Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCINF029O.1225	**ANTI-INFECTIVE AGENTS** **HEPATITIS C DIRECT ACTING ANTIVIRALS** See Table 1 for a List of Medications
Effective Date: 2/1/2026	**Review/Revised Date**: 03/16, 05/16, 10/16, 12/16, 01/17, 04/17, 07/17, 08/17, 11/17, 07/18, 12/18, 03/19, 10/19, 10/20, 01/21, 08/21, 09/21, 10/21, 04/22, 10/22, 03/23, 11/23, 02/24, 10/24, 10/25 (JH)
Original Effective Date: 04/16	**P&T Committee Meeting Date**: 04/16, 06/16, 10/16 , 12/16, 12/16 (Chair), 01/17 (cv), 02/17, 04/17 (cv), 08/17, 08/17 (cv), 12/17, 08/18, 02/19, 04/19, 12/19, 12/20, 02/21, 10/21, 12/21, 04/22, 12/22, 04/23, 12/23, 04/24, 12/24, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:
Prior authorization is NOT required for preferred Direct Acting Antivirals (DAA) regimens (generic Epclusa® and Mavyret® tablet) for treatment-naive patients with hepatitis C virus.

Mavyret® tablet and sofosbuvir/ velpatasvir (generic Epclusa) tablet will be covered for patients undergoing solid organ transplantation after confirmation donated solid organ is from a hepatitis C virus (HCV) viremic donor

For treatment-experienced and for non-preferred DAAs, all the following criteria (1-6) must be met:
1. Documentation of confirmed diagnosis of hepatitis C (HCV) infection (B18.2)
2. Documentation of baseline quantitative HCV RNA level
3. Documentation that ALL the following pre-treatment testing has been performed

   a. Genotype testing in past three years is only required for the following population:
      i. Patients with decompensated cirrhosis
      ii. Patients with prior treatment experience with a direct-acting antiviral (DAA) regimen
      iii. For regimen which is not pan-genotypic (e.g., Harvoni®, Zepatier®)
   b. Cirrhosis status as clinically determined (e.g., clinical, laboratory, or radiologic evidence)
   c. History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience
4. In treatment experienced patients, evaluation is required to assess if this is likely a reinfection indicated by at least one of the following:
   a. Patient has ongoing risk factors for hepatitis C reinfection (for example, sexually active men who have sex with men, persons who inject drugs),
   b. Hepatitis C infection is a different genotype than previous

   Note: If patient is reinfected with Hep C, use regimens recommended for treatment naïve patients.
5. For coverage of non-preferred regimen, the prescriber must submit medical rationale in support of the use of non-preferred drug(s).
6. For coverage of the following regimen, NS5A resistance testing is required to detect any potential resistant variant.
   a. Elbasvir/grazoprevir (Zepatier®) for GT 1a infection
   b. Ledipasvir/sofosbuvir (Harvoni®) for GT 1a treatment-experienced infection
   c. Sofosbuvir/velpatasvir (Epclusa®) for GT 3 in cirrhosis or treatment-experienced infection
7. For coverage of pellet formulation, the prescriber must submit medical rationale in support of its use over the available tablet formulation (such as use in pediatric patients or inability to swallow)
8. Retreatment or treatment failure due to non-compliance will be reviewed case-by-case with considerations including, but not limited to, evidence of safety and efficacy, readiness to start therapy, and plan to ensure therapy compliance.

EXCLUSION CRITERIA:
NS3/4A protease inhibitors (e.g., Mavyret, Vosevi, and Zepatier) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B or C)

AGE RESTRICTIONS:
Must be consistent with FDA approved labeling

PRESCRIBER RESTRICTIONS: N/A

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCINF029O	ANTI-INFECTIVE AGENTS HEPATITIS C DIRECT ACTING ANTIVIRALS See Table 1 for a List of Medications

COVERED REGIMEN AND DURATION:

Must be consistent with FDA approved labeling

QUANTITY LIMIT: 28 day-supply per dispense.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Direct acting antiviral (DAA) agents are highly effective oral medications indicated for the treatment of patients infected with chronic hepatitis C infection.
Effective 1/1/2017, coverage of Hepatitis C Direct Acting Antivirals will be consistent with Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria for Hepatitis C Direct-Acting Antivirals.

Due to the minimal side effect profile and high efficacy of these agents, HCV-infected donor organs are able to be used in transplant procedures with success. Patients receiving these viremic organs may be treated with the DAA therapies and avoid the development of acute hepatitis and other non-hepatic complications.[3]

FDA APPROVED INDICATIONS:

Table 1: Preferred and Non-Preferred Direct Acting Antivirals (DAA)

Drug (PI revised date)	FDA Approved Indications
Preferred Agents	
Sofosbuvir/velpatasvir 400-100mg tablet (generic Epclusa®)	Treatment of adult and pediatric patients 3 years of age and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infection: - Without cirrhosis or with compensated cirrhosis - With decompensated cirrhosis for use in combination

	with ribavirin
Mavyret® 100-40mg tablet (glecaprevir/pibrentasvir)	Treatment of HCV in adults and pediatric patients 3 years of age and older: - GT 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A) - GT 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
Non-Preferred Agents	
• Epclusa® 40-100mg tablet • Epclusa® 200-50mg tablet • Epclusa® 150-37.5mg pellet packet • Epclusa® 200-50mg pellet packet	Treatment of adult and pediatric patients 3 years of age and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infection: - Without cirrhosis or with compensated cirrhosis With decompensated cirrhosis for use in combination with ribavirin
• Ledipasvir/Sofosbuvir 90-400mg tablet • Harvoni® 90-400mg tablet • Harvoni® 45-200mg tablet • Harovni® 33.75-150mg pellet packet • Harvoni® 45-200mg pellet packet	Treatment of HCV in adults and pediatric patients 3 years of age and older: - GT 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis - GT 1 infection with decompensated cirrhosis, in combination with ribavirin - GT 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin
• Mavyret 50-20 mg Pellet Packets	Treatment of HCV in adults and pediatric patients 3 years of age and older: - GT 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A) - GT 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
• Sovaldi® 200mg tablet • Sovaldi® 400mg tablet • Sovaldi® 150mg pellet packet • Sovaldi® 200mg pellet packet	- Adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen - Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin
Zepatier® 50-100mg tablet (elbasvir/grazoprevir)	In combination with or without ribavirin for the treatment of chronic HCV genotypes 1 or 4 infection in adults and pediatric patients 12 years of age and older or weighing at least 30 kg
Vosevi® 40-100-100mg tablet (sofosbuvir/velpatasvir/voxilaprevir)	Treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: - Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor - Genotype 1a or 3 infection and have previously been

	treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor Additional benefit of VOSEVI over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

REFERENCE/RESOURCES:

1. Oregon Health Authority, Health Systems Division. Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria. Effective on 10/1/2025. Available at: https://www.oregon.gov/oha/HSD/OHP/Tools/Oregon%20Medicaid%20PA%20Criteria%20October%201,%202025.pdf. Accessed on 10/21/2025
2. Drug Package Inserts
3. American Association for the Study of Liver Disease (AASLD) and Infectious Diseases Society of America (IDSA). Recommendations for testing, managing, and treating hepatitis C. Available at: https://www.hcvguidelines.org/ (Accessed October 21, 2025)

Appendix 1: Direct Acting Antivirals and Mechanism of Actions

Brand Name	Mechanism of Action		
	NS5A	NS5B	NS3/4A PI
Daklinza	daclatasvir	--	--
Epclusa	velpatasvir	sofosbuvir	--
Harvoni	ledipasvir	sofosbuvir	--
Incivik	--	--	telaprevir
Mavyret	pibrentasvir	--	glecaprevir
Sovaldi	--	sofosbuvir	--
Technivie	ombitasvir	--	paritaprevir
Victrelis	--	--	boceprevir
Vosevi	velpatasvir	sofosbuvir	voxilaprevir
Zepatier	elbasvir	--	grazoprevir

PI – protease inhibitor