

ALASKA MEDICAID  
Prior Authorization Criteria

**Direct Acting Antivirals for Hepatitis C (HCV) Genotype 1**  
**VieKira Pak™ (Ombitasvir + Paritaprevir + Ritonavir plus Dasabuvir)**  
**Sovaldi® (Sofosbuvir), Olysio® (Simeprevir),**  
**Harvoni® (Sofosbuvir + Ledipasvir)**

**Criteria for Approval**

1. Adult patient age  $\geq$  18 years old; **AND**
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype 1 (GT 1), and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. Documentation of previously trialed HCV therapies, dates of therapy, whether full therapy was completed or discontinued early, and, if discontinued early, the reason for the discontinuation is included in the authorization request; **AND**
5. Agrees to complete regimen; **AND**
6. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); any positive results are to be explained by prescriber.
7. If HCV/HIV co-infected
  - Must provide documentation of CD4 count, HIV viral load, regimen.
8. If requesting a simeprevir containing regimen
  - Must report status of the NS3 Q80K polymorphism if genotype 1a;
  - Must be simeprevir naïve.
9. For renewal authorizations
  - For regimens with durations longer than 8 weeks, HCV RNA must be submitted for treatment weeks 4 and 8; **AND**
  - HCV RNA  $<$  25 IU/mL at treatment week 4; **OR**
  - If HCV RNA detectable at treatment week 4, HCV RNA at week 6 is lower than week 4 or undetectable.

**Quantity Limit**

Harvoni – One 400 mg/90 mg tablet per day (28 tablets/28 days)  
Olysio – One 150 mg tablet per day (28 tablets/28 days)  
Sovaldi – One 400 mg tablet per day (28 tablets/28 days)  
VieKira Dose Pak – Four tablets per day (112 tablets/28 days)

ALASKA MEDICAID  
Prior Authorization Criteria

**Duration of Approval**

1. Based on HCV genotype and prior treatment experience
  - Refer to Table 1 for regimen durations; authorization duration will be approved as follows:

<b>Regimen Duration</b>	<b>Authorization Duration</b>
8 weeks	8 weeks
12 weeks	8 weeks + 4 weeks
24 weeks	8 weeks + 8 weeks + 8 weeks

2. Limits
  - Retreatment not authorized within two (2) years
3. Lost or stolen medication
  - Lost or stolen medication replacement requests will not be authorized.

**Criteria for Denial**

1. Patient is not abstaining from the use of illicit drugs and alcohol as evidenced by submitted urine confirmation test results.
  2. Diagnostic/disease severity evidence is not submitted with the request.
  3. HCV RNA results not submitted with the request.
  4. For regimens containing ribavirin, patient is pregnant or lactating.
  5. For regimens containing simeprevir, patient is not simeprevir naïve.
  6. For regimens containing sofosbuvir, patient has severe renal impairment (eGFR < 30 mL/min/1.73m<sup>2</sup>) or end stage renal disease (ESRD) requiring hemodialysis.
  7. Patient has a Child-Pugh score greater than 6 [class B or C] and treatment is not being managed by a liver disease specialist.
  8. Patient is taking a concomitant medication that has a significant clinical interaction or is contraindicated with any of the agents.
  9. HCV genotype is 2, 3, 4, 5, 6 or mixed (refer to respective criteria).
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ALASKA MEDICAID  
Prior Authorization Criteria

**Regimen**

<b>Table 1<sup>†</sup></b>			
<b>Genotype</b>	<b>Regimen</b>	<b>Duration</b>	
<b>First Line Preferred – Treatment naïve or Treatment experienced</b>			<b>Exclusions</b>
GT 1a, without cirrhosis Metavir F2-3	VieKira Pak + ribavirin <sup>‡,§</sup>	12 weeks	<i>Child-Pugh B or greater; ESRD; pregnancy</i>
GT 1a, with cirrhosis Metavir F4	VieKira Pak + ribavirin <sup>‡,§</sup>	24 weeks	<i>Child-Pugh B or greater; ESRD; pregnancy</i>
GT 1b, without cirrhosis Metavir F2-3	VieKira Pak	12 weeks	<i>Child-Pugh B or greater; ESRD</i>
GT 1b, with cirrhosis Metavir F4	VieKira Pak + ribavirin <sup>‡,§</sup>	12 weeks	<i>Child-Pugh B or greater; ESRD; pregnancy</i>
GT 1, s/p liver transplant	VieKira Pak + ribavirin <sup>‡,§</sup>	24 weeks	<i>Abnml liver function, Fibrosis &gt;F2; pregnancy</i>
<i>If patient has documented exclusions to first line therapy, approval may be considered for second line therapy.</i>			
<b>Second Line – Treatment naïve</b>			<b>Exclusions</b>
GT 1, without cirrhosis, HCV RNA ≤ 6 million IU/mL Metavir F2-3, treatment naïve	Harvoni	8 weeks	<i>Treatment experienced; severe renal impairment, ESRD; HIV</i>
GT 1, without cirrhosis, HCV RNA > 6 million IU/mL Metavir F2-3, treatment naïve	Harvoni	12 weeks	<i>Treatment experienced; severe renal impairment, ESRD</i>
GT 1, with cirrhosis, Metavir F4, treatment naïve	Harvoni	12 weeks	<i>Treatment experienced; severe renal impairment, ESRD; decompensation</i>
<b>Second Line – Treatment experienced</b>			
GT 1ab, without cirrhosis, Metavir F2-3 treatment experienced	Harvoni	12 weeks	<i>Severe renal impairment, ESRD</i>
GT 1, with cirrhosis, Metavir F4 treatment experienced	Harvoni + ribavirin <sup>‡,§</sup> Harvoni	12 weeks 24 weeks	<i>Severe renal impairment, ESRD; decompensation</i>

ALASKA MEDICAID  
Prior Authorization Criteria

**Table 1<sup>†</sup>**

Genotype	Regimen	Duration	
<i>If patient has documented exclusions to second line therapy, approval may be considered for third line therapy.</i>			
<b>Third Line</b>			<b>Exclusions</b>
GT 1 Metavir F2-4	Interferon-based regimens with HCV direct acting antiviral + ribavirin <sup>‡,§</sup>		<i>Severe renal impairment, ESRD; decompensation; contraindication/intolerance to interferon</i>
<i>If patient has documented exclusions to third line therapy, approval may be considered for fourth line therapy.</i>			
<b>Fourth Line</b>			<b>Exclusions</b>
GT 1 Metavir F2-3	Sovaldi + Olysio ± ribavirin <sup>‡,§</sup>	12 weeks	<i>Severe renal impairment, ESRD; decompensation; pregnancy</i>
GT 1 Metavir F4	Sovaldi + Olysio ± ribavirin <sup>‡,§</sup>	24 weeks	<i>Severe renal impairment, ESRD; decompensation; pregnancy</i>
<i>If patient has documented exclusions to first line therapy, the following regimens may be considered but shall be restricted to liver disease specialists.</i>			
<b>Restricted to Specialist</b>			
GT 1, decompensated cirrhosis; treatment naïve or prior sofosbuvir-based failure	Harvoni + ribavirin <sup>‡,§</sup>		<i>Restricted to Specialist</i>
GT 1, decompensated cirrhosis with anemia or ribavirin intolerance	Harvoni		<i>Restricted to Specialist</i>
GT 1, Hepatocellular Carcinoma (HCC)	Sovaldi		<i>Restricted to Specialist</i>

<sup>†</sup>Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration; <sup>‡</sup>Weight based ribavirin; <sup>§</sup>Refer to FDA approved labeling for use in individuals with impaired renal function

**Additional Considerations**

- Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes.
- Therapy with regimens containing ritonavir requires the co-infected patient to be on a suppressive antiretroviral drug regimen to decrease the risk of selection of HIV-1 protease inhibitor resistant strains.
- Combination treatment with ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

ALASKA MEDICAID  
Prior Authorization Criteria

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**References**

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