Hepatitis C Antivirals

Included Products: Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir), ribavirin

Criteria apply for: Mavyret with history of treatment, sofosbuvir/velpatasvir with history of treatment, Vosevi (all requests), and all non-preferred (non-formulary HepC agents).

Criteria do NOT apply for: Mavyret and sofosbuvir/velpatasvir without treatment history ("treatment naïve").

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Hepatitis C			
Initial Criteria		**If yes**	**If no**
1.	What is the diagnosis being treated?	Record ICD10 and continue to #2.	
2.	Is the request for treatment of Hepatitis C Infection?	Continue to #3.	Do not approve.
3.	Has ALL of the following pre-treatment testing been documented? a. Genotype testing in past 3 years is required if the patient has decompensated cirrhosis, any prior treatment experience with a DAA regimen, and if prescribed a regimen which is not pan-genotypic. b. History of previous HCV treatment and outcome	Continue to #4.	Do not approve.
4.	Which regimen is requested?	Document and continue to #5.	
5.	Has the patient been treated with a direct acting antiviral regimen previously?	Continue to #6.	Continue to #8.
6.	Did the patient achieve a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen?	Continue to #7.	Continue to #8. (Document as treatment failure. Use regimens as indicated for treatment experienced.)

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7.	Is this likely a reinfection, indicated by at least one of the following: a. Does the patient have ongoing risk factors for hepatitis C reinfection (e.g. sexually active men who have sex with men, persons who inject drugs), OR b. Is the hepatitis C infection a different genotype than previous?	Continue to #8. (Document as reinfection. Use regimens recommended for treatment naïve.)	Continue to #8. (Document as treatment failure. Use regimens indicated for treatment experienced.)
8.	Is the prescribed drug a. Zepatier for genotype 1a OR b. Harvoni for GT 1a treatment-experienced infection; OR c. Sofosbuvir/velpatasvir for GT3 in cirrhosis or treatment experienced infection for genotype 3 infection?	Continue to #9.	Continue to #10.
9.	Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #10? Note: Baseline NS5A resistance testing is required.	Do not approve.	Document test result and continue to #10.
10.	Is the prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see Table below)?	Continue to #15.	Do not approve.
11.	Approve for appropriate duration from table below.		

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Approved Regimens

Age 12+

Treatment Naïve (Genotypes 1-6)		
DAA-Treatment naïve, confirmed reinfection or prior treatment with PEG/RBV	Non-cirrhotic	Mavyret for 8 weeks Sof/Vel for 12 weeks
	Compensated cirrhosis	Mavyret for 8 weeks Sof/Vel for 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated Cirrhosis	Sof/Vel with RBV for 12 weeks Sof/Vel for 24 weeks (if ribavirin ineligible)
Treatment Experienced (Genotypes 1-6)		
Sofosbuvir based regimen treatment failures including: Sofosbuvir + RBV LED/SOF Vel/SOF	Non-cirrhotic or compensated cirrhosis	Vosevi for 12 weeks Mavyret for 16 weeks (except GT3)
Elbasvir/grazoprevir treatment failure	Non-cirrhotic or compensated cirrhosis	Vosevi for 12 weeks
Mavyret treatment failure	Non-cirrhotic or compensated cirrhosis	Vosevi x 12 weeks (+ RBV if cirrhosis) Mavyret + Sovaldi + RBV for 16 weeks
Multiple DAA Treatment Failures Vosevi Mavyret + Sovaldi	Non-cirrhotic or compensated cirrhosis	Mavyret + Sovaldi + RBV for 16-24 weeks Vosevi for 24 weeks
Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin		
Treatment-Naïve Definition: No previous treatment OR those that discontinued within 4 weeks of initiation OR confirmed reinfection after achieving SVR following HCV.		
Treatment-Experience Definition: Patients who received more than 4 weeks of HCV DAA Therapy		

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Approved Regimens

3-12 years of age

Treatment Naïve (Genotypes 1-6)		
DAA-Treatment naïve, confirmed reinfection or prior treatment with PEG/RBV	Non-cirrhotic or compensated cirrhosis	Mavyret for 8 weeks Sof/Vel for 12 weeks
	Decompensated Cirrhosis	Sof/Vel with RBV for 12 weeks

Treatment Experienced (Genotypes 1-6)
Note: Efficacy and safety extremely limited in treatment experienced to other DAAs in this population. Can consider recommended treatment regimens in adults if FDA approved for pediatric use. Recommend consulting with hepatologist.
Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin
Treatment-Naïve Definition: No previous treatment OR those that discontinued within 4 weeks of initiation OR confirmed reinfection after achieving SVR following HCV.
Treatment-Experience Definition: Patients who received more than 4 weeks of HCV DAA Therapy

REFERENCES

- HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C