Hepatitis C Direct-Acting Antivirals

Goals:

- Approve use of cost-effective treatments supported by the medical evidence.
- Provide consistent patient evaluations across hepatitis C treatments.
- Ensure appropriate patient regimen based on prior treatment experience and genotype.

Length of Authorization:

• 8-24 weeks

Requires PA:

- Non-preferred direct acting antivirals (DAAs)
- Preferred regimens for patients with treatment experience with a DAA

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Ap	Approval Criteria			
1.	What diagnosis is being treated?	Record ICD10 code.		
2.	Is the request for treatment of Hepatitis C infection?	Yes: Go to #3 Document baseline quantitative HCV RNA level	No: Pass to RPh. Deny; medical appropriateness.	
3.	 Has <u>all</u> the following pre-treatment testing been documented: a. Genotype testing in past 3 years is required if the patient has decompensated cirrhosis, <u>prior</u> <u>treatment experience</u> with a DAA regimen, and if prescribed a regimen which is not pan-genotypic b. History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience 	Yes: Record results of each test and go to #4	No : Pass to RPh. Request updated testing.	
4.	Which regimen is requested?	Document and go to #5		
5.	Has the patient been treated with a direct acting antiviral regimen previously?	Yes: Go to #6	No: Go to #8	

Approval Criteria		
6. Did the patient achieve a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen?	Yes: Go to #7	No: Document as treatment failure and treat as indicated for treatment experienced. Go to #8
 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 	Yes: Document as reinfection. Use regimens recommended for treatment naïve patients. Go to #8	No: Document as treatment failure and treat as indicated for treatment experienced. Go to #8
 8. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; <u>or</u> b) Ledipasvir/sofosbuvir for GT 1a <u>treatment-experienced</u> infection; <u>or</u> c) Sofosbuvir/velpatasvir for GT 3 in <u>cirrhosis</u> or <u>treatment-experienced</u> infection 	Yes: Go to #9	No: Go 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. 	Yes: Pass to RPh; deny for appropriateness	No: Go to #10 Document test and result.
 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 1 and Table 2)? Note: Safety and efficacy of DAAs for children < 3 years of age have not been established Pediatric dosing available in Table 3 and Table 4 	Yes: Approve for 8-24 weeks based on duration of treatment indicated for approved regimen Referral will be made for optional case management (patient may choose to opt-in).	No: Pass to RPh. Deny; medical appropriateness.

Table 1: Recommended Treatment Regimens for Adults, and Adolescents 12 years of age and older with Hepatitis C virus.

Treatment naïve, confirmed Non-cirrhotic or compensated SOF/VEL x 12 weeks PEGylated interferon/ribavirin Compensated cirrhosis G/P x 8 weeks Compensated cirrhosis G/P X 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3) Decompensated Cirrhosis SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3) Treatment Experienced (Genotype 1-6) SOF/VEL x 24 weeks (if ribavirin ineligible*) SOF/VEL x 24 weeks (if ribavirin lineligible*) Sofosbuvir based regimen treatment failures, including; Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x12 weeks Sofosbuvir + ribavirin Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x12 weeks (except GT3) Sofosbuvir + ribavirin Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) Glecaprevir/pibrentasvir treatment failures Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) Multiple DAA Treatment Failures, including; Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) Multiple DAA Treatment Failures, including; Non-cirrhotic or compensated cirrhosis SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) Multiple DAA Treatment Failures, including; Non-cirrhotic or compensated cirrhos	Treatment History	Cirrhosis Status	Recommended Regimen	
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Table 2: Recommended Treatment Regimens for children ages 3 - 12 years of age with Hepatitis C virus.

Treatment History	Cirrhosis Status	Recommended Regimen		
Treatment Naïve Genotype 1-6				
Treatment naïve, confirmed	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks		
reinfection or prior treatment with		G/P x 8 weeks		
pegylated interferon/ribavirin	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks		
Treatment Experienced with DA	A regimen			
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.				
Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; RBV = ribavirin; SOF = sofosbuvir;				
SOF/VEL = sofosbuvir/velpatasvir				
 All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C). There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director. 				

Table 3: Recommended dosage of sofosbuvir/velpatasvir in pediatric patients 3 years of age and older: Body weight

Body weight	Dosing of solospuvii/velpatasvii
Less than 17 kg	One 150 mg/37.5 mg pellet packet once daily
17 kg to less than 30 kg	One 200 mg50 mg pellet packet OR tablet once daily
At least 30 kg	Two 200 mg/50 mg pellet packets once daily OR one 400
	mg/100 mg tablet once daily

Table 4: Recommended dosage of glecaprevir/pibrentasvir in pediatric patients 3 years of age and older:

Body weight	Dosing of glecaprevir/pibrentasvir
Less than 20 kg	Three 50mg/20 mg pellet packets once daily
20 kg to less than 30 kg	Four 50 mg/20 mg pellet packets once daily
30 kg to less than 45 kg	Five 50 mg/20 mg pellet packets once daily
45 kg and greater	Three 100mg/40 mg tablets once daily
OR	
12 years of age and older	

P&T Review: Implementation: 4/22 (MH); 10/21; 6/20; 9/19; 1/19; 11/18; 9/18; 1/18; 9/17; 9/16; 1/16; 5/15; 3/15; 1/15; 9/14; 1/14 1/1/23; 7/1/20; 1/1/20; 3/1/2019; 1/1/2019; 3/1/2018; 1/1/2018; 2/12/16; 4/15; 1/15