Protocol for Direct Acting Antivirals for Hepatitis C
Updated April 2024

Approved June 2016
Updated and approved October 2017
Updated and approved July 2018
Updated and approved July 2021

This protocol covers (but is not limited to) the following medications:

Sovaldi (sofosbuvir)
Harvoni (sofosbuvir/ledipasvir)
Zepatier (elbasvir/grazoprevir)
Epclusa (sofosbuvir/velpatasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Mavyret (glecaprevir/pibrentasvir)

Please refer to individual drug package insert for specific genotypes and other guidelines

Preferred Agents:
Mavyret
sofosbuvir-velpatasvir

Request for non-preferred agent require that the patient is unable to take Mavyret and sofosbuvir-velpatasvir as indicated, for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval

Criteria for Approval

A) For Treatment Naïve Patients:
1. Patient is treatment naïve and has a confirmed diagnosis of hepatitis C **AND**

2. Medication is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

B) For Treatment Experienced Patients:
1. Medicaid is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**

2. Diagnosis of chronic hepatitis C, labs showing detectable HCV RNA levels from within the past 90 days and genotype must be received, **AND**

3. Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, reinfected, partial responder, or non-compliant.

4. Patient has been educated on the importance of compliance with their treatment regimen.

5. Patient must not have ANY of the following:
   a. Contraindications to requested Hepatitis C therapy (See package insert for complete list)
   b. Patient must not be on any therapies identified by the prescribing information or AASLD/IDSA guidelines as therapies not recommended for co-administration, (see package insert and guidelines for complete list)
   c. Limited life expectancy (<12 months due to non-liver related comorbidities). Per AASLD guidelines [2015], HCV therapy would not improve symptoms or prognosis in this patient population and do not require treatment.

6. If combined with ribavirin patient will meet ALL of the following:
   a. Patient has no contraindication (See package insert for complete list) to ribavirin
   b. Neither the patient nor the partner of the patient is pregnant
   c. If patient or their partner is of childbearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy.

7. For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

8. Prescriber attests that patient has been assessed for HBV infection

9. For regimens that depend on testing [e.g., baseline high fold-change NS5A RASs (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), Baseline Q80K polymorphism, Y93H], a copy of the lab work must be received.

Approval Duration:

- Epclusa: 12 or 24 weeks depending on genotype, comorbidities, drug regimen, and other considerations.
- Mavyret: 8, 12, 16, or 24 weeks depending on genotype, comorbidities, drug regimen, and other considerations.

Quantity Level Limit:

- Epclusa (sofosbuvir-velpatasvir) tablets 400-100 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) tablets 200-50 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) pellets 200-50 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) pellets 150-37.5 mg: 28 per 28 days

- Mavyret (glecaprevir-pibrentasvir) tablets 100-40 mg: 84 per 28 days
- Mavyret (glecaprevir-pibrentasvir) pellets 50-20 mg: 140 per 28 days

References:

1. American Association for the Study of Liver Diseases (AASLD)/Infectious Disease Society of America (IDSA). Recommendations for Testing, Managing, and Treating Hepatitis C. January 29, 2014. Updated on January 21, 2021. Accessed on: May 25, 2021.Available at https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_January_21_2021.pdf.
2. Harvoni® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; October 2014.
3. Sovaldi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; December 2013.
4. Zepatier® [Prescribing Information]. Merck & Co. Inc., Whitehouse Station, NJ; January 2016.
5. Epclusa® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; June 2016.
6. Vosevi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; July 2017.
7. Mavyret® [Prescribing Information]. AbbVie Inc., North Chicago, Il 60064: August 2017