UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2014 P 1146-1
Program	Prior Authorization/Notification
Medication	Harvoni™ (ledipasvir/sofosbuvir)
P&T Approval Date	10/2014
Effective Date	10/15/2014

1. Background:

Harvoni™ (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.[1]

2. Coverage Criteria:

A. Treatment-Naïve Patients without Cirrhosis and have a pre-treatment HCV RNA less than 6 million IU/mL:

1. **Harvoni** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1 infection

   -AND-

   b. Patient has a pre-treatment HCV RNA less than 6 million IU/mL

   -AND-

   d. Patient is without cirrhosis.

Authorization will be issued for 8 weeks.

B. Treatment-Naïve Patients with or without Cirrhosis and have a pre-treatment HCV RNA equal to or greater than 6 million IU/mL:

1. **Harvoni** will be approved based on **both** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1 infection

   -AND-

   b. Patient has a pre-treatment HCV RNA equal to or greater than 6 million IU/mL

Authorization will be issued for 12 weeks.

C. Treatment-Experienced Patients without Cirrhosis:

1. **Harvoni** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1 infection

   -AND-

   b. Patient has experienced failure with a previous treatment regimen that included either peginterferon alfa + ribavirin **or** an HCV protease inhibitor (e.g. Incivek, Olysio, Victrelis) + peginterferon alfa + ribavirin

   -AND-

   c. Patient is without cirrhosis

Authorization will be issued for 12 weeks.

D. Treatment-Experienced Patients with Cirrhosis:

1. **Harvoni** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1 infection

   -AND-

   b. Patient has experienced failure with a previous treatment regimen that included either peginterferon alfa + ribavirin **or** an HCV protease inhibitor (e.g. Incivek, Olysio, Victrelis) + peginterferon alfa + ribavirin

   -AND-

   c. Patient has cirrhosis

Authorization will be issued for 24 weeks.

3. Additional Clinical Rules:

Supply Limits may be in place.

4. References:

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2014.

Program	Prior Authorization/Notification - Harvoni™ (ledipasvir/sofosbuvir)
Change Control	
10/2014	New program.