# Prior Authorization for Hepatitis C Treatment

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Tanana Chiefs Conference

# Disclosure

- **No financial disclosures that would be a potential conflict of interest with this presentation**

# Verify Insurance Medication Coverage

- Medicare – call the Part D coverage
- Medicaid – Hepatitis C Direct Acting Antivirals form: http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/AK_Hep_C_DAA_Fax_Form_20171001.pdf

# Medication Coverage, cont.

- Blue Cross – phone to request form, may complete over phone or fax
- Aetna – phone to request HCV Treatment Medication Precertification Request
- VA – contact 907-257-4700 VA Pharmacy
- Other insurances – call phone # on back of card

# Patient Assistance Programs

- Gilead/Support Path Program

  Harvoni & Epclusa – www.mysupportpath.com

- Patients of Native American descent fall under different guidelines due to the Affordable Care Act. Gilead will pay for the medication if the patient proves that they are not eligible for any other insurance. They may be approved during the “off” season, open season for ACA is generally Nov – Dec each year, in which case February through August would be the best timeframe to apply for the Support Path Program.

# Patient Assistance Programs

- Abbvie Patient Assistance

  Mavyret – Call 1-877-MAVYRET
- Others

## Alaska Medicaid Prior Authorization Form

## Hepatitis C Direct Acting Antivirals – New Starts (effective 10/1/2017)

Fax this request to: 1-888-603-7696 Questions: Call Magellan Medicaid Administration at 800-331-4475

Or mail this request to: Medicaid PA Unit, 14100 Magellan Plaza, Maryland Heights, MO 63043

**If the following information is not complete, correct, or legible, the PA process can be delayed or the request may be denied. Use one form per member please.**

### *Member Information*

**LAST NAME:** **FIRST NAME:**

**ID NUMBER:** **DATE OF BIRTH:** - -

### *Prescriber Information*

**LAST NAME:** **FIRST NAME:**

**NPI NUMBER:** **SPECIALTY:**

**PHONE NUMBER:** - - **FAX NUMBER:** - -

### *Pharmacy Information*

**NAME:** **NPI NUMBER:**

**PHONE NUMBER:** - - **FAX NUMBER:** - -

**INSTRUCTIONS TO THE PROVIDER- Please note the following criteria for approval and for denial of Hepatitis C direct acting antivirals (DAA):**

Clinical Criteria: http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx

Additional Information

- All questions must be answered or the prior authorization (PA) request will be considered incomplete.
- If incomplete information is submitted, 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.
- Claims will not be approved for more than a 28 day supply at a time.
- HCV RNA results from 12 weeks post-treatment (SVR 12) are required to be maintained in the medical record, to be made available at the State of Alaska's request.
- Lost or stolen medications will not be replaced.
- 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;
- Certain medication regimens will require testing for the presence of resistance-associated viral polymorphisms.
- 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, pregnancy status as well as considerations for HIV/HCV and HBV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration.
- Approval will be based on preferred drug selection.
- Prescribers must assess patient readiness and a signed patient attestation must be included in the prior authorization request.



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| **Last Name:** | **ID Number:** |
|---|---|

***Clinical Criteria Documentation***

1. What is the diagnosis for which this drug is being requested? **(please attach documentation)**

☐ Chronic Hepatitis C, genotype 1a
☐ Chronic Hepatitis C, genotype 1b
☐ Chronic Hepatitis C, genotype 2
☐ Chronic Hepatitis C, genotype 3
☐ Chronic Hepatitis C, genotype 4
☐ Chronic Hepatitis C, genotype 5
☐ Chronic Hepatitis C, genotype 6
☐ Chronic Hepatitis C, mixed genotypes: _____ _____ _____
☐ Hepatocellular Carcinoma awaiting liver transplant
☐ Other _____

2. Is the requesting prescriber an Alaska Medicaid provider? ☐ Yes ☐ No

3. Has the patient had prior treatment for Chronic Hepatitis C? ☐ Yes ☐ No
   a. If yes, please list regimen and dates below:

| Prior Hepatitis C Regimen(s): | Inclusive Dates: | Prior Regimen completed? | If discontinued early, state the reason: |
|---|---|---|---|
| | | | |
| | | | |

4. Metavir Fibrosis Score, equivalent **(attach documentation)** ☐ Unknown ☐ F0 ☐ F1 ☐ F2 ☐ F3 ☐ F4

5. Does the patient have extrahepatic manifestations of Chronic Hepatitis C, the etiology of which can only be attributable to the HCV infection? If yes, specify which manifestations, and submit documentation. ☐ Yes ☐ No

6. Baseline HCV Viral Load **(attach documentation):** _____ IU/mL Date:

7. Child-Pugh Score: Points: ☐ A ☐ B ☐ C

8. Current (within previous 90 days) renal function (creatinine clearance or GFR, estimated): _____ mL/min

9. Is patient HIV co-infected? ☐ Yes ☐ No

10. Patient has been screened for HBV (HBsAg and anti-HBc) ☐ Yes ☐ No
    HBV status ☐ Positive; refer to specialist ☐ Negative

11. If patient is female, patient has been screened and counseled on pregnancy. ☐ Yes / not pregnant ☐ No

12. Is a current list of all of the patient's medications attached? **(attach documentation)** ☐ Yes ☐ No
    The list should include all scheduled maintenance and as needed (PRN) medications the patient will be taking while on HCV therapy.



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|---|---|

| | | |
|---|---|---|
| 13. Is a signed **Patient Readiness Assessment Form** attached? | ☐ Yes ☐ No | |
| 14. The patient has been evaluated for treatment readiness, identification of potential impediments to successful therapy, including an assessment for current/historical alcohol and substance misuse (e.g., compliance difficulty, missed appointments, inadequate social support, or sub-therapeutic management of comorbid mental and physical health conditions). Possible tools include SBIRT (SAMHSA), AUDIT-C (WHO), NM-ASSIST (NIDA). | ☐ Yes ☐ No | |
| 14a. If patient is identified as having barriers to treatment, please acknowledge actions taken by this or another provider involved in the patient's care to address those barriers. | ☐ Attending treatment/support program<br>☐ Referred to treatment/support program<br>☐ Not attending / not referred to treatment program<br>☐ Connected with other services/resources | |
| 14b. I would like to refer the patient to the Alaska Medicaid Coordinated Care Initiative to help connect her/him to additional resources (http://dhss.alaska.gov/dhcs/Pages/amcci/providers.aspx). | ☐ Yes | ☐ No |
| 15. The patient has been provided with education on the effects of alcohol and substance use/misuse on liver and overall health, risks contributing to re-infection, and drug product specific information. | ☐ Yes | ☐ No |
| 16. The patient agrees to abstain from alcohol use during treatment. | ☐ Yes | ☐ No |

| Please note any other information pertinent to this PA request including unique circumstances that should be considered: | | |
|---|---|---|
| | | |
| Prescriber Initials | ***I attest that HCV RNA levels will be obtained and maintained for patient at 12-weeks post-therapy completion and shall be provided upon request.*** | |
| | | |

***Direct Prescriber Signature (Required) – No surrogates*** ***Date***

*(By signature, the Prescriber confirms the above information is accurate and verifiable by patient records.)*



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| **Prescriber Specialty:** | **Specialty of Consultant Prescriber (if applicable):** |
|---|---|
| ☐ Gastroenterologist<br>☐ Hepatologist<br>☐ Infectious Disease Specialist<br>☐ Internal Med<br>☐ Family Med<br>☐ Other _____ | ☐ Gastroenterologist<br>☐ Hepatologist<br>☐ Infectious Disease Specialist<br>☐ Other _____<br>☐ No other prescriber was consulted<br><br>**Specialist Consulted if not prescriber:**_____ |

**Requested Regimen**

| **Requested Regimen** | **Regimen** | **Duration** | **Restricted to Specialist or Consultation with Specialist (identify specialist above)** |
|---|---|---|---|
| ☐ | Mavyret | ☐ 8 weeks<br>☐ 12 weeks<br>☐ 16 weeks<br>☐ Other: _____ | ☐ Decompensated Cirrhosis (Child Pugh B or C)<br>☐ Hepatocellular Carcinoma (HCC)<br>☐ Status Post Liver Transplant<br>☐ Mixed Genotype<br>☐ Youth ages 12 up to 18<br>☐ Previous treatment with both an NS3/4A PI and an NS5A inhibitor<br>☐ HBV Coinfection |
| ☐ | Epclusa | | |
| ☐ | Zepatier[§] | | |
| ☐ | Other: | | |

[§]Requires baseline resistance-associated substitutions (RAS) testing

| **Resistance-Associated Substitutions (RAS) Testing in Treatment Experienced Patients and Per FDA-Label** | | |
|---|---|---|
| If retreatment, is resistance testing documentation attached? *(required)* | ☐ Yes | ☐ No |
| Does the product you selected require RAS testing in treatment-naïve individuals? | ☐ Yes *(attach results)* | ☐ No |
| Resistance-associated substitutions identified *(attach results)* | ☐ Yes *(attach results)* | ☐ No |
| | Variants Identified: | |

| **For Patients with Hepatocellular Carcinoma (HCC) Awaiting Liver Transplant** | | |
|---|---|---|
| Documentation is attached showing patient meets Milan criteria defined as:<br>• The presence of a tumor 5cm or less in diameter in patients with a single tumor **OR**<br>• No more than three tumor nodules, each 3cm or less in diameter, in patients with multiple tumors **AND**<br>• No extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor. | ☐ Yes | ☐ No |



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# Patient Attestation

- We use a patient attestation for every patient, ANTHC has a very user friendly option on their website:

https://anthc.org/wp-content/uploads/2017/11/Attestation-of-Readiness.pdf

## Pre-Treatment Agreement & Patient/Provider Attestation of Readiness

**Medication & Treatment Regimen:** _____

**To receive treatment, please review the following statements and initial beside the responses:**

___ I agree to not drink alcohol or use recreational drugs during the treatment.

___ I will tell my provider if I have any serious medical conditions (such as heart disease, high blood pressure, diabetes, high cholesterol, rheumatoid arthritis, or drug addiction), or psychiatric conditions (depression, history of suicide attempts, bipolar disorder, or psychosis).

___ I am willing to visit the clinic and see a provider on a regular schedule for the entire length of the treatment and at 12 weeks after end of treatment. If I am unable to attend an appointment, I will let my provider know ahead of time and I will reschedule my appointment.

___ I understand my treatment will be stopped if I cannot attend appointments.

___ I understand that my provider can stop my treatment if the provider feels that stopping it is in the best interest of my health and well-being.

___ I understand that my hepatitis C may not respond to treatment.

___ If I have any problems with the medications or side effects that bother me, I will let my provider or nurse know right away.

___ I will do my best to take my medications as prescribed by my provider. If I am unable to do so, I will contact my provider.

___ I will protect myself and others from hepatitis C by not sharing needles, toothbrushes, razors or nail clippers, and covering cuts to prevent blood exposure.

___ If female, I understand that I cannot be pregnant or breastfeeding during treatment. I understand that my treatment will be stopped if I become pregnant. ___Not applicable, I am surgically sterile or post-menopausal.

If using ribavirin: ___ Not applicable, ribavirin will not be used.

___ I will use 2 acceptable methods of birth control during treatment and for 6 months after I stop treatment.

___ If female, I understand that I cannot be pregnant or breastfeeding during treatment & for 6 months after treatment. I understand that my treatment will be stopped if I become pregnant. ___ Not applicable, I am surgically sterile or post-menopausal.

___ If male, I understand that I should not father a child during treatment and for 6 months after treatment. ___ Not applicable, I am surgically sterile.

**My signature below means that I have read and understand or the meaning of the information has been explained to me. I agree to complete treatment.**

| | | |
|---|---|---|
| **Patient's Name (PLEASE PRINT)** | **Patient's Signature** | **Date** |
| **Provider's Name (PLEASE PRINT)** | **Provider's Signature** | **Date** |

# Physician Staff Support

- Prior Authorization & Physician staff should work hand in hand to complete insurance requirements and ensure documentation from pre-treatment through SVR (sustained virologic response) 12 weeks after treatment.