

CRITERIA FOR PRIOR AUTHORIZATION

Fixed Combination Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ledipasvir/Sofosbuvir (Harvoni®)

CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Sofosbuvir/Ledipasvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m²) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon-based regimen
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 capsule per day
- Patient must have one of the following:
 - Advanced fibrosis (Metavir F3)
 - Compensated cirrhosis
 - Organ transplant
 - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
 - Proteinuria
 - Nephrotic syndrome
 - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with ledipasvir/sofosbuvir therapy
- For Genotypes 1 and/or 4: the PDL preferred drug, which covers Genotypes 1 and 4, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

PA Criteria

RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
 - Genotype 1 (one of the following)
 - Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – **8 weeks total therapy**
 - Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – **12 weeks total therapy**
 - Treatment-naïve, with cirrhosis– **12 weeks total therapy**
 - Treatment-experienced, without cirrhosis – **12 weeks total therapy**
 - Treatment-experienced, with cirrhosis:
 - **24 weeks total therapy alone**
 - **12 weeks total therapy if used with Ribavirin**
 - Genotype 4, 5, or 6
 - **12 weeks total therapy**

LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

DATE

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE