HEPATITIS C AGENTS
DIRECT-ACTING ANTIVIRALS

Drug Class: Hepatitis C Agents: Direct-Acting Antivirals

FDA-approved uses: Treatment of FDA approved indications for chronic hepatitis C (HCV) infection.

- ❒ **Daklinza™** (daclatasvir) - genotypes 1 or 3 in combination with sofosbuvir
- ❒ **Epclusa®** (sofosbuvir/velpatasvir) - genotypes 1, 2, 3, 4, 5, or 6 with or without ribavirin
- ❒ **Harvoni™** (ledipasvir/sofosbuvir) –genotypes 1, 4, 5, or 6 with or without ribavirin
- ❒ **Mavyret™** (glecaprevir/pibrentasvir) – genotypes 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A). Also indicated for genotype 1 previously treated with regimens containing either an NS5A inhibitor or an NS3/4A PI but not both.
- ❒ **Olysio®** (simeprevir) - genotype 1 or 4 as a component of a combination regimen
- ❒ **Sovaldi®** (sofosbuvir) - genotype 1, 2, 3, or 4 as a component of a combination regimen
- ❒ **Technivie™** (ombitasvir/paritaprevir/ritonavir) – genotype 4 (without cirrhosis) in combination with ribavirin
- ❒ **Viekira PAK™, Viekira XR™** (ombitasvir/paritaprevir/ritonavir/dasabuvir) - genotype 1 with or without ribavirin including in those with compensated cirrhosis.
- ❒ **Vosevi™** (sofobuvir/velpatasvir/voxilaprevir) – genotypes 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A) and previously treatment with an NS5A inhibitor or have genotype 1a or 3 and previously treated with sofosbuvir without an NS5A inhibitor.
- ❒ **Zepatier™** (elbasvir/grazoprevir) - genotype 1 or 4 with or without ribavirin

Available dosage forms:

- ❒ Daklinza™ 30, 60, 90 mg tablet
- ❒ Epclusa® 400-100 mg tablet
- ❒ Harvoni™ 90 mg tablet
- ❒ Mavyret™ 100-40 mg tablet
- ❒ Olysio® 150 mg capsule
- ❒ Sovaldi® 400 mg tablet
- ❒ Technivie™ 12.5-75 mg tablet
- ❒ Viekira PAK™ 12.5-75-50 mg tablet
- ❒ Viekira XR™ 8.33-50 mg tablet
- ❒ Vosevi™ 400-100-100 mg tablet
- ❒ Zepatier™ 50-100 mg tablet

Hepatitis C Prior authorization form is available at:
https://michigan.fhsc.com/Providers/Forms.asp

Please Refer to the Michigan Medicaid Preferred Drug List (PDL) for preferred agents at:
https://michigan.fhsc.com/Providers/DrugInfo.asp

Coverage Criteria:

1. The patient must be 12 years of age or older for Harvoni and Epclusa and 18 years of age or older for all other agents.
2. The patient must have the diagnosis of chronic hepatitis C.

For initial requests:

1. The patient's RNA viral load must be documented prior to initiation of treatment (lab results must be submitted).
2. The calculated Child-Pugh score must be documented, if the patient has cirrhosis.
3. The Genotype must be obtained (lab results preferred).
4. The patient must have one of the following:
   a) HIV co-infection
   b) Prior liver transplant
   c) Serious extra hepatic manifestation of hepatitis C, such as cryoglobulinemia or membranoproliferative glomerulonephritis
   d) Metavir fibrosis score as follows (supporting documentation must be submitted):
   [**NOTE: Coverage to expand to F1 or above on 10/01/2018; then expand again to F0 or above on 10/01/2019**]

   Metavir score of F1–F4 as documented by one of the following:

   - A liver biopsy demonstrating F1, F2, F3, or F4 (or cirrhosis)
   - A calculated predictive biomarker score supporting a level of fibrosis of F1–F4
     - Fibrotest ≥0.28
     - Fibrosure ≥0.27 (scores must be calculated where appropriate with supporting labs submitted)]; OR
   - Ultrasound evidence supporting a level of fibrosis of F1–F4
     - Shear Wave Velocity ≥ 1.28 meters/second

   OR

   Metavir score of F2–F4 as documented by one of the following:
   - A calculated predictive biomarker score supporting a level of fibrosis of F2–F4
     - APRI ≥ 0.5, OR
     - FIB-4 ≥1.45, OR
     - Fibrospect ≥ 42
   - Ultrasound evidence supporting a level of fibrosis of F2–F4 (Please note that these biomarkers do not discrimate below F2 and cannot determine differences between F0 and F1).
     - Fibroscan ≥7.0 kPA

   OR

   - Ultrasound/ MRI or CT of the abdomen which demonstrates one of the following documented in the radiology report: cirrhosis, esophageal varices, ascites, splenomegaly; **OR**
   - EGD demonstrating esophageal varices; **OR**

- Clinical signs and symptoms consistent with substantial or advanced fibrosis or cirrhosis
  - History of hepatic encephalopathy requiring treatment with medication or hospitalization within the past 12 months
  - History of portal hypertension as demonstrated by variceal bleeding or radiographic evidence of a transjugular intrahepatic portsystemic shunt (TIPS) procedure
  - Ascites

5. Lab testing **(copy of results must be submitted unless otherwise noted):**
   - Genotype
   - Detectable HCV RNA viral load (within the past year)
   - ALT/AST (within the past six months)
   - CBC (within the past six months)
   - GFR (within the past six months)
   - PT/INR (within the past six months) –required for metavir scores F3, F4 or biopsy-proven cirrhosis
   - Bilirubin (within the past six months) –required for metavir scores F3, F4 or biopsy-proven cirrhosis
   - Albumin (within the past six months) –required for metavir scores F3, F4 or biopsy-proven cirrhosis
6. The medication must be prescribed by a gastroenterologist, hepatologist, liver transplant or infectious disease physician. If the prescribing provider is not one of the identified specialists noted, the prescriber must submit documentation of consultation/collaboration of the specific case with one of the afore-mentioned specialists which reflects discussion of the history and agreement with the plan of care with the date noted in the progress note.
7. Documentation of the patient's use of illegal drugs or abuse of alcohol must be noted (i.e., current use of illegal drugs or abuse of alcohol within the past 6 months). The Department will consider this in terms of optimizing treatment.
8. Documentation of commitment to the planned course of treatment and monitoring (including SVR 12) as well as patient education addressing ways to reduce the risks for re-infection must be submitted.
9. Patients with a Metavir F4 score must have liver imaging (preferably an abdominal ultrasound or CT, but MRI accepted) with results for hepatocellular carcinoma (HCC) surveillance submitted. If positive for HCC, please indicate how this will be addressed in the plan of care.

For renewal requests:

The patient's most recent RNA viral load must be documented and must show a 2 log decrease or be undetectable by treatment week 12.

For retreatment requests:

Document post-treatment and current HCV RNA and reconfirm genotype.