Information:**

Diagnosis of chronic hepatitis C (CHC) genotype 1, 4, 5, or 6 confirmed by detectable serum HCV RNA by quantitative assay. Baseline viral load by quantitative assay including genotype and treatment status of patient (naive, relapser, nonresponder). Documentation that patient does or does not have cirrhosis (compensated or decompensated). Documentation that the patient did or did not have a liver transplant. The patient has either genotype 1 or 4 with decompensated cirrhosis. Documentation of previous therapies. GENOTYPES 1 AND 4: Genotype 1 CHC treatment naive patients: 12 weeks, Treatment-experienced with cirrhosis: 24 weeks, Alternative dosing ribavirin for 12 weeks may be considered in this population, Genotype 4 CHC Treatment naive patients: 12 weeks, Genotype 1 or 4 CHC with decompensated cirrhosis plus ribavirin: 12 weeks, Patients who have advanced fibrosis, in whom a previous sofosbuvir-containing regimen has failed: 24 weeks, Genotype 1 or 4 CHC with decompensated cirrhosis for patients in whom a prior sofosbuvir based therapy has failed: 24 weeks, Treatment-naive and experienced patients with Genotype 1 or 4 infection post liver transplantation, including compensated cirrhosis: 12 Weeks, Treatment-naive and experienced patients with Genotype 1 or 4 infection post liver transplantation, including compensated cirrhosis and RBV intolerant or ineligible: 24 Weeks. GENOTYPES 5 AND 6: Treatment-naive or treatment experienced patients with CHC genotype 5 or 6 infection: 12 weeks.

**Age Restrictions:****Prescriber Restrictions:**

Gastroenterologist, Hepatologist or Infectious Disease physician

**Coverage Duration:**

12 to 24 weeks based on genotype and prior treatment, cirrhosis, or liver transplant status.

**Other Criteria:**

Proprietary

Last Updated: 11/20/15