New Hampshire Medicaid Fee-for-Service Program

Hepatitis C Criteria

Approval Date: June 29, 2023

General Criteria for Approval

Treatment naïve patients (1-year lookback) are exempt from prior authorization when a preferred drug that is FDA (Food and Drug Administration)-approved for treatment naïve patients is prescribed.

1. Diagnosis of chronic hepatitis C virus (HCV)
    a. Document genotype for treatment-experienced patients
    b. Document if additional diagnosis of human immunodeficiency virus (HIV) and/or cirrhosis
2. Patient is ≥ 18 years of age or otherwise specified by package insert
3. Drug must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious disease physician, or the prescriber must have completed continuing medical education on the treatment of hepatitis C
4. Patient has been tested for hepatitis B infection by measuring HBsAg and anti-HBc

Criteria for Specific Hepatitis C Drug Classes

AASLD/IDSA HCV Guideline Recommendations

More information can be found at https://www.hcvguidelines.org/.

1. Treatment is strongly recommended for all persons with chronic HCV infection (except those with a short life expectancy who cannot be remediated).
2. Recommended regimens are considered equivalent.
3. Alternative regimens are effective but relative to recommended regimens, have potential disadvantages, limitations for use in certain patient populations, or less supporting data.

Recommended Treatments and Alternative Treatments by Genotype

Any Genotype – Simplified Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	N/A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	N/A
	with compensated cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	N/A
		sofosbuvir/velpatasvir (Epclusa®) (except genotype 3 with Y93H present)	12	P (generic)	N/A

Genotype 1a – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®) For patients who are HIV-uninfected and whose HCV RNA level is < 6 million IU/mL.	8	P (generic)	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A B
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A

Genotype 1a – Alternative Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A
	with compensated cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A

Genotype 1b – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®) For patients who are HIV-uninfected and whose HCV RNA level is < 6 million IU/mL.	8	P (generic)	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A

Genotype 2 – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B

Genotype 3 – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A

Genotype 3 – Alternative Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**with compensated** cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (for patients with baseline NS5A RAS Y93H))	12	NP	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) with weight-based ribavirin for patients with baseline NS5A RAS Y93H)	12	NP	Class IIa, Level A

Genotype 4 – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		elbasvir/grazoprevir (Zepatier®)	12	NP	Class IIa, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B

Genotype 5/6 – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B

Sofosbuvir-Based Treatment Failures – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Experienced	**with or without** cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	NP	Class I, Level A

Sofosbuvir-Based Treatment Failures – Alternative Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Experienced	**with or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®) (except for NS3/4 protease inhibitor inclusive combination DAA regimen failures) *Not for genotype 3 infection with sofosbuvir/NS5A inhibitor experience	16	P	Class I, Level A

Glecaprevir/Pibrentasvir-Based Treatment Failures – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Experienced	**with or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	16	P	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	NP	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (compensated cirrhosis, addition of weight-based ribavirin is recommended)	12	NP	Class IIa, Level C

Sofosbuvir/Velpatasvir/Voxilaprevir Treatment Failures – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Experienced	**with or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®) plus daily sofosbuvir and weight-based ribavirin	16	P/NP	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (plus weight-based ribavirin)	24	NP	Class IIa, Level B

Grading System Used to Rate the Level of the Evidence and Strength of the Recommendation for Each Recommendation Classification

- Class I — conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective
- Class II — conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment
- Class IIa — weight of evidence and/or opinion is in favor of usefulness and efficacy
- Class IIb — usefulness and efficacy are less well established by evidence and/or opinion
- Class III — conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful

Level of Evidence

- **Level A** — data derived from multiple randomized clinical trials, meta-analyses, or equivalent
- **Level B** — data derived from a single randomized trial, nonrandomized studies, or equivalent
- **Level C** — consensus opinion of experts, case studies, or standard of care

Criteria for Denial

DI = Drug Interaction

Do not approve if concomitant use with the following meds or conditions	Epclusa® (sofosbuvir/ velpatasvir)	Harvoni ® (ledipasvir/ sofosbuvir)	Mayyret® (glecaprevir/ pibrentasvir	Sovaldi® (sofosbuvir)	Vosevi® (sofosbuvir/ velpatasvir/ voxilaprevir)	Zepatier® (elbasvir/ grazoprevir)
Carbamazepine, phenytoin, phenobarbital, oxcarbazepine	X	X	X (carbamazepine, phenytoin only)	X	X	X
rifabutin, rifampin, rifapentine	X	X	X (rifampin only)	X	X	X (rifampin only)
tipranavir/ritonavir, cobicistat/elvitegravir/ emtricitabine/tenofovir	X	X		X (tipranavir/ ritonavir)	X (tipranavir/ ritonavir)	X
St John's wort		X	X	X	X	X
Rosuvastatin		X			X	
hepatitis C protease inhibitor (PI) or PI-containing combination product		X		X		X
Alfuzosin		X				
pimozide, efavirenz	X (efavirenz only)		X (efavirenz only)		X (efavirenz only)	X (efavirenz only)
darunavir/ritonavir, lopinavir/ritonavir, rilpivirine			X (darunavir, lopinavir, ritonavir only)		X (lopinavir)	X
amiodarone	X	X		X	X	
cyclosporine					X	X
Atazanavir, atazanavir/ritonavir, lopinavir/ritonavir, rilpivirine			X (atazanavir only)		X (no DI with rilpivirine)	X (no DI with rilpivirine)
Combination with ribavirin in women who are				X		

Do not approve if concomitant use with the following meds or conditions	Epclusa® (sofosbuvir/ velpatasvir)	Harvoni ® (ledipasvir/ sofosbuvir)	Mayyret® (glecaprevir/ pibrentasvir	Sovaldi® (sofosbuvir)	Vosevi® (sofosbuvir/ velpatasvir/ voxilaprevir)	Zepatier® (elbasvir/ grazoprevir)
pregnant or may become pregnant or men whose female partners are pregnant						
topotecan	X				X	
Patients with severe hepatic impairment (Child-Pugh C)			X			X
Decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C])				X	X	X
Severe renal impairment (eGFR < 30 mL/min/1.73 m^2) **OR** End-stage renal disease (ESRD) requiring hemodialysis		X	X	X		
Received liver transplant	X			X		

Additional Criteria for Consideration

1. Do not approve outside of FDA-indicated genotype.
2. Non-preferred drugs on the Preferred Drug List (PDL) require additional prior authorization (PA).
3. Confirmation if patient will be on concurrent proton pump inhibitor.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New criteria	05/12/2015
Commissioner	Approval	06/30/2015
DUR Board	Revision	05/31/2016
Commissioner	Approval	07/12/2016

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	10/11/2016
Commissioner	Approval	11/22/2016
DUR Board	Revision	03/20/2017
Commissioner	Approval	06/12/2017
DUR Board	Revision	10/24/2017
Commissioner	Approval	12/05/2017
DUR Board	Revision	09/27/2018
Commissioner Designee	Approval	11/27/2018
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019
DUR Board	Revision	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	12/02/2021
Commissioner Designee	Approval	01/14/2022
DUR Board	Revision	06/19/2023
Commissioner Designee	Approval	06/29/2023