

**Idaho Medicaid – Prior Authorization Therapeutic Criteria Hepatitis C Agents
July 1, 2020**

DRUG NAME (Preferred agents in BOLD)

Elbasvir/Grazoprevir (*Zepatier™*)

Glecaprevir/Pibrentasvir (*Mavyret™*)

Ledipasvir/Sofosbuvir (*Harvoni™*) tablets/pellets

Sofosbuvir (*Sovaldi®*) tablets/pellets

Sofosbuvir/Velpatasvir (*Generic*)

Sofosbuvir/Velpatasvir (*Epclusa®*)

Sofosbuvir/Velpatasvir/Voxilaprevir (*Vosevi™*)

Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (*Viekira PAK™*)

Hepatitis-C Prior authorization form is available at website:

<http://www.healthandwelfare.idaho.gov/Medical/PrescriptionDrugs/PriorAuthorizationForms/tabid/206/Default.aspx>

Please refer to Idaho Medicaid's Preferred Drug List for preferred agents at website:

<http://healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/IDMPDL.pdf>

COVERED USES:

Treatment of FDA approved indications for HCV infection.

AGE RESTRICTIONS:

FDA approved for ages 18 years or older.

Exceptions are 12 years and older for glecaprevir/pibrentasvir (*Mavyret™*), 3 years and older for sofosbuvir (*Sovaldi®*), ledipasvir/sofosbuvir (*Harvoni™*) and 6 years and older for sofosbuvir/velpatasvir (*Epclusa®*).

INCLUSION CRITERIA (All criteria must be met):

- FDA approved HCV genotypes for chronic infection or hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Documented hepatitis-C infection.
- Prescribed within the FDA approved indications/combinations/doses.
- Documentation that the provider has discussed with patient the potential risks and benefits of HCV therapy that a shared decision has been made for antiviral treatment.
- Documentation that adherence counseling has been performed and risk factors for nonadherence (such as mental illness, substance use disorder, or nonadherence to treatments for other chronic diseases) have been reviewed.
- Required testing for resistance polymorphism prior to treatment:
 - Elbasvir/Grazoprevir (*Zepatier™*): Presence of virus with NS5A resistance-associated polymorphisms, in patients with genotype 1a infection; prior to initiation.
 - Test for evidence of current or previous Hepatitis B virus (HBV) infection.
 - HBV surface antigen and HBV core antibody.

EXCLUSION CRITERIA:

- Non-FDA approved indications/drug combinations/dosing regimens.
- Agents not FDA approved for decompensated liver disease.
- Prior authorization requests that have incomplete documentation with no follow up response within 30 days of submission.
- For agents prescribed in combination with ribavirin: pregnant women or those who may plan to become pregnant during the course of treatment.
- Documented ongoing non-adherence to prior medications, medical treatment or failure to complete HCV disease evaluation appointments and procedures or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment.
- Known hypersensitivity to any component of agent requested.
- Co-administration with drugs that are contraindicated with hepatitis C agent requested.
- Clinical contraindications for the use of HCV agents per manufactures recommendations:
 - Viekira PAK™, Zepatier™, Vosevi™: Moderate to severe hepatic impairment (Child-Pugh B or C) for
 - Mavyret™, Vosevi™: Concomitant use with atazanavir or rifampin. Decompensated cirrhosis.

REQUIRED MEDICAL INFORMATION:

- Diagnosis of chronic HCV (ICD-10 B18.2) with confirmed genotype or diagnosis of hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Documentation of clinical assessment to rule out co-infection for HBV.
 - HBV surface antigen (HBsAg) positive = Active or Chronic HBV infection.
 - Anti-HBs positive= Past or resolved infection or immunization.
 - HBV-DNA viral load submitted to determine dominant virus and treatment plan for co-infection.
- Documented evidence of fibrosis score:
 - Ideally two non-invasive tests for fibrosis should be done as not test is sensitive or specific enough on its own. We recommend any combination of APRI, FIB4, FibroSure®, FibroTest®, FIBROSpect®, ultrasound, MRI, or transient elastography.
 - Recommend imaging for patients with possible cirrhosis.
- Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count, testing for resistance polymorphism and negative pregnancy test (if applicable).
- Previous history of HCV treatment if any. Hepatocellular carcinoma (HCC) screening in patients with cirrhosis.

COVERAGE DURATION:

- FDA approved treatment regimens/durations.

TREATMENT/MONITORING CRITERIA:

- Recommended that health care provider obtains a HCV-RNA viral count at 4 weeks of treatment and 12 weeks after completion of treatment (SVR12)
- Coinfection of HBV/HCV:
 - Patients with low or undetectable HBV DNA levels must be monitored at regular intervals during HCV treatments.

- Patients with HCV who have cleared the HBV virus, whether spontaneously resolving the infection or following treatment, should be monitored for HBV reactivation while on HCV therapy.
- Healthcare provider must submit a post 3 month treatment (SVR12) results to Idaho Medicaid to confirm clearance of HCV/RNA.

OTHER:

The criteria for HCV agents are based upon the most current evidence provided. Newer agents not reviewed by the Pharmacy & Therapeutics Committee will be evaluated on a case-by-case basis. Idaho Medicaid recognizes that these criteria may change and be revised, as new information becomes available.

REFERENCES:

Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations.

From the Department of Veterans Affairs National Hepatitis C Resource Center Program and the National Hepatitis C Resource Center Program and National Viral Hepatitis Program in the Office of Patient Care Services Updated August 27, 2018 . <https://www.hepatitis.va.gov/pdf/treatment-considerations-2018-08-27.pdf>

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. November 6, 2019 Update.

Product Information: SOVALDI® oral tablets, oral pellets, sofosbuvir oral tablets, oral pellets Gilead Sciences (per manufacturer), Foster City, CA, 2019.

Product Information: HARVONI® oral tablets, oral pellets, ledipasvir, sofosbuvir oral tablets, oral pellets Gilead Sciences Inc. (per manufacturer), Foster City, CA, 2019.

Product Information: VIEKIRA PAK™ oral tablets, ombitasvir paritaprevir ritonavir oral tablets and dasabuvir oral tablets. AbbVie Inc. (per manufacturer), North Chicago, IL 2017.

Product Information: ZEPATIER™ oral tablets, elbasvir, grazoprevir oral tablets. Merck Sharp & Dohme Corp. (per manufacturer), Whitehouse Station, NJ, 2017.

Product Information: EPCLUSA® oral tablets , sofosbuvir velpatasvir oral tablets. Gilead Sciences Inc (per manufacturer), Foster City, CA, 2020.

Product Information: MAVYRET™) oral tablets, glecaprevir pibrentasvir oral tablets. AbbVie Inc (per manufacturer), North Chicago, IL, 2019

Product Information: VOSEVI™ oral tablets, sofosbuvir velpatasvir voxilaprevir oral tablets. Gilead Sciences Inc (per manufacturer), Foster City, CA, 2017.