

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)
EFFECTIVE 7/1/2015

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 (includes extrahepatic manifestations of advancing disease); **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:

Regimen Duration	Authorization Duration
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/1.73m²) 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).

ALASKA MEDICAID
Prior Authorization Criteria

Regimens

Table 1[†]			
Genotype	Regimen	Duration	
Preferred agent – Treatment naïve or Treatment experienced			Exclusions
GT 1a, without cirrhosis Metavir F2-3	VieKira Pak + ribavirin ^{‡,§}	12 weeks	<i>Child-Pugh B or greater; ESRD; pregnancy</i>
GT 1a, with cirrhosis Metavir F4	VieKira Pak + ribavirin ^{‡,§}	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 ^{‡,§}	12 weeks	<i>Child-Pugh B or greater; ESRD; pregnancy</i>
GT 1, s/p liver transplant	VieKira Pak + ribavirin ^{‡,§}	24 weeks	<i>Abnml liver function, Fibrosis >F2; pregnancy</i>
Preferred agent – Treatment naïve			Exclusions
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>
Preferred agent – Treatment experienced			
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 ^{‡,§} Harvoni	12 weeks 24 weeks	<i>Severe renal impairment, ESRD; decompensation</i>

ALASKA MEDICAID
Prior Authorization Criteria

Table 1[†]

Genotype	Regimen	Duration
Restricted to Specialist		
GT 1, decompensated cirrhosis; treatment naïve or prior sofosbuvir-based failure	Harvoni + ribavirin ^{‡,§}	<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>

[†]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; [‡]Weight based ribavirin; [§]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.

References

1. Harvoni [package insert]. Foster City, CA; Gilead, October 2014.
2. Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. November 2014.
3. Sovaldi [package insert]. Foster City, CA; Gilead, November 2014.
4. Viekira Pak [package insert]. North Chicago, IL; Abb Vie Inc., December 2014.
5. FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
6. American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C; revision date 12/29/2014. Available at: <http://www.hcvguidelines.org/>. Accessed January 9, 2015.
7. Poynard T, Ratzu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis C: detection and significance. *Semin Liver Dis.* 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.

ALASKA MEDICAID
Prior Authorization Criteria

8. McEvoy GK, ed. in chief, Snow ED, ed. *AHFS: Drug Information*. Bethesda, MD: American Society of Health-System Pharmacists; 2014:756-764,811-826.
9. Tice JA, Ollendorf DA, Chahal HS, *et al.* California Technology Assessment Forum: the comparative clinical effectiveness and value of novel combination therapies for the treatment of patients with genotype 1 chronic hepatitis C infection. Institute for Clinical and Economic Review; Boston, MA. November 17, 2014. Available at: <http://www.ctaf.org/reports/newest-treatments-hepatitis-c-genotype-1>. Accessed January 15, 2015.
10. California Technology Assessment Forum. Newest treatments for hepatitis C, genotype 1: whom to treat, how to pay; voting questions and results: December 18, 2014 public meeting. Available at: <http://www.ctaf.org/reports/newest-treatments-hepatitis-c-genotype-1>. Accessed January 15, 2015.
11. Hézode C, Roudot-Thoraval F, Nguyen S. *et al.* Daily cannabis smoking as a risk factor for progression of fibrosis in chronic hepatitis C. *Hepatology*. 2005;42:63-71.
12. Wiley TE, McCarthy M, Breidi L, *et al.* Impact of alcohol on the histological and clinical progression of hepatitis C infection. *Hepatology*. 1998;28:805-809.
13. Payancé A, Scotto B, Perarnau JM, *et al.* Severe chronic hepatitis secondary to prolonged use of ecstasy and cocaine. *Clin Res Hepatology Gastroenterol*. 2013;37(5):e109-113.
14. Lieber CS. Alcohol and hepatitis C. Retrieved from <http://pubs.niaaa.nih.gov/publications/arh25-4/245-254.htm>. Accessed September 29, 2014.
15. Pateria P, deBoer B, MacQuillan G. Liver abnormalities in drug and substance abusers. *Best Practice & Research Clinical Gastroenterology*. 2013;27:577-596.
16. McMahon BJ, Hennessy TW, Christensen C, *et al.* Epidemiology and risk factors for hepatitis C in Alaska Natives. *Hepatology*. 2004;39:325-332.