

New Hampshire Medicaid Fee-for-Service Program Hepatitis C Criteria

Approval Date: January 14, 2022

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 old 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

Genotype 1a – Recommended 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	
		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	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A B	
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A	
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A	
		elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A	
Treatment-Experienced (previous failure of PEG-IFN /RBV)	without cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (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	
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A	
	with compensated cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A	
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A	
		glecaprevir/pibrentasvir (Mavyret®)	12	P	Class I, Level B	

Genotype 1a – Alternative Treatments					
Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Experienced (previous failure of PEG-IFN /RBV)	with compensated cirrhosis	ledipasvir/sofosbuvir (Harvoni®) and weight-based RBV	12	P (generic)	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	
Treatment-Experienced (previous failure of PEG-IFN /RBV)	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
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	12	P	Class I, Level B

Genotype 1b – Alternative Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Experienced (previous failure of PEG-IFN /RBV)	with compensated cirrhosis	ledipasvir/sofosbuvir (Harvoni®) and weight-based RBV	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
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	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®)	12	P	Class I, Level B
Treatment-Experienced (previous failure of sofosbuvir and RBV)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level B
		glecaprevir/pibrentasvir (Mavyret®)	12	P	Class IIb, Level B
Treatment-Experienced (previous failure of sofosbuvir and NSSA inhibitor – excluding glecaprevir/pibrentasvir failures)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	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
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	without cirrhosis	sofosbuvir/velpatasvir (Epclusa®) (for patients without baseline Y93H RAS to velpatasvir)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	P	Class IIb, Level B
		glecaprevir/pibrentasvir (Mavyret®)	16	P	Class IIa, Level B
Treatment-Experienced (previous failure of sofosbuvir and RBV)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	P	Class I, Level B
		glecaprevir/pibrentasvir (Mavyret®)	16	P	Class IIb, Level B
Treatment-Experienced (previous failure of DAAs, including NS5A inhibitors – excluding glecaprevir/pibrentasvir failures)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	P	Class I, Level A
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) and weight-based RBV (those with NS5A inhibitor failure and compensated cirrhosis)	12	P	Class IIa, Level C

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 for velpatasvir)	12	P	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) with weight-based ribavirin for patients with baseline NS5A RAS Y93H for velpatasvir	12	P	Class IIa, Level A
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	without cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	16	P	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (when Y93H present)	12	P	Class IIb, Level B
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®) and weight-based RBV	12	P (generic)	Class II, Level B
		elbasvir /grazoprevir (Zepatier®) and sofosbuvir (Sovaldi®)	12	NP	Class I, Level B

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
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	without cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		elbasvir/grazoprevir (Zepatier®) (for patients who experienced virologic relapse after prior peginterferon/ribavirin therapy)	12	NP	Class IIa, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		elbasvir/grazoprevir (Zepatier®) (for patients who experienced virologic relapse after prior peginterferon/ribavirin therapy)	12	NP	Class IIa, Level B
		glecaprevir/pibrentasvir (Mavyret®)	12	P	Class IIa, Level B
Treatment-Experienced (previous failure of DAAs, including NS5A inhibitors – excluding glecaprevir/pibrentasvir failures)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	P	Class I, Level A

Genotype 4 – Alternative Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	with compensated cirrhosis	ledipasvir/sofosbuvir(Harvoni®) and weight-based RBV	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 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
	with compensated 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
Treatment-Experienced (previous failure of PEG-IFN/ RBV)	without cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class IIa, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class IIa, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B
	with compensated cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	12	P	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class IIa, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B
Treatment-Experienced (previous failure of DAAs, including NS5A inhibitors – excluding glecaprevir/pibrentasvir failures)	without cirrhosis or with compensated cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	P	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

Patients with hepatocellular carcinoma awaiting liver transplant, administer Sovaldi® in combination with ribavirin for up to 48 weeks or until the time of liver transplantation, whichever occurs first, to prevent post-transplant HCV re-infection.

Criteria for Denial

DI = Drug Interaction

Do not approve if concomitant use with the following meds or conditions	Epclusa® (sofosbuvir/ velpatasvir)	Harvoni® (ledipasvir/ sofosbuvir)	Mayvret® (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

Do not approve if concomitant use with the following meds or conditions	Epclusa® (sofosbuvir/ velpatasvir)	Harvoni® (ledipasvir/ sofosbuvir)	Mayvret® (glecaprevir/ pibrentasvir)	Sovaldi® (sofosbuvir)	Vosevi® (sofosbuvir/ velpatasvir/ voxilaprevir)	Zepatier® (elbasvir/ grazoprevir)
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 pregnant or may become pregnant or men whose female partners are pregnant				X		
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.
4. Confirmation if patient will be screened for substance use or alcohol use during therapy.

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
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