SPECIALTY GUIDELINE MANAGEMENT

HARVONI (ledipasvir and sofosbuvir)

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Harvoni is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Treatment plan including treatment regimen and duration
- Baseline or current viral load and corresponding week of treatment
- Genotype and subtype (if applicable)
- METAVIR fibrosis score (if available)
- Prior treatment regimen(s) and response
- Liver transplantation status
- Prescriber specialty

C. EXCLUSIONS
- Prior treatment with a Sovaldi-based regimen
- Use with other drugs containing sofosbuvir, including Sovaldi

D. CRITERIA FOR APPROVAL
1. Chronic hepatitis C virus infection, genotype 1
   a. Authorization of 8 weeks may be granted for treatment-naïve members without cirrhosis who have a baseline HCV RNA < 6 million IU/mL.
   b. Authorization of 12 weeks may be granted for treatment-naïve members without cirrhosis who have a baseline HCV RNA > 6 million IU/mL.
   c. Authorization of 12 weeks may be granted for treatment-naïve members with compensated cirrhosis.
   d. Authorization of 12 weeks may be granted for members without cirrhosis who failed prior treatment (relapse or nonresponse) with a pegylated interferon (PEG-IFN) and ribavirin (RBV) regimen with or without a NS3/4A protease inhibitor.
   e. Authorization of 24 weeks may be granted for members with compensated cirrhosis who failed prior treatment (relapse or nonresponse) with a PEG-IFN and RBV regimen with or without a NS3/4A protease inhibitor.

E. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
1. **Dosing Limits**
   The following dosing limits apply:
   - 90mg ledipasvir/400mg sofosbuvir per day

2. **Dispensing Limits**
   A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

**REFERENCES**