SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
Healthy Connections MEDICAID

Hepatitis C (HCV) Criteria

Revised: 06/26/2024

HEPATITIS C (HCV) THERAPY

Length of Authorization: Initial request up to 16 weeks of therapy

APPROVAL CRITERIA

- Diagnosis of chronic hepatitis C virus (HCV)
- Must be 18 years of age or older (3 years of age or older for Epclusa®, Harvoni®, Mavyret®, or Sovaldi®) — see AASLD guidelines for recommended regimens)
- Prescriber must submit copies of the following lab results within **6 months** of the request:
  - WBC
  - Hemoglobin
  - Creatinine
  - Sodium
  - Serum albumin
  - Total bilirubin
  - INR
  - AST
  - ALT
  - Platelet count
  - HCV genotype
  - HCV quantitative RNA
  - HIV antibody
  - HBV sAg (surface antigen)
  - Staging of liver disease (Metavir score)
  - APRI score
  - FIB-4 score
  - Fibrosure Assay or similar test
  - Ultrasound (only if F3/F4)
- HCV PA form is located at https://southcarolina.fhsc.com/Downloads/provider/SCRx_PAform_Hepatitis_C.pdf
- Recent chart note including the patient's current weight, height, and a current medication list must be submitted to evaluate for potential drug interactions. If Harvoni or Epclusa and receiving a PPI, document if it will be held during therapy and, if not, that the patient was instructed on proper administration. If there are medications that should not be used with the requested medication (e.g., amiodarone or carbamazepine with sofosbuvir) an alternative regimen must be used (allowing an appropriate interval before starting Hepatitis C therapy based on the discontinued medication).
- For **compensated cirrhosis**, the results of the most recent ultrasound (within the last 6 months) must be documented. If the case has been presented at the Southeast Viral Interactive Case Conference (SVICC), the case number and date presented must be documented.
  - **Note**: SVICC presentation is not required for compensated or non-cirrhotic patients. This is for documentation purposes only. If the case has been presented to SVICC, forward the request to the Clinical Account Manager.
- For **decompensated cirrhosis**, the treatment must be used in combination with ribavirin in accordance with the American Association for the Study of Liver Diseases (AASLD) guidelines. If not, rationale for not using Ribavirin must be provided. Patient must be referred to a transplant center or subspecialty care (i.e., gastroenterologist, hepatologist, or infectious disease physician). If the patient has not been referred to a transplant center or specialty care, the case must be presented at the Southeast Viral Interactive Case Conference (SVICC) (https://www.seaet.com/calendar/). The case number and date presented must be documented. Forward requests presented to SVICC to the Clinical Account Manager.
- For **treatment experienced** patients, the name of the specific drug regimen and duration of therapy must be documented.
  - **Note**: if previously treated with interferon alone, then consider the patient treatment naïve.
- Any potential compliance issues have been addressed (if documentation of previous non-compliance with other therapies, physician appointments).

- If the patient has a diagnosis of active cancer, a copy of the oncology chart note including all current medications, prognosis, and treatment plan must be submitted. Forward request to a Clinical Pharmacist for review.
- If all criteria are met for approval, verify active Medicaid coverage for duration of anticipated length of therapy (use "patient eligibility" **and** "coverage details" on patient tab). If coverage ends before treatment can be completed, the request should **not** be approved.
- All requests for retreatment with previous use of a DAA must include updated genotype results.

PDL CRITERIA

Approval for a non-preferred medication requires a clinical reason all preferred medications for the patient's genotype cannot be used.

MEDICATION-SPECIFIC CRITERIA

- NS5a Inhibitors – daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir
- NS3/4A Inhibitor – grazoprevir, paritaprevir
- Requests for any regimen not listed below and not included in AASLD guidelines should be forwarded for South Carolina Clinical Manager review

EPCLUSA® (SOFOSBUVIR/VELPATASVIR)

- **Preferred i**ndicated for genotypes 1, 2, 3, 4, 5, and 6
- Patient is not taking a concomitant medication that has a significant clinical interaction (such as PPIs)
- Duration of therapy:
- Without cirrhosis and patients with compensated cirrhosis (Child-Pugh A) for 12-week duration; **OR**
- Decompensated cirrhosis (Child-Pugh B or C) in combination with ribavirin for 12-week duration (24 weeks if RBV ineligible (such as Hgb, 8 or eGFR < 50)

MAVYRET® (GLECAPREVIR/PIBRENTASVIR)

- **Preferred** indicated for genotypes 1, 2, 3, 4, 5, and 6 (Vosevi® is preferred for retreatment after another DAA), **not** indicated if Child-Pugh B or C (decompensated cirrhosis)
- Patient is not taking a concomitant medication that has a significant clinical interaction; **AND** used as part of an AASLD recommended regimen.
- The recommended duration of treatment:
  - DAA treatment-naïve patients without cirrhosis or compensated cirrhosis – 8 weeks
  - Genotype 1 treatment experienced (with a NS5A inhibitor and no NS3/4A inhibitor) – 16 weeks
  - Genotype 1 treatment experienced (with a NS3/4A inhibitor and no NS5A inhibitor) – 12 weeks
  - Genotype 1, 2, 4, 5, 6 treatments experienced (with IFN/RBV and/or sofosbuvir) and no cirrhosis – 8 weeks
  - Genotype 1, 2, 4, 5, 6 treatments experienced (with IFN/RBV and/or sofosbuvir) and compensated cirrhosis – 12 weeks
  - Genotype 3 treatment experienced (with IFN/RBV and/or sofosbuvir) – 16 weeks

VOSEVI® (VELPATASVIR/VOXILAPREVIR)

- **Preferred (retreatment only)** for genotypes 1, 2, 3, 4, 5, and 6 and no cirrhosis or compensated cirrhosis (if decompensated cirrhosis Epclusa and RBV would be the preferred product)
- Patient is not taking a concomitant medication that has a significant clinical interaction; **AND**
- Used as part of an AASLD recommended regimen.

- The recommended duration of treatment:
  - Genotype 1, 2, 3, 4, 5, and 6 and treatment experienced with a NS5A inhibitor and no cirrhosis or compensated cirrhosis – 12 weeks
  - Genotype 1a and 3 and treatment experienced with sofosbuvir and no NS5A inhibitor – 12 weeks

HARVONI® (LEDIPASVIR/SOFOSBUVIR)

- **Non-preferred** indicated for genotypes 1, 4, 5, and 6
- Patient is not taking a concomitant medication that has a significant clinical interaction; **AND**
- Must be prescribed according to current Hepatitis C Treatment Guidelines

VIEKIRA PAK® OR VIEKIRA XR® (OMBITASVIR, PARITAPREVIR, RITONAVIR)

- **Non-preferred** indicated for genotype 1
- Must be prescribed according to current Hepatitis C Treatment Guidelines

ZEPATIER® (ELBASVIR/GRAZOPREVIR)

- **Non-preferred** indicated for genotypes 1 and 4
- Patient is not taking a concomitant medication that has a significant clinical interaction
- Patients with genotype 1a must undergo testing for the presence of NS5A resistance-associated polymorphisms prior to initiating therapy, unless patient has Cr Cl < 35 mL/min (Mavyret® would still be preferred)
- Must be prescribed according to current Hepatitis C Treatment Guidelines

LENGTH OF AUTHORIZATION

- **Initial Approval** – use specific reason codes based on genotype (return fax indicating duration of approval and specific expectation of updated viral load for renewal)
- **Renewal** – use specific reason codes based on initial approval and genotype.
- If the approvable duration of therapy is 24 weeks, then a viral load from treatment week (TW) 12 is required.
- Renewals should **not** be granted if patient has been **non-compliant**. Request additional information as to why the patient has been non-compliant and forward the request to the South Carolina Clinical Manager for review.

REVISION HISTORY

Date	Issues/Updates
06/26/2024	• Initial draft creation