ALASKA MEDICAID
Prior Authorization Criteria

Direct Acting Antivirals for Hepatitis C (HCV)
Genotypes 2, 3, 4
Sovaldi® (sofosbuvir)

Criteria for Approval

1. Adult patient age ≥ 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 2, 3, or 4 (GT 2, 3, or 4), 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. 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.

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
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.

Regimen

Table 1[†]			
Genotype	**Regimen**	**Duration**	
			Exclusions
GT 2 *Metavir F2-4*	sofosbuvir + ribavirin[‡,§]	12 weeks	*Severe renal impairment, ESRD; pregnancy*
			Exclusions
GT 3 *Metavir F2-4*	sofosbuvir + ribavirin[‡,§]	24 weeks	*Severe renal impairment, ESRD; pregnancy*
GT 4 *Metavir F2-4*	sofosbuvir + peginterferon alfa + ribavirin[‡,§]	12 weeks	*Severe renal impairment, ESRD; pregnancy; interferon-ineligible*
GT 2,3,4 *Hepatocellular carcinoma awaiting liver transplantation* *AND* *Meets Milan criteria:* *In single hepatocellular (HC) carcinomas, tumor ≤ 5 cm in diameter, OR* *In multiple HC carcinomas, no more than 3 tumor nodules, each ≤ 3 cm in diameter, AND* *No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.*	sofosbuvir + ribavirin[‡,§]	48 weeks *or until liver transplant*	*Severe renal impairment, ESRD; pregnancy*
Restricted to Specialist			
GT 2, 3, 4 *decompensated cirrhosis*			*Restricted to Specialist*
Mixed genotype			*Restricted to Specialist*

[†]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

Quantity Limit

Sovaldi – One 400 mg tablet per day (28 tablets/28 days)

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 sofosbuvir, patient has severe renal impairment (eGFR < 30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis.
6. Patient has a Child-Pugh score greater than 6 [class B or C] and treatment is not being managed by a liver disease specialist.
7. Patient is taking a concomitant medication that has a significant clinical interaction or is contraindicated with any of the agents.
8. HCV genotype is 1a or 1b (refer to respective criteria).

Additional Considerations

- Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes.
- 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

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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.
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