I. Medication Description

Harvoni is a fixed-dose combination of ledipasvir and sofosbuvir which are direct-acting antiviral agents against the hepatitis C virus. Ledipasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. Resistance selection in cell culture and cross-resistance studies indicate ledipasvir targets NS5A as its mode of action. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Harvoni can be granted if the following criteria are met:

- Member is at least 18 years of age or at least 12 years of age (and weighs at least 35kg) AND
- Medication is prescribed by a:
  - hepatologist, gastroenterologist, infectious disease specialist, transplant physician, healthcare practitioner under the direct supervision of one of the preceding listed specialists, or a healthcare practitioner experienced and trained in the treatment of HCV infection prescriber working in collaboration with one of these specialists, or a prescriber who has clinical experience with the management and treatment of HCV infection (defined as the management AND treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months) OR
  - healthcare professional in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria AND
- A diagnosis of chronic hepatitis C has been established and baseline viral load reported AND
- Genotype and subgenotype (if available) is confirmed and documented AND
- The Harvoni combination product will not be used with any other hepatitis C therapy or any therapies identified in its prescribing information that are not recommended for coadministration with Harvoni AND
- Usage is in accordance with current AASLD/IDSA treatment guidelines for chronic hepatitis C (http://www.hcvguidelines.org)
IV. **Quantity Limitations**

Coverage is provided for up to 28 tablets per each 28 days.

V. **Coverage Duration**

- Coverage duration will be determined in accordance with medication prescribing information and recommendations from current AASLD/IDSA treatment guidelines for chronic hepatitis C ([http://www.hcvguidelines.org](http://www.hcvguidelines.org)).

VI. **Coverage Renewal Criteria**

Coverage is not available for renewal.

VII. **Billing/Coding Information**

Available as fixed a dose oral tablets containing 90mg of ledipasvir and 400mg of sofosbuvir.

VIII. **Summary of Policy Changes**

- 10/15/14: new policy
- 12/1/14: prioritization of patients based on disease severity added
- 3/1/15: ViekiraPak is preferred agent for the treatment of genotype 1 disease
- 3/15/15: no policy changes
- 4/15/15: guideline updated to reflect changes in recommendations for the use of ViekiraPak outside of genotype 1 disease
- 7/1/15: formulary distinctions made
- 8/1/15: Harvoni is the preferred product over Viekira
- 9/1/15: coverage criteria opened to treat less urgent-need patients
- 12/15/15: no policy changes
- 4/22/16: Coverage criteria opened to allow consideration despite disease severity; specialist qualifications clarified
- 7/15/16: Harvoni 8-week limits apply to specific populations
- 9/15/16: no policy changes
- 4/12/17: updated to include pediatric indication
- 5/12/17: coverage duration updated to allow determination in accordance with prescribing information and AASLD/IDSA guidelines
- 10/11/17: no policy changes

IX. **References**

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.