Proposed Addendum to the 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

Addendum:

1. Remove previous criterion # 6 which read: Initial quantity dispensed will be limited to 14 days dosage units (14-14-28-28 format)
2. Delete Viekira Pak

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)

Preferred Agents:
Mavyret
sofosbuvir-velpatasvir

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

Criteria for Approval

A. For Treatment Naïve Patients:

1. Patient is treatment naïve and has a confirmed diagnosis of hepatitis C **AND**

2. Requests for non-preferred agents will require that patient is unable to take two formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval **AND**

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

B. For Treatment Experienced Patients:

1. Requests for non-preferred agents will require that patient is unable to take two formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval **AND**

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

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

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

~~5.~~ Patient has been educated on the importance of compliance with their treatment regimen.

6. Patient must not have any of the following:
   a. Contraindications to requested Hepatitis C therapy (See PI 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 PI 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.

7. If combined with ribavirin patient will meet ALL the following:
   7.1 Patient has no contraindication (See PI for complete list) to ribavirin
   7.2 Neither the patient nor the partner of the patient is pregnant
   7.3 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.

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

9. Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAg, anti-HBc). [AASLD/IDSA 2016]. Copy of lab work must be received.

10. 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

Please refer to tables for alternative scoring equivalents

Child-Turcotte-Pugh (CTP) Classification for Severity of Cirrhosis

Clinical and Lab Criteria	**Points***		
	1	**2**	**3**
Encephalopathy	None	Grade 1 or 2 (or precipitant-induced)	Grade 3 or 4 (or chronic)
Ascites	None	Mild/Moderate (diuretic-responsive)	Severe (diuretic-refractory)
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin time (PT) [sec prolonged] or INR	<4 <1.7	4-6 1.7-2.3	>6 >2.3
***CTP class is obtained by adding score for each parameter (total points)**			
Class A = 5 to 6 points (least severe liver disease)			
Class B = 7 to 9 points (moderately severe liver disease)			
Class C = 10 to 15 points (most severe liver disease)			

From: Core Concepts. Evaluation and Prognosis of Patients with Cirrhosis (Karla Thornton, MD, MPH)

Comparison of Scoring Systems for Histological Stage (Fibrosis)

METAVIR	Batts-Ludwig	Knodell	Ishak
0	0	0	0
1	1	1	1
1	1	1	2
2	2	--	3
3	3	3	4
4	4	4	5
4	4	4	6

Stage (F)	IASL*	Batts-Ludwig	Metavir	Ishak
0	No fibrosis	No fibrosis	No fibrosis	No fibrosis
1	Mild fibrosis	Fibrosis portal expansion	Periportal fibrotic expansion	Fibrosis expansion of some portal areas with or without short fibrous septa
2	Moderate fibrosis	Rare bridges or septae	Periportal septae 1 (septum)	Fibrous expansion of most portal areas with or· without short fibrous septa
3	Severe fibrosis	Numerous bridges or septae	Porto-central septae	Fibrous expansion of most portal areas with occasional portal to portal bridging
4	Cirrhosis	Cirrhosis	Cirrhosis	Fibrous expansion of most portal areas with marked bridging (portal to portal and portal to central)
5				Marked bridging (portal to portal and portal to central) with occasional nodules (incomplete cirrhosis)
6				Cirrhosis

*IASL = The International Assocratmn for the Study of Liver

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. Published Harvoni® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; October 2014.
2. Sovaldi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; December 2013.
3. Zepatier® [Prescribing Information]. Merck & Co. Inc., Whitehouse Station, NJ; January 2016.
4. Epclusa® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; June 2016.
5. Vosevi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; July 2017.
6. Mavyret® [Prescribing Information]. AbbVie Inc., North Chicago, Il 60064: August 2017.