DRUG NAME (Preferred agents in BOLD)
Daclatasvir (*Daklinza™*)
Elbasvir/Grazoprevir (*Zepatier™*)
**Glecaprevir/Pibrentasvir (Mavyret™)**
Ledipasvir/Sofosbuvir (*Harvoni™*)
Simeprevir (*Olysio®*)
Sofosbuvir (*Sovaldi®*)
**Sofosbuvir/Velpatasvir (Epclusa®)**
**Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi™)**
Ombitasvir/Paritaprevir/Ritonavir (*Technivie™*)
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (*Viekira PAK™*)
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (*Viekira XR™*)

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 chronic hepatitis C (HCV) infection.

AGE RESTRICTIONS:
FDA approved for ages 18 years or older.
Exceptions are 12 years and older for Sofosbuvir (*Sovaldi®*) and Ledipasvir/Sofosbuvir (*Harvoni™*).

PRESCRIBER RESTRICTIONS:
Prescriber must be an experienced HCV practitioner or in collaboration/consultation with one.

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.
  o Acute HCV infections will require a 6 month follow up HCV-RNA to rule out spontaneously clearing of infection before treatment will be considered.
• Prescribed within the FDA approved indications/combinations/doses.
• Under the care of and/or collaboration with an experienced HCV practitioner.
• Documentation that the provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment.
• Adherence counseling performed and documented understanding of compliance to treatment by patient.
• Patient has no history of alcohol or substance abuse within the 6 months prior to treatment or has documented evidence of successful completion of 6 months of abstinence for injection drug use and/or substance abuse/alcohol dependency (if applicable).
• Negative urine toxicology and Ethyl Glucuronide (EtG) alcohol screening test within 1 month of request.
• Required testing for resistance polymorphism prior to treatment:
  o Daclatasvir (Daklinza™): Genotype 1a patients with cirrhosis, consider testing for the presence of virus with NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93.
  o Simeprevir (Olysio®): Genotype 1a, prior to initiation, tests for the presence of virus with NS3 Q80K polymorphism; sustained virologic response rates may be lower and other treatments should be considered.
  o Elbasvir/Grazoprevir (Zepatier™): Presence of virus with NS5A resistance-associated polymorphisms, in patients with genotype 1a infection; prior to initiation.
  o Test for evidence of current or previous Hepatitis B virus (HBV) infection.
    ▪ HBV surface antigen and hepatitis B 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.
• Acute HCV infection without a 6 month follow up HCV-RNA test to rule out spontaneous clearing of virus.
• 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.
• Documented active history of intravenous drug abuse/alcohol dependency/substance abuse.
• Known hypersensitivity to any component of agent requested.
• Hepatitis C agents not recommended in patients with a history of relapse.
• Co-administration with drugs that are contraindicated with hepatitis C agent requested.
• Clinical contraindications for the use of hepatitis C agents per manufactures recommendations:
  o Moderate to severe hepatic impairment (Child-Pugh B or C) for Viekira PAK™/ Viekira XR™/ Zepatier™, Vosevi™
  o Severe renal impairment (eGFR less than 30ml/min/1.73m²) or hemodialysis (Sovaldi® / Harvoni™).
  o Patients with HCV genotype 4 with cirrhosis (Technivie™).
  o Concomitant use with atazanavir or rifampin (Mavyret™, Vosevi™)

REQUIRED MEDICAL INFORMATION:
• Diagnosis of chronic hepatitis-C infection (ICD-10 B18.2) with confirmed genotype of 1, 2, 3, 4, 5 or 6 or diagnosis of hepatic carcinoma secondary to HCV awaiting liver transplantation.
• Documentation of clinical assessment to rule out co-infection for hepatitis B (HBV).
- Hepatitis B 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 is for co-infection.

- Documented evidence of fibrosis score (F0-F4)
  - FibroSure®, FibroTest®, and FIBROSpect® testing, alone, are not recommended for the routine use in the diagnosis of fibrosis scoring. Additional documentation with ultrasound/MRI or APRI/FIB-4 is required to confirm fibrosis score.
- 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).
- Patients with a history of intravenous drug/substance abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence for injection drug/substance abuse and/or alcohol dependency.
- A random urine toxicology and Ethyl Glucuronide (EtG) alcohol screening within 1 month of request.
- Previous history of HCV treatment (treatment naive or treatment experienced).

**COVERAGE DURATION:**
- FDA approved treatment regimens/durations.

**TREATMENT/MONITORING CRITERIA:**
- Healthcare provider must submit a HCV-RNA viral count prior to 4 weeks of treatment for all genotype treatments to determine compliance and efficacy of treatment.
- Healthcare provider must submit a HCV-RNA viral count after the completion for all 12-WEEK TREATMENTS.
- Healthcare provider must submit a HCV-RNA viral count after the completion for all 16-WEEK TREATMENTS.
- Healthcare provider must submit a HCV-RNA viral count at weeks 12, and after the completion for all 24-WEEK TREATMENTS.
- Requests for renewal will be denied in patients who have not achieved HCV-RNA below the limit of detection after 4 weeks of therapy or in patients who have not demonstrated a 1-log decrease in HCV RNA (response) after 4 weeks.
- All treatment must be discontinued if HCV RNA is >25 IU/ml at week 4 or at any other time point thereafter.
- Drug treatment approval will be denied if there is a discontinuation or dose reduction of any component of combination treatment plan.
- Coinfection of HBV/HCV:
  - Patients with low or undetectable HBV DNA levels must be monitored at regular intervals during hepatitis C treatments.
  - Patients with HCV who have resolved the HBV virus, whether spontaneously resolving the infection or following treatment, should be monitored for HBV reactivation while on HCV therapy.
- Patients with a history of substance/alcohol abuse will require monthly random urine toxicology and/or Ethyl Glucuronide (EtG) alcohol screening while on treatment.
- Healthcare provider must submit a sustained viral response (SVR) 12 weeks after completion of therapy.
OTHER:
The criteria for Hepatitis C 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 as new information becomes available, these criteria may change and revised if necessary.

REFERENCES:


Product Information: SOVALDI® oral tablets, sofosbuvir oral tablets. Gilead Sciences (per manufacturer), Foster City, CA, 2015.

Product Information: HARVONI® oral tablets, ledipasvir, sofosbuvir oral tablets. Gilead Sciences Inc. (per manufacturer), Foster City, CA, 2016.


Product Information: VIEKIRA PAK™ oral tablets, ombitasvir paritaprevir ritonavir oral tablets and dasabuvir oral tablets. AbbVie Inc. (per manufacturer), North Chicago, IL, 2014.


Product Information: TECHNIVIE™ oral tablets, ombitasvir paritaprevir ritonavir oral tablets. AbbVie Inc. (per Manufacturer), North Chicago, IL, 2015.


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


Product Information: MAVYRET™ oral tablets, glecaprevir pibrentasvir oral tablets. AbbVie Inc (per manufacturer), North Chicago, IL, 2017