Clinical Criteria for Hepatitis C (HCV) Therapy

Pre-Treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented*;
- Patients who have prior exposure to DAA therapy must have a pre-DAA genotype and post-DAA genotype documented (Appendix A);
- HCV RNA quantitative within 180 days of application for therapy, unless the patient is cirrhotic then the baseline lab values must be within 90 days of prior authorization request;
    - INR (cirrhotic patients only)
    - Albumin (cirrhotic patients only)
    - Total Bilirubin (cirrhotic patients only)
- Liver biopsy or other accepted fibrosis test (ex. fibrosure, hepascore/fibroscore, fibroscan, point shear wave elastography (PSWE) acoustic radiation force impulse imaging (AFRI)*;
- Previous HCV treatment history and outcome;
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- HBV status and, if active HBV disease, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy;
- Drug resistance testing as indicated; and

*Not required in the treatment of HCV-Uninfected Recipients of Non-liver Organs from HCV-Viremic Donors

Patient Treatment Plan

- It is recommended that the patient have a treatment plan developed by the treating clinician. Sample treatment plan documents are available for use. If the patient or their partner is of childbearing age, at least two (2) forms of contraception must be used (by the patient or their partner) if a RBV-containing regimen is prescribed throughout the duration of therapy and for six (6) months after the regimen is completed.

Drug Therapy

- Must be in accordance with FDA-approved indications.
- RBV= Ribavirin, IFN = Interferon, CTP = Child-Turcotte-Pugh

Treatment Naïve Patients			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
1a	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 8 wks* Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1a	***Alternative Regimens*** Zepatier + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Zepatier + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 8 wks* Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1b			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks (if no Y93 RAS) Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
3		***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks (if Y93 RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
4			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
5 or 6			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks

*if HCV RNA < 6 million

Treatment Experienced Patients arrange by treatment			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
IFN + RBV Experienced			
1a	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks
1a	***Alternative Regimens*** Zepatier (elbasvir/grazoprevir) + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks Zepatier (elbasvir/grazoprevir) + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1b		***Alternative Regimens*** Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks (if no Y93 RAS) Mavyret (glecaprevir/pibrentasvir) x 16 wks	Mavyret (glecaprevir/pibrentasvir) x 16 wks	*No currently FDA approved treatment regimens*
3	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks (if Y93 RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks	
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks Zepatier (elbasvir/grazoprevir) x 12 wks	*No currently FDA approved treatment regimens*
4		***Alternative Regimens*** Harvoni ledipasvir/sofosbuvir) + RBV x 12 wks	
5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	*No currently FDA approved treatment regimens*
NS3 PI Experienced			
1a or 1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks
1a or 1b			***Alternative Regimens***

			Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
SOF Experienced and NS5A Naïve			
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x12 wks	*No currently FDA approved treatment regimens*
NS5A Experienced			
1a or 1b	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
1a or 1b	***Alternative Regimens*** Mavyret (glecaprevir/pibrentasvir) x 16 wks	***Alternative Regimens*** Mavyret (glecaprevir/pibrentasvir) x 16 wks	
2	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
DAA Experienced			
3	Mavyret (glecaprevir/pibrentasvir) x 16 wks Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Mavyret (glecaprevir/pibrentasvir) x 16 wks Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
4,5 or 6	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*

Post Liver and Kidney Transplant Patients			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
1	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks*
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
3			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks*
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
4			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*
5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
5 or 6			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*

*24 week duration should be used in treatment experienced patients

Treatment of HCV-Uninfected Recipients of Non-liver Organs from HCV-Viremic Donors	
Genotype	**No need to evaluate for cirrhosis**
Genotype is not required for approval with pangenotypic regimens.	Epclusa (sofosbuvir/velpatasvir) x 12 weeks Mavyret (glecaprevir/pibrentasvir) x 8 weeks

Pediatric Patients Treatment Naïve or IFN Experienced	
Genotype	**No Cirrhosis or Compensated Cirrhosis**
1	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks
3	Mavyret (glecaprevir/pibrentasvir) x 8 wks
4,5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks

Pediatric Dosing					
Epclusa (sofosbuvir/velpatasir) For patients ≥ 3 years old		**Harvoni (ledipasavir/sofobuvir) For patients ≥ 3 years old**		**Mavyret (glecaprevir/pibrentasvir) For patients ≥ 3 years**	
Body Weight	Once Daily Dose	Body Weight	Once Daily Dose	Body Weight	Once Daily Dose
< 17 kg	150 mg/ 37.5 mg	< 17 kg	33.75 mg/ 150 mg	< 20 kg	150 mg/ 60 mg
17 kg to < 30 kg	200 mg/ 50 mg	17 kg to < 35 kg	45 mg/ 200 mg	20 kg to < 30 kg	200 mg/ 80 mg
≥ 30 kg	400 mg/ 100 mg	≥ 35 kg	90 mg/ 400 mg	30 kg to < 45 kg	250 mg/ 100 mg
				45 kg and ≥ 12 years of age	300 mg/ 120 mg

Genotype Determined or Multiple Genotypes	
No cirrhosis or Compensated Cirrhosis	**Decompensated Cirrhosis (CTP B or C)**
Epclusa (sofosbuvir/velpatasvir) x 12 weeks Mavyret (glecaprevir/pibrentasvir) x 8 weeks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
	Alternative Regimens Epclusa (sofosbuvir/velpatasvir) x 24 wks

Appendix A: HCV Treatment Definitions

Retreatment: Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR and current need for an additional course of therapy to treat chronic HCV infection.

Conditions required:

- Detectable HCV RNA at 12 weeks post treatment.
- HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection: Exposure to an HCV treatment regimen, which results in achievement of SVR.

Conditions required:

- Detectable HCV RNA > 12 weeks post treatment
- HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- Current infection has been present ≥ 6 months.