

## Direct Acting Antivirals for Hepatitis C (HCV) Therapeutic Class

All Genotypes

All FDA Approved Direct Acting Antivirals for HCV

### Indications:

Treatment of chronic hepatitis C virus

### Quantity Limit:

Not to exceed the FDA-approved dose per day, FDA-approved duration

### Additional Considerations:

These guidelines cover all direct acting antiviral products used for the treatment of chronic hepatitis C viral infection as defined in the FDA label.

Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes and to mitigate the risk for development of viral resistance to direct acting antivirals and reinfection. Prescribers must perform a patient readiness assessment prior to treatment and patient must attest to treatment compliance.

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.

### Criteria for Approval:

1. Diagnosis of chronic Hepatitis C infection; **AND**
2. Documentation of chronic hepatitis C infection status, HCV genotype, viral resistance-status (when applicable), hepatic status (Child-Pugh score), and HCV viral load is included in the authorization request; **AND**
3. Adult patient age  $\geq$  18 years old (OR youth between age 12 and 18 years followed by a specialist, directly or in consultation); **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, and viral resistance-status, is included in the authorization request; **AND**
5. Patient readiness has been assessed and patient attestation of compliance is submitted and on file in the patient's medical record (prescribers may consider using the Alaska PDMP, available at <http://alaskapdmp.com> as a tool to aid in the review); **AND**
6. The patient agrees to complete regimen and understanding of risks of reinfection and contributors of liver damage through submitted signed attestation; **AND**
7. The prescriber agrees to maintain HCV RNA levels obtained at 12-weeks post-therapy completion to demonstrate Sustained Virologic Response (SVR); **AND**

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8. Patient has been screened for HBV (HBsAg and anti-HBc); **AND**
9. If HCV/HIV co-infected, prescriber must provide documentation of CD4 count, HIV viral load, and HIV treatment regimen; **AND**
10. If the patient's HCV genotype and drug product selection requires resistance-associated polymorphism testing, the required testing must be completed and the results submitted with the request:
  - Required for regimens whereby the FDA requires such testing prior to treatment to ensure appropriateness;
  - May be required if deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.

**Criteria for Renewal Authorization Approval:**

1. For regimens with durations longer than 16 weeks, HCV RNA may be required to be submitted with the renewal authorization for treatment week 4 and in sufficient time for renewal authorization request review; **AND**
2. HCV RNA must be less than 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). This information shall be made available upon request; **AND**
4. Extended durations will not be approved if:
  - No clinical evidence exists to demonstrate the clinical benefit and effectiveness of doing so; **OR**
  - Patient non-compliance with the prescribed regimen precipitated the need to extend the duration; **AND**
5. Neither extended authorization nor re-authorization of treatment will be granted in situations of treatment failure where the pharmacy provider made an error in dispensing the medication; in such cases, the pharmacy provider shall be responsible for rectifying the error at no cost to Alaska Medicaid or the patient; **AND**
6. Lost or stolen medication replacement requests will not be authorized.

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**Authorized Regimens:**

<b>Table 1: Alaska Medicaid Authorized Preferred Regimens</b>				
Genotype	Treatment Experience	Preferred Agent	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
GT 1,2,3,4,5,6	Naïve	Mavyret™	8 weeks*	12 weeks
GT 1,2,3,5,6	PRS	Mavyret™	8 weeks*	12 weeks
GT 3	PRS	Mavyret™	16 weeks*	16 weeks
GT 1	(+ NS3/4A PI NS5A inh. [naïve])	Mavyret™	12 weeks	12 weeks
	(+ NS3/4A PI [naïve] + NS5A Inh.)	Mavyret™	16 weeks*	16 weeks

PRS = Treatment experienced with interferon, peg-interferon, ribavirin, and/or sofosbuvir; PI = protease inhibitor

HCV Infection with Special Conditions	Preferred Agent	Additional Requirements
Hepatocellular carcinoma awaiting liver transplantation AND meets Milan Criteria <sup>§</sup>	Restricted to FDA-approved products with labeled indication	Restricted to specialist (includes consultation with specialist) and products with FDA-approved indication
Post Liver Transplant		
Decompensated cirrhosis (Child Pugh B or C)		
Mixed Genotype		
Youth ages 12 up to 18 years		
Previously treated with both an NS3/4A PI and an NS5A inhibitor	Zepatier (for FDA approved indication)	Documentation of the specific clinical contraindication must be submitted with authorization request.
Unable to use preferred agent due to clinical contraindication (GT1 and GT4)		
Unable to use preferred agent due to clinical contraindication (GT2 and GT3)		

\* 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> 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.

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**Criteria for Denial:**

1. Request is for diagnosis of acute hepatitis C infection; **OR**
2. Request is for a non-preferred agent when a medically appropriate preferred agent is available; **OR**
3. Request is for a preferred agent for duration exceeding FDA-approved duration for the specific indication; **OR**
4. Patient readiness has not been assessed and attested to by prescriber via signed attestation; **OR**
5. Patient has active substance dependency issues and has not been referred for treatment; **OR**
6. Signed patient attestation not included with prior authorization request; **OR**
7. Patient has a Child-Pugh score greater than 6 (class B or C) and treatment is not being managed by or in consultation with a liver disease specialist; **OR**
8. Patient taking concomitant medications or other products that counteract the clinical efficacy of the HCV DAA or present a clinical safety risk; **OR**
9. Patient is between the ages of 12 and 18 years and treatment is not being managed by or in consultation with a liver disease specialist; **OR**
10. Request is for a non-preferred agent when a less expensive, medically appropriate preferred agent is available.

**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 available with the submittal of a new complete PA request.

**Regulatory Authority:**

Alaska Medicaid prior authorization clinical criteria for use are developed under the authority granted to the Alaska Medicaid Drug Utilization Review Committee in compliance with 7 AAC 120.120, 7 AAC 120.130, 7 AAC 120.140, 42 USC 1396r-8, and 42 CFR 456 Subpart K. The Committee considers each of the following in the development of clinical criteria for use as outlined in 7 AAC 105.230(c): medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects as well as service-specific requirements. Drugs which fall into a specific therapeutic category but are approved by the FDA after the most recent revision of that therapeutic drug class review will be subject to the same standards set by DUR Committee for the relevant therapeutic category's prior authorization clinical criteria for use. This includes a requirement to utilize or trial preferred agents prior to the utilization of a non-preferred agent within a given therapeutic category unless a documented clinical contraindication exists.

Covered outpatient drugs must meet the parameters defined in 7 AAC 120.110. Drugs which the FDA has approved but clinical benefit has not been established will not be approved.

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