



February 12, 2016

«AddressBlock»

Dear CCO Medical Directors and Pharmacy Directors:

On November 5, 2015, Centers for Medicare & Medicaid Services (CMS) issued Release No. 172 concerning Medicaid beneficiary access to direct acting antiviral (DAA) treatments of hepatitis C (HCV). CMS expressed concern that in many states, Medicaid managed care plans' "conditions for payment for DAA HCV drugs appear to be more restrictive than coverage under the states' fee-for-service (FFS) programs." The Release suggests greater restriction may violate 42 CFR §438.210. The release explains this federal regulation requires any services covered by the managed care plan "be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid." The regulation further sets requirements on the managed care plan definition of "medically necessary services." CMS, through the release, explains that a "managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan." The Oregon Health Authority carefully reviewed federal law in light of Release No. 172, and understands the concerns raised apply to Oregon's CCOs.

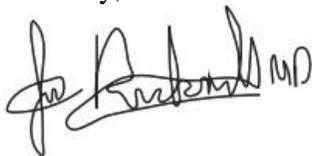
Release No. 172 specifically addresses coverage limitations based on metavir fibrosis scoring, a required period of abstinence from drug and alcohol abuse, and prescribing by, or in consultation with, a specific provider type. I am attaching the current coverage criteria for DAA HCV drug coverage in FFS OHP. Effective January 1, 2015, the Oregon Pharmacy and Therapeutics (P&T) Committee approved DAA coverage for metavir fibrosis scores F3 and F4, along with clinical indications as attached. This coverage determination was based on medical evidence available at the time that showed DAA agents are medically appropriate, safe and effective for these fibrosis stages. The coverage recommendation was also based on the "Community Standard" recommended by the Hepatitis C Advisory Committee. In addition, evidence showed that waiting to treat until stage F4 would result in both poorer clinical outcomes and decreased efficacy of DAAs.

On January 28, 2016, the P&T Committee recommended additional changes to clarify coverage and expand coverage for certain clinical indications including transplant patients and HIV coinfection. Their recommendation, which I have attached, will go into effect February 12, 2016 if approved. Current and historic PA criteria is available in the Oregon Medicaid PA Criteria section of the Pharmaceutical Services Program policy page, available at <http://www.oregon.gov/oha/healthplan/Pages/pharmacy-policy.aspx>. As new agents come to market and as new medical evidence becomes available, our P&T will periodically review medical evidence to ensure appropriate access to DAA HCV agents.

Release No. 172 urges states to "carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access." Please assist me in meeting this obligation by sending your CCO's current coverage criteria for DAA HCV drugs and by updating coverage in whatever ways are necessary to comply with federal Medicaid law.

Thank you for your commitment to the health and wellbeing of Oregonians. We look forward to collaborating to achieve the triple aim for all OHP beneficiaries.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Rickards MD". The signature is fluid and cursive, with the letters "MD" written in a slightly larger, more distinct font at the end.

Dr. Jim Rickards, MD, MBA  
Chief Medical Officer, Oregon Health Authority

cc: Lynne Saxton, OHA Director  
Lori Coyner, State Medicaid Director  
Dr. Varsha Chauhan, MD, Chief Health Systems Officer  
Leslie Clement, Health Policy and Analytics Division Director

Encl: Medicaid Drug Rebate Program Notice, Release No. 172, CMS, November 5, 2015  
FFS Hepatitis C DAA coverage criteria, effective January 1, 2016 (current)  
Revised FFS Hepatitis C DAA coverage criteria, effective February 12, 2016



**Center for Medicaid and CHIP Services**

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**NOVEMBER 5, 2015**

**MEDICAID DRUG REBATE PROGRAM NOTICE**

**Release No. 172**

## **For State Technical Contacts**

### **ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS**

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

#### **Rules Regarding Medicaid Drug Coverage**

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term “medically accepted indication” as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

When establishing formularies, states must ensure compliance with the requirements in section 1927(d)(4), including the requirements of section 1927(d)(4)(C) of the Act. Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an identified population if, based on the drug's labeling, or in the case of a drug the prescribed use of which is not approved under the FDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.

CMS is aware that, given the costs of these new DAA HCV drugs, states have raised concerns about the budgetary impact to their Medicaid programs and beneficiary access to needed care. The agency shares these concerns. However, the recent launch of multiple DAA HCV drugs in the marketplace is creating competition in this class that may result in downward pressure on the prices of these drugs. This competition may enhance the ability of states to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices for both their FFS and managed care programs, thereby reducing costs. CMS encourages states to take advantage of such opportunities.

To that end, manufacturers have a role to play in ensuring access and affordability to these medications. CMS has sent a letter to the manufacturers of these DAA HCV drugs, asking them to provide information regarding any value-based purchasing arrangements they offer for these drugs so that states might be able to participate in such arrangements.

#### *Permissible Limitations to Medicaid Drug Coverage*

CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4<sup>1</sup>.

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<sup>1</sup> The metavir scoring system is used to assess inflammation and fibrosis by histopathological evaluation of a liver biopsy of patients with hepatitis C. The stages, indicated by F0 through F4, represent the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis; a chronic degenerative liver disease state in which normal liver cells are damaged and are then replaced by scar tissue. For more information about liver fibrosis please read Ramon Batallar and David A. Brenner, Liver fibrosis *Journal of Clinical Investigation*. 2005 Feb 1; 115(2): 209–218 by visiting <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC546435/>

Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types, like gastroenterologists, hepatologists, liver transplant specialists, or infectious disease specialists in order for payments to be provided for the drug.

While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes,<sup>2</sup> such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their coverage policies. These resources include pharmacy and therapeutics (P&T) committees, drug utilization review (DUR) boards, and comparative analysis of the costs to treat HCV patients in light of the efficacy of these newer regimens in terms of cure rates, when compared to those of preexistent therapies. Additionally, CMS notes the availability of guidelines for states to refer to regarding testing, managing, and treating HCV put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA), which can be found at <http://www.hcvguidelines.org/full-report-view>. CMS also suggests that states consider implementing programs that provide patients on HCV treatment with supportive care that will enhance their adherence to regimens, thereby increasing the success rates.

#### Coverage under Medicaid Managed Care Plans

CMS is also concerned that in many states, Medicaid managed care organizations (MCOs) or other managed care arrangements' conditions for payment for DAA HCV drugs appear to be more restrictive than coverage under the states' fee-for-service (FFS) programs. Furthermore, in states with multiple MCOs or arrangements, the conditions for payment for DAA HCV drugs often differ between various plans.

CMS reminds states that the drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements. As with their FFS program, states are urged to carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access. States have the option to include these drugs in the managed care contracts and capitation rates or to "carve out" the drugs used in the treatment of chronic HCV

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<sup>2</sup> In accordance with section 1927(d)(5) of the Act, a state plan may establish a prior authorization program as a condition of coverage or payment for a covered outpatient drug; however, the program must provide responses by telephone or other telecommunication device within 24 hours of a request for prior authorization, and, except for those drugs restricted or excluded from coverage pursuant to section 1927(d)(2) of the Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

infections from managed care contracts and capitation rates and instead provide access to these drugs through FFS or other arrangements.

Consistent with the regulation at 42 CFR §438.210, services covered under Medicaid managed care contracts (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid. While managed care plans may place appropriate limits on DAA HCV drugs using criteria applied under the state plan, such as medical necessity, the managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.

CMS notes that managed care plans are permitted to use other utilization controls provided that the services, as controlled under the health plan's policies, can be reasonably expected to achieve their purpose. However, states should carefully monitor utilization controls and the HCV coverage policies of their managed care plans to ensure that the organizations are providing appropriate access to covered services and benefits consistent with 42 CFR §438.210.

CMS recognizes the challenges of defining policies in the face of new and innovative drug treatments. It will monitor the policies and conditions states impose for the coverage of DAA HCV drugs to ensure compliance with the requirements of the Act and access to effective, clinically appropriate, and medically necessary treatments for beneficiaries. CMS will monitor state compliance with their approved state plans, the statute, and regulations to assure that access to these medications is maintained.

CMS shares with states the common goal of ensuring access to quality care for Medicaid beneficiaries. Given the complexities that have arisen with the introduction of the DAA HCV drugs, CMS will continue to work with State Medicaid agencies to continue providing and improving care to persons infected with chronic HCV infections. If you have any questions, please contact John M. Coster, Ph.D., R.Ph., Director of the Division of Pharmacy, at [John.Coster@cms.hhs.gov](mailto:John.Coster@cms.hhs.gov).

/s/

Alissa Mooney DeBoy  
Acting Director  
Disabled and Elderly Health Programs Group



# FFS Hepatitis C DAA Coverage Criteria

EFFECTIVE JANUARY 1, 2016 (CURRENT)



## Hepatitis C Direct-Acting Antivirals

### Goal(s):

- Approve cost effective treatments of chronic Hepatitis C, which are supported by the medical literature when there is available evidence.
- Treat the patient population in greatest need of treatment and who will benefit the most from therapy.
- Provide consistent patient evaluations across all hepatitis C treatments.

### Length of Authorization:

- 8-12 weeks

### Requires PA:

- All drug regimens in the Hepatitis C PDL Class

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of Chronic Hepatitis C Virus?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh; deny for appropriateness.
3. What regimen is requested?	<b>Document and Go to #4.</b>	
4. Does the regimen contain a drug not yet reviewed by P&T?	<b>Yes:</b> Go to #5	<b>No:</b> Go to #6
5. Will the prescriber change to a preferred product already reviewed for efficacy and safety by the P&T Committee?	<b>Yes:</b> Inform Provider of covered alternatives in class	<b>No:</b> Pass to RPh; deny for appropriateness.  Forward to DMAP for further review to determine appropriateness and coverage in light of most recent community standards and comorbidity.
6. Is the medication being prescribed by or in consultation with a hepatologist or gastroenterologist with experience in Hepatitis C?	<b>Yes:</b> Go to #7.	<b>No:</b> Pass to RPh; deny for appropriateness.  Forward to DMAP for further review to determine appropriateness of prescriber.

## Approval Criteria

<p>7. Does the patient have a biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4) OR radiologic, laboratory, or clinical evidence of cirrhosis without ongoing progressive decompensation (MELD score between 8 and 11), and expected survival from non-HCV associated morbidity should be greater than 5 years?</p>	<p><b>Yes:</b> Go to #8.</p>	<p><b>No:</b> Go to #9.</p> <p><b>Note:</b> Patients with a MELD score &gt;11 may be eligible for therapy, but only after review by the DMAP medical director.</p> <p>If patient has Metavir F0-F2, a treatment option remains pegylated interferon and ribavirin; refer to that specific PA Criteria</p>
<p>8. Does the patient have decompensated cirrhosis?</p>	<p><b>Yes:</b> Pass to RPh; deny for appropriateness</p>	<p><b>No:</b> Go to #11</p>
<p>9. Does the patient have one of the following extrahepatic manifestations of hepatitis C and who have formal documentation from a relevant specialist that their condition is HCV related, and expected survival from non-HCV associated morbidity should be greater than 5 years?</p> <ol style="list-style-type: none"> <li>Type 2 or 3 cryoglobulinemia with end-organ manifestations (vasculitis)</li> <li>Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis</li> </ol>	<p><b>Yes:</b> Go to #11.</p>	<p><b>No:</b> Go to 10.</p>
<p>10. Does the patient have Hepatitis C Virus in the transplant setting, including the following scenarios:</p> <ol style="list-style-type: none"> <li>Patient is listed for a transplant and it is essential to prevent recurrent hepatitis C infection post-transplant</li> <li>Post-transplant patients with Stage 4 fibrosis</li> <li>Post-transplant patients with fibrosing cholestatic hepatitis due to HCV infection</li> </ol> <p><b>And</b> expected survival from non-HCV associated morbidity should be greater than 5 years?</p>	<p><b>Yes:</b> Go to #11.</p>	<p><b>No:</b> Pass to RPh; deny for medical appropriateness.</p> <p>Note: Other scenarios not included can be brought to the Medical Director on a case by case basis.</p>

<b>Approval Criteria</b>		
11. Has the patient been abstinent from IV drug, illicit drugs and marijuana use, AND alcohol abuse for $\geq 6$ months? AND If the patient has a history of alcohol abuse, has the patient been abstinent from alcohol use for $\geq 6$ months?	<b>Yes:</b> Go to #12.	<b>No:</b> Pass to RPh; deny for appropriateness.
12. Does the patient have significant renal impairment (CrCl $\leq 30$ mL/min) or end state renal disease (ESRD)?	<b>Yes:</b> Pass to RPh; deny for appropriateness.	<b>No:</b> Go to #13.
13. Does the patient have a baseline HCV RNA level?	<b>Yes:</b> Record value and go to #14	<b>No:</b> Pass to RPH. Request provider obtains baseline lab value.
14. What Hepatitis C genotype is the patient? Record Genotype:	Record Genotype and go to #15.	
15. Is the prescribed drug ledipasvir/sofosbuvir (Harvoni®) and is the regimen and duration appropriate for patient genotype based on the dosing and administration table below?	<b>Yes:</b> Approve for 8-12 weeks based on dosing and administration table.	<b>No:</b> Go to #16 If prescribed other DAA, encourage prescriber to use our preferred product
16. Is the prescribed drug sofosbuvir (Solvaldi®)?	<b>Yes:</b> Go to #17	<b>No:</b> Go to #18
17. Does the patient have Genotype 2 hepatitis C infection?	<b>Yes:</b> Approve for 12 weeks based on dosing and administration table below	<b>No:</b> Go to #18 If prescribed other DAA, encourage prescriber to use our preferred product
18. Is the prescribed drug ombitasvir, paritaprevir, and ritonavir; dasabuvir (Viekira Pak®)?	<b>Yes:</b> Go to #19	<b>No:</b> Pass to RPh; deny for appropriateness. Encourage prescriber to use our preferred DAA.
19. Has the patient been off all ethinyl estradiol containing products for at least a week OR is willing to discontinue any products one week prior to starting therapy?  If the patient is not on any ethinyl estradiol medications, go to #20.	<b>Yes:</b> Go to #20	<b>No:</b> Pass to RPh; deny for appropriateness.

Approval Criteria		
<p>20. If the patient was or is on any other medications that due to drug-drug interactions are contraindicated with the use of Viekira Pak (See Table 2 below), has the patient stopped this medication at least a week ago or is willing to discontinue this medication (and it is appropriate) at least one week prior to starting therapy?</p> <p>If the patient is not on any medications in Table 2 that are contraindicated, go to #21.</p>	<b>Yes:</b> Go to #21	<b>No:</b> Pass to RPh; deny for appropriateness.
21. Does the patient have HIV coinfection?	<b>Yes:</b> Go to #22	<b>No:</b> Go to #23
22. Is the patient not receiving suppressive antiretroviral therapy (who may be at increased risk of HIV-1 protease inhibitor drug resistance) OR on therapy with significant antiretroviral drug-interactions (efavirenz, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine).	<b>Yes:</b> Pass to RPh; deny for appropriateness.	<b>No:</b> Go to #23
23. Is the patient treatment naïve with or without cirrhosis or treatment experienced without cirrhosis?	<b>Yes:</b> Approve for 12 weeks based on appropriate dosing and administration from table below	<b>No:</b> Go to #24
24. Has the patient failed previous therapy with a direct acting antiviral?	<b>Yes:</b> Pass to RPh; deny for appropriateness. Use of Viekira has not been studied in this population.	<b>No:</b> Go to #25
25. If the patient failed previous therapy with peginterferon/ribavirin dual therapy, did the patient relapse or have a partial response?	<b>Yes:</b> Approve for 12 weeks based on dosing and administration table below	<b>No:</b> Go to #26
26. Does the patient have cirrhosis and had a previous null response to dual therapy with peginterferon and ribavirin therapy or a post-liver transplant patient?	<b>Yes:</b> Approve for 24 weeks based on dosing and administration table below	<b>No:</b> Pass to RPh; deny for appropriateness. Encourage

**Table 1: Dosage and Administration:**

Genotype 1			
Naïve	Without Cirrhosis and HCV RNA < 6 million IU/mL	LDV/SOF 1 tablet QDay	8 weeks

	Without Cirrhosis and HCV RNA $\geq$ 6 million IU/mL	LDV/SOF 1 tablet QDay	12 weeks
	Without Cirrhosis; Genotype 1b	Paritaprevir/R+Ombitasvir+Dasabuvir	12 weeks
	Without Cirrhosis; Genotype 1a	Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks
	With Cirrhosis	LDV/SOF 1 tablet QDay Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks
Experienced	Without Cirrhosis	LDV/SOF 1 tablet QDay Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks
	With Cirrhosis	LDV/SOF 1 tablet QDay + RBV Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks-24 weeks*
<b>Genotype 2</b>			
Naïve and Experienced	With or Without Cirrhosis	SOF 400 mg QDay + RBV	12 weeks**
<b>Genotype 3</b>			
Naïve or Experienced	With or Without Cirrhosis	LDV/SOF 1 tablet QDay + RBV	12 weeks
<b>Genotype 4 and 6</b>			
Naïve or Experienced	With or Without Cirrhosis	LDV/SOF 1 tablet QDay	12 weeks
*24 weeks of therapy with Paritaprevir/R+Ombitasvir+Dasabuvir + RBV should be reserved for treatment experienced, genotype 1a, null responders or post-liver transplant patients			
**Previous nonresponders to PEG/RBV with cirrhosis may benefit by extension of therapy to 16 weeks			
Abbreviations: LDV/SOF: Ledipasvir and sofosbuvir (Harvoni®); RBV: ribavirin; SOF: sofosbuvir (Sovaldi®)			

**Table 2: Drugs Contraindicated with Viekira Pak**

Alfuzosin HCL	Methylergonovine
Carbamazepine	St. John's Wort
Phenytoin	Lovastatin
Phenobarbital	Pimozide
Gemfibrozil	Efavirenz
Rifampin	Sildenafil*
Ergotamine	Triazolam
Dihydroergotamine	Midazolam
Ergonovine	
*When dosed as REVATIO for the treatment of pulmonary arterial hypertension (PAH)	

P&T/DUR Review: 5/15; 3/15; 1/15; 9/14; 1/14  
Implementation: 10/15; 4/15, 1/15; 9/14; 7/14; 3/14



# Revised FFS Hepatitis C DAA Coverage Criteria

Effective February 12, 2016

## Hepatitis C Direct-Acting Antivirals

### Goals:

- Approve use of cost-effective treatments supported by the medical evidence.
- Prioritize populations in greatest need of treatment who will benefit the most from therapy.
- Provide consistent patient evaluations across all hepatitis C treatments.

### Length of Authorization:

- 6 weeks

### Requires PA:

- All direct-acting antivirals for treatment of Hepatitis C

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization?	<b>Yes:</b> Go to Renewal Criteria	<b>No:</b> Go to #2
2. What diagnosis is being treated?	Record ICD10 code.	
3. Is the request for treatment of Hepatitis C infection?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh; deny for appropriateness.
4. Has the patient had all of the following appropriate pre-treatment testing? <ul style="list-style-type: none"> <li>• Genotype testing in past 3 years; <b>AND</b></li> <li>• Baseline HCV RNA level in the past 6 months; <b>AND</b></li> <li>• HIV status in past 6 months; <b>AND</b></li> <li>• Pregnancy test if a woman of child-bearing age in past 30 days</li> </ul>	<b>Yes:</b> Record results and go to #5	<b>No:</b> Pass to RPh. Request updated testing before approving treatment.
5. Has the patient failed treatment with any HCV NS5A inhibitor (including daclatasvir plus sofosbuvir, ledipasvir/sofosbuvir, or paritaprevir/ritonavir/ombitasvir plus dasabuvir)?  Note: Patients who failed treatment with sofosbuvir +/- ribavirin or pegylated interferon can be retreated (See table below)	<b>Yes:</b> Pass to RPh; deny for appropriateness.  Note: If patient needs urgent retreatment, resistance testing must be done to indicate susceptibility to prescribed regimen for retreatment	<b>No:</b> Go to #6

<b>Approval Criteria</b>		
6. What regimen is requested?	Document and go to #7	
7. Is the regimen prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist with experience in treatment of Hepatitis C?	<b>Yes:</b> Go to #8	<b>No:</b> Pass to RPh; deny for appropriateness.  Forward to DMAP for further manual review to determine appropriateness of prescriber.
8. Does the patient have: <ul style="list-style-type: none"> <li>• A biopsy, transient elastography (Fibroscan®) or serum test (FibroSure®) to indicate advanced fibrosis (METAVIR F3) or cirrhosis (METAVIR F4); <b><u>OR</u></b></li> <li>• Radiologic, laboratory (APRI score &gt; 1.5 or FIB-4 score &gt;3.25), or clinical evidence (ascites, portal hypertension) of cirrhosis; <b><u>AND</u></b></li> <li>• Expected survival from non-HCV-associated morbidities of greater than 5 years?</li> </ul>	<b>Yes:</b> Go to #12	<b>No:</b> Go to #9
9. Does the patient have one of the following extrahepatic manifestations of Hepatitis C (with documentation from a relevant specialist that their condition is related to HCV) and have an expected survival from non-HCV-associated morbidities greater than 5 years? <ol style="list-style-type: none"> <li>a. Type 2 or 3 cryoglobulinemia with end-organ manifestations (i.e., leukocytoclastic vasculitis); <b><u>OR</u></b></li> <li>b. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; <b><u>OR</u></b></li> <li>c. Porphyria cutanea tarda</li> </ol>	<b>Yes:</b> Go to #12	<b>No:</b> Go to #10

Approval Criteria		
10. Does the patient have Hepatitis C in the transplant setting, including the following scenarios: a) Patient is listed for a transplant and it is essential to prevent recurrent hepatitis C infection post-transplant; <b>OR</b> b) Post solid organ transplant; <b>AND</b> c) Expected survival from non-HCV-associated morbidities of greater than 5 years?	<b>Yes:</b> Go to #12	<b>No:</b> Go to # 11
11. Does the patient have HIV coinfection and METAVIR stage F2 or greater (APRI $\geq$ 1.0) <b>AND</b> the patient is under treatment by a specialist with experience in HIV?	<b>Yes:</b> Go to #12	<b>No:</b> Pass to RPh; deny for medical appropriateness.  Note: Other scenarios not included can be brought to the OHP Medical Director on a case-by-case basis.
12. Has the patient been evaluated for current alcohol and substance use with a validated screening instrument?	<b>Yes:</b> Go to #13	<b>No:</b> Pass to RPh; deny for medical appropriateness.  Request current evaluation for alcohol and substance use before treatment.
13. Is the patient actively using illicit drugs or abusing alcohol?	<b>Yes:</b> Go to #14	<b>No:</b> Go to #15
14. Is the patient enrolled in a treatment program under the care of an addiction specialist?	<b>Yes:</b> Go to #15	<b>No:</b> Pass to RPh; deny for medical appropriateness.
15. Does the patient have significant renal impairment (CrCl $\leq$ 30 mL/min) or end-stage renal disease?	<b>Yes:</b> Pass to RPh; deny for appropriateness.	<b>No:</b> Go to #16  Note: Treatment may be considered in patients with genotype 1 with paritaprevir/ritonavir/ombitasvir and dasabuvir in those without cirrhosis and for whom the urgency to treat is high.

Approval Criteria		
16. Will the patient and provider comply with all case management and adherence monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load?	<b>Yes:</b> Go to #17	<b>No:</b> Pass to RPh; deny for appropriateness.
17. Is the prescribed drug regimen a recommended regimen based on the patient's genotype and cirrhosis status (see Table 1)?	<b>Yes:</b> Approve for 6 weeks to allow for 4 week HCV RNA level	<b>No:</b> Pass to RPh; deny for appropriateness.

Renewal Criteria		
1. Has the patient been adherent to and tolerated initial therapy?	<b>Yes:</b> Go to #2	<b>No:</b> Pass to RPh; deny for medical appropriateness.
2. Is the HCV RNA level at week 4 detectable (HCV RNA is $\geq 25$ IU/mL)?	<b>Yes:</b> Reassess HCV RNA in 2 weeks. Go to #3	<b>No:</b> Approve for additional 2-10 weeks based on genotype and regimen (Table 1).
3. Has the HCV RNA increased (i.e., $>1 \log_{10}$ IU/mL from nadir)?	<b>Yes:</b> Discontinue treatment.	<b>No:</b> Approve for additional 2-10 weeks based on genotype and regimen (Table 1).
Note: HCV RNA levels must be assessed at 12 weeks after completion of treatment to determine whether SVR was achieved.		

**Table 1: Recommended Treatment Regimens for Chronic Hepatitis C.**

Genotype	Cirrhosis Status	Approved Regimen <sup>^</sup>	Duration of Treatment
<b>Genotype 1</b>			
Treatment-naïve	<b>NO</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	8-12 weeks <i>Note: If HCV RNA &lt; 6 million IU/mL, give LDV/SOF for <u>8 weeks</u></i>
	<b>YES</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	12 weeks
Treatment-experienced	<b>NO</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	12 weeks
	<b>YES</b>	<ul style="list-style-type: none"> <li>• LDV/SOF + RBV</li> </ul>	12 weeks
<b>Genotype 2</b>			
Naïve or Experienced	<b>YES/NO</b>	<ul style="list-style-type: none"> <li>• SOF + RBV</li> </ul>	12 weeks*
<b>Genotype 3</b>			
Naïve or Experienced	<b>NO</b>	<ul style="list-style-type: none"> <li>• LDV/SOF + RBV</li> </ul>	12 weeks
Naïve or Experienced	<b>YES</b>	<ul style="list-style-type: none"> <li>• DCV + SOF + RBV</li> </ul>	12 weeks
<b>Genotype 4</b>			
Naïve or Experienced	<b>NO</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	12 weeks
Naïve or Experienced	<b>YES</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	12 weeks
<b>Genotype 6</b>			
Naïve or Experienced	<b>YES/NO</b>	<ul style="list-style-type: none"> <li>• LDV/SOF</li> </ul>	12 weeks
<p>*Previous non-responders to PEG/RBV with cirrhosis may benefit by extension of therapy to 16 weeks</p> <p><b>Abbreviations:</b> DCV = daclatasvir (Daklinza®); LDV/SOF = ledipasvir and sofosbuvir (Harvoni®); RBV = ribavirin; SOF = sofosbuvir (Sovaldi®).</p> <p><b>^Approved regimens are:</b></p> <ul style="list-style-type: none"> <li>• DCV: 1 tablet once daily</li> <li>• RBV: twice daily (weight-based dosing)</li> <li>• LDS/SOF: 1 tablet once daily</li> <li>• SOF: 1 tablet once daily</li> </ul> <p><b>Clinical Notes:</b></p> <p>Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are sparse. Awaiting availability of a pangenotypic regimen may be considered. Until then, when treatment is necessary, the choice of antiviral combination and duration of treatment should maximize efficacy against each genotype represented in the assay. When the correct combination or duration is unclear, expert consultation should be sought</p> <p>Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin-containing regimen is chosen is required.</p>			

P&T/DUR Review: 1/16 (MH); 5/15; 3/15; 1/15; 9/14; 1/14  
Implementation: TBD; 10/15; 4/15, 1/15; 9/14; 7/14; 3/14