

ALASKA MEDICAID  
Prior Authorization Criteria

**Direct Acting Antivirals for Hepatitis C (HCV)**

**Genotypes 2, 3, 5, 6**

**Daklinza® (daclatasvir 30mg or 60mg)**

**Harvoni® (ledipasvir 90mg & sofosbuvir 400mg)**

**Sovaldi® (sofosbuvir 400mg)**

**Indications:**

“Daklinza is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.”<sup>1</sup>

“Harvoni is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6 infection.”<sup>2</sup>

“Sovaldi is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen.”<sup>3</sup>

Table 1: FDA Labeled Indications							
	Daklinza + Sovaldi	Harvoni	Olysio + Sovaldi	Sovaldi	Technivie	VieKira	Zepatier
Genotype 1a	Yes	Yes	Yes	Yes	X	Yes	Yes
Genotype 1b	Yes	Yes	Yes	Yes	X	Yes	Yes
Genotype 2	X	X	X	Yes	X	X	X
Genotype 3	Yes	X	X	Yes	X	X	X
Genotype 4	X	Yes	Yes	Yes	Yes	X	Yes
Genotype 5	X	Yes	X	X	X	X	X
Genotype 6	X	Yes	X	X	X	X	X

**Quantity Limit**

Daklinza – One tablet once per day in combination with sofosbuvir (28 tablets /28 days)

Harvoni – One tablet once per day (28 tablets /28 days)

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

**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.

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**Criteria for Approval: Treatment Naïve**

1. Adult patient age  $\geq$  18 years old; **AND**
2. Documentation of HCV genotype, subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype (GT) 2, 3, 5, 6 and Metavir Fibrosis score F2-F4 or equivalent (includes extrahepatic manifestations of advancing disease); **AND**
4. To confirm the Metavir fibrosis stage, at least one of the following tests or procedures must be submitted: biopsy, elastography, FibroSure, FibroTest, HepaScore, or FibroScan (*Note: APRI and FIB-4 will not be accepted as confirmation of the Metavir fibrosis stage*); **AND**
5. The Hepatitis C disease activity score must be submitted with the authorization request; **AND**
6. 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**
7. The patient agrees to complete regimen; **AND**
8. The prescriber agrees to maintain HCV RNA levels obtained at 12-weeks and 24-weeks post-therapy completion to demonstrate Sustained Virologic Response (SVR); **AND**
9. If the patient’s HCV genotype and medication regimen are listed in Table 2 as requiring resistance-associated polymorphism testing, the required testing must be completed and the results submitted with the request; **AND**
10. Patient has been tested for the use of illicit drugs, controlled substances, and alcohol within the previous 90 days (results submitted with request); **AND**
  - If the test is positive for alcohol or illicit substances, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.
  - If the test is positive for a prescription controlled substance or a metabolite, the prescriber must document whether the patient has an active prescription for the attributable controlled substance (prescribers may consider using the Alaska PDMP, available at <http://alaskapdmp.com> as a tool to aid in the review).
  - If the test is positive for an unprescribed controlled substance or metabolite, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.
  - If the prescriber believes that the test documents an inaccurate or false positive result, an explanation must be submitted, and will be considered on a case-by-case basis.
11. If HCV/HIV co-infected, prescriber must provide documentation of CD4 count, HIV viral load, and treatment regimen.

Table 2: Required Resistance-Associated Polymorphism Testing			
Patient Treatment History	Requested Medication	Genotype	Required polymorphism testing
Treatment Naïve or Prior Peg-IFN Treatment	Daklinza	3	NS5A
DAA Treatment Experienced*	All Medications	All Genotypes	NS5A NS3

\* Previous treatment with Daklinza, Harvoni, Incivek, Sovaldi, Technivie, Viekira, Victrelis, or Zepatier, for example.

HCV GT 2, 3, 5, 6 DAA PA Criteria

Version: 4

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Effective for Dates of Service: 7/1/2016 and thereafter

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**Criteria for Renewal Authorization Approval, with Approval Duration:**

1. For regimens with durations longer than 12 weeks, HCV RNA must be submitted for treatment weeks 4 and 8; **AND**
2. HCV RNA < 25 IU/mL at treatment week 4; **AND,**
3. The prescriber must maintain documentation in the patient’s medical chart of the following information: HCV RNA level at treatment weeks 4 and 8, as well as HCV RNA levels after completion of therapy at week 12 post therapy (SVR12), and week 24 post therapy (SVR24).
  - This information shall be made available upon request.
4. Based on HCV genotype and prior treatment experience
  - Refer to Table 3 for regimen durations; authorization duration will be approved as follows:

Regimen Duration	Authorization Duration
12 weeks	12 weeks
24 weeks	12 weeks + 12 weeks*

\*or under the discretion of Alaska Medicaid

5. Lost or stolen medication replacement requests will not be authorized.

**Authorized Regimens: Treatment Naïve**

<b>Table 3<sup>†</sup> :</b>		
<b>Alaska Medicaid Preferred regimens for treatment naïve, or prior treatment with PegIFN + ribavirin</b>		
Genotype	Regimen	Duration
GT 2 <i>Metavir F2-4</i>	Sovaldi + ribavirin <sup>‡,§*</sup>	12 weeks
GT 3 <i>Metavir F2-4</i>	Sovaldi + ribavirin <sup>‡,§*</sup>	24 weeks
GT 3 <i>Metavir F2-3</i>	Sovaldi + Daklinza	12 weeks
GT 5 <i>Metavir F2-4</i>	Harvoni	12 weeks
GT 6 <i>Metavir F2-4</i>	Harvoni	12 weeks
GT 2, 3 Hepatocellular carcinoma awaiting liver transplantation AND meets Milan Criteria <sup>□</sup>	Sovaldi + ribavirin <sup>‡,§*</sup>	48 weeks or until liver transplant
GT 2, 3, 5, or 6 with decompensated cirrhosis [Child-Pugh B or C]		Restricted to specialist
Mixed genotype		Restricted to specialist

<sup>†</sup>Prescribers are advised to review FDA approved labeling and other 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-infection to ensure appropriate monitoring schema are taken into consideration;

<sup>‡</sup>Weight based ribavirin; <sup>§</sup>Refer to FDA approved labeling for use in impaired renal function. \* If ribavirin is not used as part of the regimen indicated, Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized. <sup>□</sup> 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. Refer to Table 5: Additional Criteria for Denial for limitations of use.

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<b>Table 4: Authorized Clinical Reasons Ribavirin Cannot be Used<sup>18</sup></b>		
Pregnancy	Hemoglobin < 8.5 g/dL	Pancreatitis
Creatinine Clearance < 50 mL/min	Hemoglobinopathies (e.g. sickle cell disease, thalassemia major)	Platelet count <75,000 cells/mL
Documented previous severe ribavirin hypersensitivity reaction	History of significant or unstable cardiac disease	Current use of antiretroviral with clinically significant ribavirin interaction

**Daklinza, Harvoni, and Sovaldi Criteria for Denial**

1. Patient has not been tested for the use of illicit drugs, controlled substances, and alcohol within the previous 90 days (or results have not been submitted with the request); **OR**
  - If the test is positive for alcohol or illicit substances, the patient is not actively attending a treatment program for substance abuse.
  - If the test is positive for a prescription controlled substance or a metabolite, the prescriber has not documented whether the patient has an active prescription for the attributable controlled substance
  - If the test is positive for an unprescribed controlled substance or metabolite, the patient is not actively attending a treatment program for substance abuse.
2. Diagnostic/disease severity/disease activity evidence based on biopsy, elastography, FibroSure, FibroTest, HepaScore, or FibroScan is not submitted with the request or an APRI or FIB4 score alone is submitted to demonstrate disease severity/activity; **OR,**
3. HCV RNA results not submitted with the request; **OR,**
4. For regimens containing ribavirin, patient is pregnant or lactating; **OR,**
5. Patient has a Child-Pugh score greater than 6 (class B or C) and treatment is not being managed by a liver disease specialist; **OR,**

<b>Table 5: Additional Criteria for Denial<sup>†</sup></b>				
Daklinza	Genotype 2, 4, 5 or 6 infection	Concomitant use with a drug that strongly induces CYP3A		Cirrhosis (Metavir fibrosis score of 4)
Harvoni	Genotype 2 or 3 infection	Taking a concomitant drug that has a significant clinical interaction or is contraindicated	Severe renal impairment (eGFR < 30 mL/ min) or end stage renal disease (ESRD) requiring hemodialysis	
Sovaldi	Genotype 5 or 6 infection	Taking a concomitant drug that has a significant clinical interaction or is contraindicated	Severe renal impairment (eGFR < 30 mL/ min) or end stage renal disease (ESRD) requiring hemodialysis	Child-Pugh score > 6 [class B or C] and treatment is not being managed by a liver disease specialist

<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

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**Denial Due to Lack of Information:**

If incomplete information is submitted on any prior authorization request, prescribers will have 7 calendar days to respond to the request for additional information, or the request will be non-clinically denied due to lack of information.

A re-review is possible with the submittal of a new complete PA request.

**Criteria for Approval: Treatment Experienced/Retreatment Patients**

1. Adult patient age  $\geq$  18 years old; **AND**
2. Documentation of HCV genotype, subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype (GT) 2, 3, 5 or 6, and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. To confirm the Metavir fibrosis stage, the following tests or procedures will be accepted: biopsy, elastography, FibroSure, FibroTest, HepaScore, or FibroScan (*Note: APRI and FIB-4 will not be accepted as confirmation of the Metavir fibrosis stage*); **AND**
5. The Hepatitis C disease activity score must be submitted with the authorization request; **AND**
6. The patient agrees to complete regimen; **AND**
7. The prescriber agrees to maintain HCV RNA levels obtained at 12-weeks and 24-weeks post-therapy completion to demonstrate Sustained Virologic Response (SVR); **AND**
8. For patients previously treated with an NS5A inhibitor, NS5B inhibitor or a NS3/4a protease inhibitor, polymorphism testing results **MUST** be submitted (refer to Table 2); **AND**
9. If HCV/HIV co-infected, must provide documentation of CD4 count, HIV viral load, and HIV treatment regimen; **AND**
10. 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**
11. Patient has been tested for the use of illicit drugs, controlled substances, and alcohol within the previous 90 days (results submitted with request); **AND**
  - If the test is positive for alcohol or illicit substances, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.
  - If the test is positive for a prescription controlled substance or a metabolite, the prescriber must document whether the patient has an active prescription for the attributable controlled substance (prescribers may consider using the Alaska PDMP, available at <http://alaskapdmp.com> as a tool to aid in the review).
  - If the test is positive for an unprescribed controlled substance or metabolite, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.
  - If the prescriber believes that the test documents an inaccurate or false positive result, an explanation must be submitted.

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**Authorized Regimens: Treatment Experienced**

<b>Table 6<sup>†</sup></b>			
<b>Alaska Medicaid Preferred Regimens for Treatment Experienced Patients</b>			
<b>Genotype</b>	<b>Failed Treatment</b>	<b>Retreatment Regimen<sup>‡,§*</sup></b>	<b>Duration</b>
GT 2 <i>Metavir F2-4</i>	PegIFN + Ribavirin	Refer to Table 3 regimens	
GT 3 <i>Metavir F2-4</i>	PegIFN + Ribavirin	Refer to Table 3 regimens	
	Prior treatment with Direct Acting Antiviral based regimens (e.g. NS5A-inhibitor or NS5B polymerase inhibitor based regimens)	Sovaldi + Daklinza + Ribavirin	12 - 24 weeks <sup>▪</sup>
GT 5 or 6 <i>Metavir F2-4</i>	PegIFN + Ribavirin	Refer to Table 3 regimens	
	Prior treatment with Direct Acting Antiviral based regimens (e.g. NS5A-inhibitor or NS5B polymerase inhibitor based regimens)	Harvoni + Ribavirin	12 - 24 weeks <sup>▪</sup>

<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. \*If ribavirin is not used as part of the regimen indicated, Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized. <sup>▪</sup> Duration varies depending on Metavir Fibrosis score. Refer to Table 5: Additional Criteria for Denial for limitations of use.

**Daklinza, Harvoni, and Sovaldi Criteria for Denial**

Same as listed above in the section for Treatment Naïve patients.

**Criteria for Retreatment Renewal Authorization Approval, with Approval Duration:**

Same as listed above in the section for Treatment Naïve patients.

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