Appendix B

Table 1a.

State Medicaid Coverage Policies for Sofosbuvir (Solvaldi™) – Summary Findings

Methods

To identify states with policies for sofosbuvir (Solvaldi™), Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically-available and accessible online at the time of our search (May 30, 2014, September 24, 2014). Information from state policies is summarized below and described in detail in the partner report (Center for Evidence-based Policy, 2014b). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised sofosbuvir (Solvaldi™) policies that became publically-available after our search dates were excluded from our analysis.

Sofosbuvir Policy Review Findings		
States with Identified Prior Authorization Criteria for Sofosbuvir	**States where Sofosbuvir Coverage Appears to be Unrestricted[1]**	**States without an Identified Coverage Policy**
27	**7**	**16**
AL, AK, AZ, AR, CA, CO, DE, FL, ID, IL, IN, IA, LA, ME, MD, OH, OK, OR, PA, RI, SD, TN, VT, VA, WV, WI, WY	CT, GA, MA, MN, NV, NY, UT	HI, KS, KY, MI, MS, MO, MT, NE, NH, NJ, NM, NC, ND, SC, TX, WA

[1]Publicly available policies include no clear restrictions on coverage.

Summary of State Medicaid Coverage Policies for Sofosbuvir Treatment of Hepatitis C

This analysis includes the 27 publicly available coverage policies which contain restrictive criteria for coverage.

Policy Criteria	Number of States	States

Policy Criteria		Number of States	States
Disease Severity Requirement?[1]		24	
	≥ F4	3	DE, IL, OR
	≥ F3	16	AK, AZ, AR, CA, CO, FL, ID, IA, LA , OH, PA, RI, TN, VA, WV, WI
	≥ F2	3	MD, OK, SD
	Level unclear	2	AL, IN
SUD Criteria		22	
	≥ 3 months sober	3	AK, DE, IA
	≥ 6 months sober[2]	13	AZ, CA, CO, ID, MD, OK, OR, PA, RI, SD, WV, WI, WY
	≥ 12 months sober	2	IL, LA
	Requires sobriety during tx or for no specific time period	4	FL, OH, TN, VA
Specialist physician requirements		20	
	Prescribe	11	FL, IN, IA, LA, MD, OH, PA, RI, SD, TN, WI
	Prescribe or consult	9	AZ, CO, ID, IL, ME, OK, OR, VA, WV

Policy Criteria	Number of States	States
Detailed Interferon-free Eligibility Requirements	16	AK, AZ, CA, DE, FL, ID, IA, LA, ME, MD, MN, OR, PA, RI, WV, WI
Response driven therapy (e.g. continuation dependent upon achieving early viral response)	10	AZ, CA, CO, FL, ID, LA, MD, VA, WV, WI
Pt must be sofosbuvir treatment-naïve	7	AK, AZ, CO, IA, MD, PA, WV
Once in a lifetime benefit	6	AL, AZ, , CO, IL, WV, WY
Require providers to collect efficacy data (SVR12, SVR24 and/or SVR52)	5	AL, ID, IL, RI, WV,

[1]Disease severity is most often described through Metavir fibrosis scores. The scale runs from F0 to F4: F0 = no fibrosis ; F1 = portal fibrosis without septa; F2 = portal fibrosis with few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis. Policies generally include other disease severity criteria in addition to Metavir fibrosis scores. See Chart for details.

[2]Alabama's policy requests information on substance use in past 6 months but does not spell out sobriety criteria.

Reference

Center for Evidence-based Policy. (2014b). *State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Suggested citation: Center for Evidence-based Policy. (2014a*). State Medicaid Coverage Policies for Sofosbuvir – Summary Findings.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University

Table 1b.

State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C

Methods

To identify states with policies for sofosbuvir (Sovaldi™), Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically-available and accessible online at the time of our search (May 30, 2014, September 24, 2014). Information from state policies is described in detail below and summarized in the partner report (Center for Evidence-based Policy, 2014a). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised sofosbuvir (Sovaldi™) policies that became publically-available after our search dates were excluded from our analysis.

Suggested citation: Center for Evidence-based Policy. (2014b). *State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Alabama 6/17/2014 PA Instructions PA Form	Yes	Yes	Unclear	**Treatment Regimens:** Clinician must select from a list of treatment regimens by genotype on PA form. List includes all FDA approved regimens. SOF + SIM is not listed as an option. **Treatment Criteria:** • Once in a lifetime benefit • State requires submission of SVR12 and SVR24 for approved requests PA form requests the following information but does not indicate approval

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				criteria: • SUD: ○ Alcohol or drug use in past 6 months • Glomerular filtration rate • If HIV co-infection, viral load, CD4 count and whether patient is on stable HIV Rx regimen for ≥ 8 weeks • Disease Severity: "Applicable" liver disease diagnostic criteria including: ○ Metavir fibrosis score ○ Child-Turcotte-Pugh classification ○ Acoustic radiation force impulse image m/sec ○ Abdominal imaging and evidence of surface abnormalities, features of portal hypertension, ascites ○ AST to platelet ratio index ○ Fibroscan value ○ Fibrosis-4 (FIB-4) score
Alaska 4/18/2014 PA Criteria	Yes	Yes	No	**Treatment Regimens:** All FDA approved regimens listed on PA form; SOF + SIM explicitly excluded. **Treatment Criteria:** • Age 18+ years • SOF tx naïve • Disease severity: ○ ≥ stage F3 or HCC on transplant list ○ Cirrhosis documented by biopsy OR two of the following:

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				▪ Cirrhotic features on imaging ▪ Ascites ▪ Esophageal varices ▪ Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2) o Bridging fibrosis documented via biopsy • <u>SUD:</u> o Abstention from illicit drugs and alcohol for minimum of 3 months as evidenced by negative urine confirmation tests in each of the two months immediately prior to therapy • If HIV co-infection: o CD4 count > 500 cells/mm^3 w/o antiretroviral therapy OR o CD4 count > 200 cells/mm^3 with virological suppression (e.g., HIV RNA < 200 copies/mL) • Exclusions: o Pregnant or lactating o SUD w/I 3 months of tx o Decompensated cirrhosis (CTP ≥ 6, class B or C) o Severe renal impairment, ESRD o Post liver transplant **Interferon Ineligibility Criteria:** • Baseline platelet count < 90,000/μL • Baseline neutrophil count < 1,500/μL • Baseline hemoglobin < 10 g/dL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Decompensated hepatic disease • Clinical features consistent with depression • Autoimmune hepatitis or other autoimmune diseases • Intolerance of hypersensitivity to IFN • Preexisting cardiac disease
Arizona 7/17/2014 Medical Policy for Sovaldi (Sec 320-36)	Yes	Yes	Yes	**Treatment Regimens:** Arizona includes in "recommended tx regimens" all FDA approved SOF regimens. However, standard tx for genotype 3 pts in Arizona policy is SOF+RBV+PEG for 12 wks. Only IFN ineligible genotype 3 pts allowed SOF + RBV for 24 wks. Also includes non-FDA approved or studied regimens for genotype 1 null or partial responders (SOF for 12 wks + RBV and PEG for 12 to 24 wks). SOF + SIM ± RBV allowed for genotype 1 IFN ineligible, null or partial responders, *and* genotype 4 IFN ineligible. **Treatment Criteria:** • Age ≥ 18 years • Once in a lifetime benefit • Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • Disease Severity: Evidence of serious liver disease as demonstrated

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				by: ○ Ultrasound, CT or MRI evidence of "cirrhosis or severe fibrosis" of "nodular-appearing liver in combination with evidence of splenomegaly and portal hypertension" OR ○ Elastrography score ≥ 11kPa OR ○ Metavir score ≥F 3 OR ○ FibroSure (e.g. FibroTest) ≥ 0.58 OR ○ Extrahepatic manifestations including leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease • Immunity to or vaccinations for Hep A and Hep B • SUD: ○ If hx of SUD, remission for six months prior to tx ○ If hx of SUD w/I past 12 months, random drug/alcohol screens during tx • If HIV co-infection: ○ CD4 count > 500 cells/mm^3 w/o antiretroviral therapy OR ○ CD4 count > 200 cells/mm^3 with virological suppression (e.g., HIV RNA < 200 copies/mL) • Pts must participate in a "treatment adherence program" • Exclusions: ○ Previous SOF or SIM tx ○ "documented non-adherence to prior HCV medications, HCV medical tx, or failure to complete HCV disease evaluation appointments and procedures" ○ Decompensated liver disease (CTP score > 9)

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Elastography score < 11 kPa ○ Metavir score < F3 ○ FibroSure score < 0.58 ○ Any substance abuse w/l 6 months ○ Severe renal impairment or ESRD ○ Post-liver transplant **Interferon Ineligibility Criteria:** • Autoimmune hepatitis or other autoimmune diseases • Previous intolerance to IF leading to tx discontinuation: ○ Pre-existing hematological disease as evidence by: ▪ Baseline neutrophil count < 1500/µL OR ▪ Baseline platelet count < 90,000/µL OR ▪ Baseline hemoglobin < 10g/dL ○ History of psychiatric disorders: ▪ Schizophrenia ▪ Bipolar disorder ▪ Previous inpatient psychiatric admission ▪ History of suicide attempt w/i two years ▪ Unstable major depressive disorder ○ Ischemic heart disease **Response Determinant Therapy:** • Must test patient viral loads and if HCV viral load is detectable (> 100 IUs) at 4 wks for a 12 wk regimen, or at 4 or 12 wks for a 24 wk regimen, tx will be discontinued.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Arkansas 4/16/2014 PA Form PA Criteria Links	Yes	No	No	**Treatment Regimens:** Standard of Care (SOC) remains PEG+RBV+PI for genotype 1, PEG+RBV for genotypes 2,3 & 4. **Treatment Criteria:** SOF will be considered on a case-by-case basis under the following circumstances: • All genotypes pre-transplant due to shorter duration of SOF tx regimens • Genotype 1 tx naïve patients with stage 4 cirrhosis, biopsy required • Genotype 2 & 3 relapsed patients and non-responders "Any requests for 'intolerance' or 'allergy' to PEG will be reviewed on a case-by-case basis."
California 6/30/2014 Policy Web Page Tx Policy Tx Regimen Chart Tx Algorithm	Unclear	No	Yes (but requires PA and meet criteria for "investigational treatment")	**Treatment Regimens:** All FDA approved regimens allowed *except* for genotype 4. California does not include treatment of genotype 4 pts in its policy recommendations due to "insufficient evidence." CA includes the following tx regimens that are not FDA approved as tx options if pt gets approval for "coverage of investigational services": (see requirements below) • Genotype 1: SOF + SIM ± RBV • Genotype 2: SOF + PEG+ RBV • Gentoype 3: SOF + PEG + RBV

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Post liver tx patients **Treatment Criteria:** • Age ≥ 18 years • Patients with genotype 1, 2 and 3 with mild liver disease and no extra-hepatic manifestations "are not eligible for SOF or SIM-based regimens;" algorithm says to "wait" • Disease Severity: SOF or SIM requires significant liver disease as defined by: o Metavir score ≥ F3 OR o Clinical findings: "physical exam findings (palpable left lobe, splenomegaly, palmar erythema) AND low platelet count (<100,000/mm$^{3)}$ AND abdominal imaging findings" (surface abnormalities, features of portal hypertension, ascites) OR o Serum markers of advanced fibrosis/cirrhosis: ▪ APRI score > 1.5 ▪ FIB-4 > 3.25 ▪ FibroSure/FibroTest > 0.58 OR o Non-invasive assessment of liver fibrosis: ▪ Fibroscan > 9.5 kilopascals ▪ ARFI > 1.75 m/sec ▪ MRE > 6.47 kilopascals o Pts with mild liver disease (Metavir F0-F2) AND extra hepatic manifestations (leukocytoclastic vasculitis, clinical evidence of symptomatic cryoglobulinemia and membranoproliferative glomerulonephritis) "should be

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				considered for treatment" ○ Pts with HCC "should be considered for tx" • <u>SUD:</u> ○ All pts screened for SUD AND urine toxicology screen at baseline ○ Heavy alcohol use, binge alcohol use, active injection drug or illicit drug use requires referral to SUD tx before HCV tx ○ "Pts with SUD must be actively participating in tx…or be abstinent 6 months prior to tx" • Screened and/or vaccinated for Hep A and Hep B, screened for HIV • If HIV co-infection: ○ "optional candidates for HCV tx are pts who have been on a stable regimen for HIV with a suppressed HIV viral load for at least 8 wks and have a CD4 count > 200 cells/mm" • "Caution must be exercised with pts who have a hx of tx failure with prior Hep C tx due to non-adherence." • Insufficient evidence for genotypes 4, 5 or 6 so they will be "considered on a case-by-case basis" **Interferon Ineligibility Criteria:** • Platelet count < 100,000/mm^3 OR • Decompensated liver cirrhosis (CTP class B or C score ≥ 7, albumin < 3.5) • Severe mental health conditions ("including but not limited to psychotic disorders, bipolar disorder, major depression,

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				posttraumatic stress disorder) • Autoimmune diseases • Prior interferon-related adverse effect • Preexisting cardiac disease **Response Guided Treatment Criteria:** • SOF based tx: Pts have HCV RNA assessed at 4 wks tx; if detectable, reassess HCV RNA in 2 wks. "If HCV RNA increases (e.g., >1 log_{10}IU/mL from nadir) at any time point or if the 8-2k HCV RNA is detectable, discontinuation of all treatment must be strongly considered." • SIM based tx: Pts have HCV RNA assessed at 4, 12 and 24 wks. If HCV RNA detectable at any of these time points, "all treatment should be discontinued." **Coverage of Investigational Services Criteria (e.g., non-FDA approved regimens):** All of the following must apply: • "Conventional therapy will not adequately treat the intended patient's condition" • "Conventional therapy will not prevent progressive disability or premature death" • "The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service"

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				• "The investigational service is the lowest cost item or service...and is less costly than all conventional alternatives" • "There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living." • Investigational services require prior authorization.
Colorado 7/1/2014 PA Form PA Criteria	Yes	No	No	**Treatment Regimens:** Treatment regimens not specified; SOF + SIM explicitly excluded. **Treatment Criteria:** Approval for pts with genotypes 1, 2 or 4 on a "case-by-case" basis with the following criteria; patients with genotype 4 only on transplant list: • Age ≥ 18 years • Prescribed by "on in conjunction with" an infectious disease specialist, hepatologist, or gastroenterologist • SOF limited to once-in-a-lifetime benefit • Disease severity: (as determined by liver biopsy or "other accepted test"): o Extra-hepatic manifestations of HCV: leukocytoclasic vasculitis, HCC meeting Milan criteria, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia o Compensated or decompensated cirrhosis as defined by Child-Turcotte Pugh class A or B (Score 5-9 ascites), hepatic

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				encephalopathy, or variceal bleeding; o Transplant pts with fibrosing cholestatic HCV or recurrent HCV approved for re-transplantation o On transplant list with wait time < 1 year o Metavir fibrosis score ≥F3 • For genotype 1, must be tx naïve • All pts SOF naive • No severe renal impairment • SUD: o Free from substance abuse/alcohol dependence for 6 months as "documented by appropriate alcohol/drug screens." o Pts w/ SUD hx w/I 2 years must have monthly alcohol/drug screens **Response Guided Therapy:** • Pts must have HCV RNA levels assessed at 4 and 12 wks and tx discontinued if HCV RNA > LLOQ at these times • Tx discontinued if pt not medication adherent as determined by Rx fills
Connecticut 04/2014 PDL	No	Unclear	Unclear	Connecticut Medicaid has both SOF and SIM as preferred medications on its PDL. No prior authorization is required and no policy was identified.
Delaware 06/2014	Yes	Yes	No	**Treatment Regimens:** "Medication can only be approved as part of a regimen that is FDA

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
PA Criteria and Form				approved for the client's genotype. This includes indication, dosing regimen and duration" **Treatment Criteria:** Approval of SOF or SIM requires: • Documented failure of or contraindication to preferred drug (Note: failure due to noncompliance "may be considered a contraindication to retreatment.") • Disease Severity: Documentation of "an imminent need to initiate therapy such as cirrhosis or a pending liver transplant." Cirrhosis documented by: ○ Metavir score = F4 ○ "combination of an ultrasound or CT scan along with extrahepatic manifestations or clinical findings such as the presence of ascites" • SUD: ○ No use of illegal substances for 90 days prior to therapy. Drug screens required. ○ Abstinence from alcohol for 90 days prior to therapy • If HIV co-infection: ○ Undetectable HIV viral load or CD4 count ≥ 350 cells/μL • Client signs informed consent addressing need for tx adherence, side effects of RBV, risk of birth defects and commitment to contraception, commitment to avoid alcohol and illegal substances. **Interferon Ineligibility Criteria:**

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				• Previous intolerance or known hypersensitivity to IFN • Autoimmune hepatitis or other autoimmune disorders • Documentation of depression with a psychiatric consult • Platelet count < 70,000/mm^3 • Preexisting cardiac disease
Florida 5/12/2014 SOF Criteria SOF+SIM Criteria	Yes	Yes	Yes	**Treatment Regimens:** All FDA-approved SOF regimens allowed (including HIV co-infection and pts awaiting transplant) for one month under following conditions: **Treatment Criteria:** • Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or transplant physician. • SUD: ○ Documented abstention from drugs/alcohol or in treatment • Explicit patient agreement to adhere to tx including Rx regimen, Dr visits and blood tests and pt must be 100% compliant as noted by Rx fills and lab tests to continue treatment beyond 1 month • Negative pregnancy and test and agreement to use contraception • Disease Severity: Stage 3 or 4 hepatic fibrosis documented by: ○ Biopsy METAVIR score ≥ F3, OR ○ Fibroscan score ≥ 9.5 kPa, OR ○ FibroTest score ≥ 0.58, OR ○ APRI score > 1.5, OR ○ Radiological imaging consistent with cirrhosis, OR

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				○ Evidence "as attested by the prescribing physician." • No early refills allowed due to lost, stolen medication, or vacation override • SOF+SIM allowed for: ○ Genotype 1, interferon ineligible ○ No prior tx with PI ○ Prescribed by specialist ○ Documentation of cirrhosis • Exclusions: ○ SOF tx for genotypes 5 or 6, ○ SOF tx for pts with decompensated cirrhosis (Child-Pugh score > 6) ○ SOF tx for post liver transplant pts. **Interferon Ineligibility Criteria:** • Prior intolerance to interferon therapy (urticarial, angioedema, bronchoconstriction, anaphylaxis or Stevens-Johnson syndrome) • Autoimmune hepatitis or other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease (CPT > 6, class B or C – these cases require individual case review) • Major uncontrolled depressive illness • Hx of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder or suicidal ideation • Baseline neutrophil < 1500/μL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Baseline platelet < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease • Refractory diabetes mellitus • Untreated thyroid disease **Response to Therapy Criteria:** • Continuation of therapy dependent on documented response to therapy as ≥ log reduction in HCV RNA or HCV RNA < 25 IU/mL at 4 and 12 wks after initiation of therapy • Pt 100% compliant to regimen as verified by prescriber and Rx fill history • No sign of high risk behavior (recurring alcoholism, IV drug use, etc.)
Georgia 4/22/2014 PA Criteria	Yes	Yes	Yes	All FDA approved regimens allowed with no added criteria. Georgia allows SOF + SIM for pts with fibrosis stage 3 or 4, pts who have failed PEG + RBV therapy w/o a PI, and pts who are interferon ineligible
Hawaii No information available	n/a	n/a	n/a	n/a
Idaho 6/13/2014 PA Criteria PA Form	Yes	Yes	No	**Treatment Regimens:** Only FDA approved treatment regimens are allowed. **Treatment Criteria:** • Age 18+ years

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Prescribed by on in consultation with gastroenterologist, hepatologist, infectious disease physician or liver transplant specialist • Provider must submit SVR12 and SVR24 post tx • <u>Disease Severity:</u> Advanced liver disease ○ Metavir ≥ F3 OR ○ Batts-Ludwig scale 3-4 OR ○ Fibroscan measurement ? 12.5 kPa OR ○ ARFI value > 1.75 m/sec OR ○ CT/MRI with features of portal hypertension, ascites, and hepatosplenomegaly OR ○ APRI score > 1.5 OR ○ FIB-4 > 3.25 • <u>SUD:</u> ○ If hx of SUD, documentation of 6 months abstinence for injection drug use/alcohol dependency; ○ Urine/blood toxicology tests monthly for pts with hx of SUD • Due to limited evidence on tx-experienced pts, those cases will be reviewed on case-by-case basis. **Response to Treatment Criteria:** All initial approvals for 4 wks of tx with continuation determined by following: • Provider must test HCV RNA at 2 wks of tx to determine compliance and efficacy

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Provider must obtain HCV RNA at 4 and 8 wks for 12 wk therapy and 4, 8, and 12 wks for 24 wk therapy • Tx will be discontinued/renewals declined if: ○ Pt does not achieve HCV RNA below the limit of detection after 4 wks or has not demonstrated a decrease in HCV RNA from baseline after 4 wks ○ If HCV RNA > 25 IU/mL at wk 4 or any other time after ○ Positive urine or blood toxicology test **Interferon Ineligibility Criteria:** • Autoimmune hepatitis or autoimmune disorders • Major uncontrolled depressive illness • Hx of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation • Uncontrolled seizures • Moderate or severe retinopathy • Poorly controlled diabetes • Baseline neutrophil count < 750 cells/mm^3 • Baseline platelet count < 75,000 cells/mm^3 • Baseline hemoglobin < 10 g/dL • Significant ischemic cardiac disease • Prior intolerance or hypersensitivity to IFN • Symptomatic hepatitis C induced cryoglobulinemia
Illinois 8/12/2014	Yes	No	No	**Treatment Regimens:** Must be FDA approved regimen, but the alternative regimen for genotype

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
PA Criteria PA Forms				1, IFN ineligible is not allowed (e.g., SOF+RBV for 24 wks). **Treatment Criteria:** • Age 18+ years • Once in a lifetime SOF benefit • Prescribed by or in consultation with gastroenterologist, transplant hepatologist, or infectious disease specialist • Disease severity: Metavir score ≥ 4 or equivalent • SUD: ○ Documented negative standard urine drug screen w/I 15 days of PA submission ○ Pts excluded if "evidence of SUD or treatment in past 12 months based on department claims records, prescribers knowledge, medical record entry, state's narcotic prescription registry database, reports from a hospital, an ED visit, an urgent care clinic, a physician's office or practice or another setting" • Exclusions: ○ Cancer, except HCC cleared for transplant ○ Terminal disease with life expectancy < 12 months or in hospice • Dispensed for 2 wks at a time with refills available for additional 2 wks (see forms); Non-compliance or failure to fill Rx will cause termination of tx • Prescriber must report HCV RNA within first 8 weeks of tx, upon

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				completion of therapy, and at 12 months post tx
Indiana 5/1/2014 PA Form PA Criteria	Yes	Yes	Yes	**Treatment Regimens:** SOF regiment must include concurrent PEG and RBV, RBV or SIM therapy. **Treatment Criteria:** • Disease severity: Requires compensated liver disease "including cirrhosis or hepatocellular carcinoma that meets criteria for liver transplant." Dx tests not defined. • Prescribed by infectious disease or gastrointestinal specialist • Refills beyond 12 wks require documented compliance with therapy • Allows SOF + SIM therapy except in pts who have failed prior triple therapy (PEG + RBV + PI)
Iowa 10/1/2014 PA Criteria PA Form	Yes	Yes	No	**Treatment Regimens:** Only FDA approved or "compendia indicated" therapy regimens. **Treatment Criteria:** • Age 18+ years • Requires documentation of monthly pregnancy tests • SUD: ○ Abstention from alcohol and illicit drugs for a minimum of three months prior to tx confirmed by urine test • Prescribed by gastroenterologist, hepatologist, infectious disease specialist or "other hepatitis specialist" • If pt has hx of "failed tx due to non-compliance, documentation

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				that steps have been take to correct or address the causes of non-compliance" • <u>Disease Severity:</u> Metavir score ≥ F3 as documented by liver biopsy or HCC meeting Milan criteria awaiting liver transplant • Exclusions: ○ Previous tx with or failed tx with protease inhibitor ○ Decompensated cirrhosis ○ CrCl < 30 mL/min or receiving dialysis **Interferon Ineligibility Criteria:** Requests for IFN-free regimens for genotype 1 or 4 decided on case-by – case basis. • Documented life-threatening side-effects • Decompensated hepatic disease • Autoimmune hepatitis and other autoimmune disorders • Baseline neutrophil < 1500/µL • Baseline platelets < 90,000/µL • Baseline hemoglobin < 10 g/dL • Preexisting unstable cardiac disease
Kansas *No results returned in search; Discussed at July*	n/a	n/a	n/a	n/a

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
9, 2014 DUR meeting but minutes not available				
Kentucky PDL Drug Look Up	Yes	n/a	n/a	According to Magellan Medicaid Administration, Kentucky Medicaid's pharmacy benefit manager, SOF requires PA and has clinical criteria. Details were not available on-line.
Louisiana 7/1/2014 PA Criteria and form	Yes	No	No	**Treatment Regimens:** Not specified **Treatment Criteria:** • Age 18+ years • Genotype 2 or 3 OR HCC meeting Milan criteria and awaiting transplant. *(Note: Genotypes 1 and 4 do not appear to eligible unless they are on transplant list)* • Documented history of relapse or nonresponse to standard therapy • Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • Disease Severity: ○ Liver biopsy showing advanced fibrosis or cirrhosis: Metavir score ≥ F3 or Ishak stage ≥4 ○ CTP score ≤ 6, class A (compensated liver disease) • SUD: ○ No active SUD w/I one year as "attested by prescriber and substantiated by negative urine drug screen and blood

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				alcohol level" w/I 30 days of tx ○ For pts w/hx of SUD, monthly random urine drug screen and blood alcohol level. Positive test = discontinuation of tx • Signed patient treatment agreement • Exclusions: ○ Severe renal impairment or ESRD ○ Solid organ transplant except liver **Response to Treatment Criteria:** • Initial PA for 8 weeks, additional PAs required for each additional 8 wks of tx; maximum 48 wks for pre-transplant pts • PA renewals dependent upon pt HCV RNA < 25 IU/mL at tx weeks 4, 12, 20, 28 and 36 **Interferon Ineligibility Criteria:** • Platelet count < 75,000/mm^3 • Decompensated liver cirrhosis (CTP score ≥ 7 HCV mono-infection; HCV-HIV co-infection) • Severe mental health condition • Autoimmune diseases • Documented interferon-related adverse effects and/or hypersensitivities
Maine 5/5/2014 PA Form	Yes	Yes+ *Maine includes	Yes	**Treatment Regimens:** Maine defines 7 tx regimens for different pt groups. Treatment regimens or identified patient groups underlined when they differ from FDA approved

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
		regimens not specified in FDA approval		protocols. • SOF + RBV + PEG 12 wks ○ Genotype 1 tx naïve/relapsed (w/ or w/o HIV co-infection) ○ Genotype 2 tx experienced w/ prior null response or partial response with cirrhosis* ○ Genotype 3 regardless of prior tx status* ○ Genotype 4 regardless of prior tx status ○ Genotype 5 or 6 regardless of prior tx status* • SOF + RBV + PEG 12 wks followed by additional 12 wks PEG* ○ Genotype 1 prior null or partial response w/ or w/o a PI ○ Genotype 1 HIV+ prior null or partial response to PEG + RBV + PI • SOF + RBV 12 wks ○ Genotype 2 tx naïve, relapsed or null responder w/out Cirrhosis • SOF + RBV 16 wks* ○ Genotype 2 pts, tx naïve, relapsed or null responders with cirrhosis and IFN intolerant* Regimens 5 and 6 below "will only be approved in those patients who require immediate treatment because it is anticipated that safer and more effective IFN-free treatments will be available in 2015." • SOF + SIM w/ or w/o RBV 12 wks* ○ Genotype 1 pts with stage 3 or 4 fibrosis confirmed by biopsy, Child-Pugh < 6 and IFN intolerant ○ Genotype 1 pts with HIV and prior PEG + RBV non response*[1]

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• SOF + RBV 24 wks ○ Genotypes 1,2 and 3 with re-infection of allograft liver after transplant* ○ Genotype 1 IFN-intolerant and Child-Pugh > 6 ○ Genotype 3 IFN-intolerant and stage ≥ 3 fibrosis confirmed by biopsy • SOF + RBV for up to 48 wks or until transplant ○ Any genotype w/ dx of HCC awaiting transplant Form also allows providers to submit their own regimen or apply one of the above to a different population with a rationale. **Treatment Criteria:** • Prescribed by or in consultation with gastroenterologist, hepatologist, infectious disease specialist or other "hepatitis specialist" • "Documentation of counseling regarding abstinence from alcohol, IV drug use and education o how to prevent HCV transmission." • Exclusion: severe renal disease • Approval is for two 14 day fills and a subsequent 28 day fill. **Interferon Ineligibility Criteria:** • Documented life-threatening side effects or potential side effects • Decompensated cirrhosis (CTP > 6) or CPT ≥ 6 if HIV co-infected • Baseline neutrophil < 1500/μL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Baseline platelets < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of unstable or significant cardiac disease
Maryland 7/23/2014 PA Criteria PA Form	Yes	Yes	No	**Treatment Regimens:** All FDA approved regimens included. **Treatment Criteria:** • Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • Patient must be SOF tx naive • Disease Severity: Liver fibrosis equivalent to Metavir score ≥ 2 • SUD: ○ "patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state" • If HIV co-infection: ○ CD4 count > 500 cells/mm^3 w/o antiretroviral therapy ○ CD4 count > 200 cells/mm^3 if pt virologically suppressed (HIV RNA < 200 copies/mL) • Exclusions: ○ Decompensated cirrhosis (CTP score > 6, class B or C) ○ Severe renal impairment or ESRD

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Response to Treatment Criteria: • Initial approval for 8 weeks • Refuse renewal and discontinue tx if: ○ Tx wk 4: < 2 log reduction in HCV RNA ○ Tx wk 12: HCV RNA ≥ 25 IU/mL ○ Tx wk 24: HCV RNA ≥ 25 IU/mL **Interferon Ineligibility Criteria:** • Intolerance to IFN alfa • Autoimmune hepatitis or other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease • Unstable depression or mood disorder • Platelet count < 75,000/mm^3 • Hx of cardiac disease
Massachusetts 2/2014 PA Form Mass Health Drug List	Yes	Yes	No	All FDA regimens appear to be approved without additional criteria. SOF + SIM does not appear to be allowed as approval criteria for both drugs requires treatment with PEG and RBV.
Michigan Drug Info Page	n/a	n/a	n/a	As of search September 24, 2014 on Magellan's Michigan Medicaid page, SOF is not covered.
Minnesota 3/12/14 PA Criteria	Yes	Yes	No	**Treatment Regimens:** All FDA approved regimens. Concurrent SIM therapy excluded.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Treatment Criteria: • Age 18+ years • No other criteria specified **Interferon Ineligibility Criteria:** • "Tried and failed interferon therapy" • Decompensated hepatic disease • Major depressive disorder • Baseline neutrophil < 1500/µL • Baseline platelet < 90,000/µL • Baseline hemoglobin < 10 g/dL • Preexisting heart disease (stroke, MI, heart failure, arrhythmia, valvular heart disease)
Mississippi PDL	Yes	Unclear	Unclear	Pharmacy PDL list states SOF is a preferred drug but it requires manual PA. No PA criteria identified.
Missouri 9/5/2014	n/a	n/a	n/a	No policy identified. Drug Prior Authorization Policy for MO HealthNet dated 9/5/2014 included no information on hepatitis drugs, SOF or Sovaldi. The Hepatitis C Therapy PDL was last updated 10/3/2013 and does not include SOF.
Montana PDL	Yes	Unclear	Unclear	Montana's PDL notes that SOF PA approval subject to clinical criteria. Criteria not available.
Nebraska 7/17/2014 PDL PA Form	Yes	Unclear	Unclear	Nebraska has SOF as a non-preferred drug on its PDL and requires PA for all Hep C agents. PA form requests information on prior tx, hx of SUD, and cirrhosis but hasn't been updated since 9/2013. The Hep C clinical criteria is dated 9/2013 and does not include SOF.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Nevada 9/1/2014 PDL	No	Yes	Unclear	Both SOF and SIM are preferred on PDL and do not appear to require PA. Only PA form for HCV drugs dated 11/2013 and for boceprevir or telaprevir.
New Hampshire 9/2/2014 PA Form	Yes	Unclear	Unclear	State requires PA, but PA criteria not available.
New Jersey	n/a	n/a	n/a	New Jersey has managed care for pharmaceutical benefits. No information available.
New Mexico	n/a	n/a	n/a	New Mexico is a managed care state. No information available.
New York 2/20/2014 PA Form	Yes	Yes	Yes	All FDA regimens appear to be approved without additional criteria.
North Carolina 5/17/2014 PDL	n/a	n/a	n/a	No results returned. PDL as of 5/17 did not list either SOF or SIM.
North Dakota	n/a	n/a	n/a	No policy returned. Hepatitis C agents discussed at September 3, 2014 DUR meeting.
Ohio 10/1/2014 PA Criteria in PDL	Yes	Yes Ohio includes regimens not specified in FDA approval	Yes	**Treatment Regimens:** • All FDA approved regimens • SOF + SIM for IFN ineligible genotype 1 pts • Includes SOF + RBV 12 wks for genotypes 5 and 6 **Treatment Criteria:** • Age 18+ years • Prescribed by hepatologist, gastroenterologist, or infectious disease

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				specialist • Patient readiness must be assessed and providers discuss deferred therapy to wait for more effective/less toxic treatments • Vaccinate against Hep A and Hep B • SUD: ○ "Screening for and maintenance of sobriety (alcohol/controlled drugs/IV drug use) before and during treatment" • Requires evaluation of fibrosis using biopsy, imaging, or "non-invasive markers" • Disease Severity: ○ Advanced liver fibrosis of Metavir score ≥ F3 or Ishak score ≥ F4 OR ○ Extra-hepatic manifestations: lymphoma, symptomatic cryoblobulinemia, membranoproliferative glomerulonephritis • Exclusions: ○ Severe renal impairment or ESRD
Oklahoma No date PA Criteria PA Form Initial Tx Pt Contract Pharmacist	Yes	Yes	No	**Treatment Regimens:** • All SOF regimens must include RBV • All FDA approved SOF regimens approved • "New regimens will apply as approved by the FDA" **Treatment Criteria:** • Age 18+ years

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Contract PA Renewal Form				• Prescribed by gastroenterologist, infectious disease specialist, or transplant specialist or pt must have been evaluated by one of these specialists w/I three months • Disease Severity: Metavir fibrosis score ≥ 2 • Pt must sign intent to treat contract • SUD: ○ Must have no illicit IV drug use or alcohol abuse in past 6 months, and agree to no usage during tx and post tx • Documented immunization against Hep A and Hep B • "All other clinically significant issues must be addressed prior to tx including but not limited to following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease" • Monthly pregnancy test • Exclusions: ○ Decompensated liver disease (CTP > 6 class B or C) ○ Pregnancy • Adherence: discontinuation of tx if tx gap > 3 days/month
Oregon 8/13/2014 PA Criteria	Yes	Yes	Yes	**Treatment Regimens:** All FDA approved regimens; SOF + SIM for interferon ineligible genotype 1 pts. **Treatment Criteria:**

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Prescribed by or in consultation with a gastroenterologist or hepatologist • <u>Disease Severity:</u> Significant liver disease defined by: ○ Severe fibrosis (≥ F4) defined by biopsy, Fibroscan, Fibrosure, or Fibrotest OR ○ Radiologic, laboratory, or clinical evidence of cirrhosis w/o decompensation (MELD score between 8 and 11, MELD score > 11 may be eligible with medical director review) OR ○ Extra hepatic manifestations (e.g., vasculitis, glomerulonephritis, cryoglobulinemia, lymphoma) OR ○ Transplant patients after medical director review • Expected survival > 5 years • <u>SUD:</u> ○ Abstinent from IV drug and marijuana use and alcohol abuse ≥ 6 months • HIV+ patients must meet other criteria and be under care of HIV specialist • Approved for 12 wks, extension of tx dependent adherence and tolerated • Exclusion: ○ Severe renal impairment of ESRD **Interferon Ineligibility Criteria:** • Previous adverse reaction / hypersensitivity to interferon • Decompensated liver disease

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Severe or uncontrolled psychiatric disorder • Autoimmune hepatitis or other autoimmune disorders • Unstable cardiac disease • Severe cytopenias • Other comorbidities that would be exacerbated by interferon use
Pennsylvania 6/2/2014 PA Criteria PA Form PA Renewal Form	Yes	Yes	Yes	**Treatment Regimens:** All FDA approved regimens and SOF + SIM for genotype 1 interferon ineligible. **Treatment Criteria:** • Age 18+ years • Prescribed by gastroenterologist, hepatologist, infectious disease specialist or transplant specialist • Disease Severity: Metavir score ≥ F3 through biopsy, blood test or fibroscan • Negative pregnancy test and monthly tests during tx • SUD: Documented abstinence from alcohol and drugs for 6 months prior to tx: ○ Hx of SUD requires blood alcohol level and urine drug screen that supports abstinence ○ If currently in treatment, evidence of tx compliance • Ribavirin requires following: ○ Platelet count ≥ 90,000 cells/mm^3 ○ Neutrophil count ≥ 1500 cells/mm^3 ○ Hemoglobin ≥ 10 g/dL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Exclusions: ○ Prior tx (failure or incomplete) with SOF ○ Severe renal disease or ESRD **Interferon Ineligibility Criteria:** • Autoimmune hepatitis or other autoimmune disorders • Hypersensitivity to interferon • Decompensated hepatic disease • Hx of depression with suicidality or resulting in hospital admission and the recipient is currently receiving antidepressant therapy • Baseline neutrophil count < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx cardiac disease
Rhode Island 9/9/2014 PDL PA Criteria	Yes	Yes	Unclear	**Treatment Regimens:** "All requests for non-FDA approved regimens will be reviewed on a case by case basis." **Treatment Criteria:** • Prescribed by gastroenterologist, hepatologist or infectious disease specialist. Other physicians may apply to state to be recognized as eligible to prescribe DAAs for hepatitis • Disease Severity: Serious liver disease defined as stage 3 or 4 fibrosis or cirrhosis demonstrated by: ○ APRI ≥ 1.0

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Metavir score ≥ 3 ○ Fibroscan ≥ 9.5kPa ○ Fibrotest ≥ 0.58 ○ Imaging study consistent with cirrhosis • <u>SUD:</u> ○ If hx of SUD, pt must be "abuse free" for 6 months prior to tx or actively participating in a SUD tx program • Pt must sign contract • Follow-up: "If requested, provider agrees to cooperate with EOHHS data collection efforts related to SVR, compliance and relapse data. Information will be used for research purpose only and in a de-identified manner." • Program transitions: "When transitioning between publicly funded delivery systems (e.g., between fee-for-service Medicaid and managed care Medicaid or between Department of Corrections and Medicaid), any authorization granted by the prior delivery system should be honored for the portion of the treatment that remains after the transition." **Interferon Ineligibility Criteria:** • Severe psychiatric disease, particularly depression with or without suicidal risk • Hx of solid organ transplant • Autoimmune hepatitis or similar disorders • Uncontrolled endocrine disorders

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Platelet count < 75,000 • Neutrophil count < 1,500 • Hemoglobin < 10 g/dL • Hypersensitivity to interferon • Presence of inflammatory bowel disease, rheumatoid arthritis, sarcoidosis or systemic lupus • Uncontrolled seizures • Hepatitis c induced cryoglobulemia
South Carolina	Yes	Unclear	Unclear	South Carolina's PDL indicates SOF requires PA; PA criteria not identified.
South Dakota No date PA Algorithm PA Form	Yes	Yes	No	**Treatment Regimens:** SOF must be given in combination with RBV or RBV + PEG **Treatment Criteria:** • Age 18+ years • Disease Severity: Pt must have "compensated liver disease" ○ Biopsy showing Metavir ≥ F2 or Ishak score ≥ F3 OR ○ "other accepted test demonstrating liver fibrosis" • Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Documentation that pt alcohol and drug free for past 6 months • SOF must be given in combination with RBV or RBV + PEG • Exclusion: ○ Serious renal impairment or ESRD

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Tennessee 9/15/2014 Interim PA Criteria (prior to PAC committee review)	Yes	Yes	No	**Treatment Criteria:** Prescribed by "physician specialist with experience in the treatment of hepatitis C infection." • Disease Severity: Fibrosis equivalent to Metavir score ≥ F3 demonstrated by biopsy or FibroScan • SUD: o No active illicit substance use or alcohol abuse during therapy as confirmed by: ▪ Validated screening instrument such as Alcohol Use Disorders identification Test (AUDIT C) or CAGE alcohol screen or NIDA's drug screening tool ▪ Alcohol consumption tests such as: serum gamma-glutamyl transpeptidase, mean corpuscular volume, carbohydrate-deficient transferrin, urine ethylglucuronide ▪ Urine toxicology screen results o With hx of SUD, confirmation the patient has completed or is participating in tx • Exclusions: o Severe renal impairment or ESRD o Decompensated cirrhosis (CTP score ≥ 6, class B or C)
Texas	n/a	n/a	n/a	No policy identified.
Utah 9/9/2014 PA Form and Criteria	Yes	Yes	Unclear	**Treatment Criteria:** Utah has no restrictive criteria.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Vermont 7/1/2014 PDL PA Form and Criteria	Yes	Unclear	Unclear	Vermont requires all hepatitis C medications to be obtained through the state's specialty pharmacy vendor. **Treatment Criteria:** "DVHA Medical Director will review case details to determine eligibility for requested medication."
Virginia 7/1/2014 PDL and Criteria	Yes	Yes	No	**Treatment Criteria:** • Age 18+ years • Prescribed by or in consultation with hepatologist, gastroenterologist, or infectious disease specialist • Disease severity: Fibrosis Metavir score ≥ F3 with evidence of diagnostic/disease severity submitted • SUD: ○ Patient must be evaluated for current history of substance abuse and alcohol abuse with validated screening instrument • Tx naïve to SOF **Response Guided Treatment Criteria:** Authorized for 8 wks of tx; renewal requires: • Documented regimen compliance through pharmacy claims history • Maintenance of alcohol/substance abstinence ("Prescriber can submit clinical rational for tx continuation for positive tests that are false positive and not thought to be due to relapse in alcohol or substance abuse.")

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Submission of lab results showing response to therapy from a CLIA-certified laboratory
Washington	Unclear	Unclear	Unclear	Discussed at June 18, 2014 P&T Committee Meeting; no criteria published.
West Virginia 9/17/2014 PA Criteria Pt Consent Form	Yes	No	Yes	**Treatment Regimens:** • Genotypes 1, 3 & 4: SOF + PEG + RBV 12 wks • Genotype 2: SOF + RBV 12 wks • Genotype 1 IFN ineligible: SOF + SIM 12 wks, SOF + RBV 24 wks • Genotypes 1-4 pre-transplant: SOF+RBV up to 48 wks *(Note: this does not include the FDA approved regimen of SOF + RBV for 24 wks for genotype 3)* **Treatment Criteria:** • Age 18+ years • Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • No prior SOF tx • Once in a lifetime SOF benefit • SUD: o Abstention from illicit drugs and alcohol for 6 months "as indicated by patient's signature on the patient consent form" • Vaccinated against Hep A and Hep B • Disease severity: o Stage F3 or greater cirrhosis as defined by biopsy or two of following:

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				▪ Cirrhotic features on imaging ▪ Ascites ▪ Esophageal varices ▪ Reversed AST:ALT ratio (>1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR>2) o Fibrosis level of F3 or greater identified by biopsy or "other accepted method (e.g., FibroSure Assay)" o NO decompensated cirrhosis (Child-Puch score > 6), severe renal impairment, or post-liver transplant • For HIV+ pts, either: o CD4 count > 500 cells/mm3 w/o antiretroviral therapy o CD4 count > 200 cells/mm3 if pt is virological suppressed (e.g., HIV RNA < 200 copies/mL) • Exclusions: o Current SUD o Decompensated cirrhosis (CTP score ≥ 6, class B or C) o Severe renal impairment or ESRD o Post-liver transplant **Response Guided Treatment Criteria:** • Initial approval for 6 wks (except transplant pts who receive 12 wks) • Renewal depends on: o Treatment adherence o Continued abstinence o HCV RNA < 25 IU/mL at 4 wks of tx

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Transplant pts must show HCV RNA < 25 IU/mL at wks 12, 24 and 36 of tx **Interferon Ineligibility Criteria:** • Intolerance to interferon from previous tx • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease • Baseline neutrophil count < 1,500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL Provider must collect HCV RNA levels at 12 wks and 24 wks post tx and submit to WV Medicaid (SVR12 and SVR24)
Wisconsin 10/1/2014 PA Form PA Form Instructions PA Criteria	Yes	Unclear	Unclear	**Treatment Regimens:** Approved tx regimens not specified. **Treatment Criteria:** • Age 18+ years • Prescribed by gastroenterologist of infectious disease provider • Disease severity: Advanced liver disease characterized by: ○ Compensated cirrhosis ○ Metavir score ≥ F3 or evidence of bridging fibrosis ○ HCC if pt is on liver transplant list ○ Serious extra-hepatic manifestations of HCV • Negative pregnancy test

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• SUD: ○ Documentation of 6 months abstinence from alcohol abuse or illicit drug use • Exclusions: ○ Significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease) ○ Decompensated cirrhosis ○ Acute HCV ○ Post liver transplant ○ Currently abusing drugs or alcohol ○ Non-compliance with treatment 9renewals only) **Response Guided Therapy Criteria:** • Initial approval for 8 wks • Additional wks if HCV RNA < 25 IU/mL **Interferon Ineligibility Criteria:** • Platelet count < 75,000/mm^3 • Severe mental health condition • Autoimmune disease • Documented IFN-related adverse events
Wyoming 9/3/2014 PA Form	Yes	Unclear	Unclear	**Treatment Regimens:** No information on approved treatment regimens available.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Treatment Criteria: • SUD: ○ No substance abuse w/I past 6 months as documented by a drug screening w/I one month • Client completion of psychosocial readiness evaluation and preparation for hepatitis C treatment survey (https://prepc.org) • Once per lifetime benefit

ALT= alanine aminotransferase; APRI= AST to platelet ratio index; ARFI= acoustic radiation force impulse imaging; AST= aspartate aminotransferase; CD4= cluster of differentiation 4; CLIA= Clinical Laboratory Improvement Act; COPD= chronic obstructive pulmonary disease; CrCl= Creatinine Clearance; CTP= Child-Turcotte-Pugh score; DAA= direct acting antiviral; DUR= drug utilization review; DVHA= Department of Vermont Health Access; dx= diagnosis; ESRD= end stage renal disease; FDA= U.S. Food and Drug Administration; FIB-4= fibrosis-4 clinical calculator; HBV= hepatitis B virus; HCC= hepato cellular carcinoma; HCV= hepatitis C virus; HIV= Human Immunodeficiency Virus; hx= history; IASL= International Association for Study of the Liver; IFN= interferon; INR= international normalized ratio; IU= international units; LLOQ= lower limit of quantification; MELD= Model End Stage Liver Disease; MRE= magnetic resonance elastography; MRI= magnetic resonance imaging; PA= prior authorization; PDL= preferred drug list; PEG= pegylated interferon; PI= protease inhibitor; pt= patient; RBV= ribavirin; RNA= ribonucleic acid; rx= prescription; SIM= simeprevir (Olysio™); SOF= sofosbuvir (Sovaldi™); SUD= substance use disorder; SVR= sustained virological response; tx= treatment; wk= week

*Treatment regimen not included in FDA approval or not for this population

[1]The SOF + SIM is an off-label combination that is currently under FDA review for approval. There are no studies on this combination treatment in HIV+ populations.

Private Payer Sovaldi Policies

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Aetna 2/2014 PA Form PA Criteria	Yes	Yes	Yes	**Treatment Regimens:** • All FDA approved regimens on list. • Also includes post liver transplant pts • SOF + SIM option for genotype 1 interferon ineligible patients and post liver transplant **Treatment Criteria:** • Disease Severity: "For initial authorization (6 week maximum) provider must submit medical records…documenting any one of the following related to staging of liver disease:" (no levels provided) ○ Metavir scores ○ Fibroscan scores ○ FibroSURE score ○ APRI score ○ Radiological imaging consistent with cirrhosis (i.e., evidence of portal hypertension) ○ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician • Exclusion: ○ HBV co-infection **Response Guided Therapy Criteria:** • Continuation of therapy contingent on HCV RNA levels decline > $\log_{10}$ IU/mL at 4 wks of therapy

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Interferon Ineligibility Criteria: • Uncontrolled seizures • Suicidal attempt within past year • Moderate to severe retinopathy • Neutrophils < 750 cells/mm^3 w/I past month • Hemoglobin < 10 g/dL w/I past month • Platelets < 50,000 cells/mm^3 w/I past month • Major uncontrolled depressive illness with supporting treatment/counseling documents • Solid organ transplant (renal, heart or lung) • Autoimmune hepatitis or other autoimmune condition • Untreated thyroid disease • Pregnant or unwilling to comply with adequate contraception • Severe concurrent medical disease such as severe hypertension, heart failure, significant coronary heart disease, poorly controlled diabetes, COPD • Age < 2 years • Known hypersensitivity to drugs used to treat HCV • Known hypersensitivity reactions such as uticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome • Hepatic decompensation CPT > 6, class B and C or CPT ≥ 6 with HIV co-infection
Cigna 10/1/2014	Yes	Yes	Yes	**Treatment Regimens:** • All FDA approved regimens listed

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Coverage Criteria				• Also includes PEG + SOF + RBV for genotypes 5 or 6 • SOF + SIM approved for tx naïve or prior relapse and interferon ineligible OR partial or null responder to PEG + RBV **Treatment Criteria:** • Disease severity: o "documentation of the degree of hepatic fibrosis (i.e. Metavir score or alternative" (no levels defined o "compensated liver disease (i.e., CTP score ≤ 6, class A) • SUD: o "Absence of active use of illicit intravenous drugs" o "Absence of active alcohol abuse" • Participation in a hepatitis C disease state management program • SOF tx naive **Interferon Ineligibility Criteria:** • Hx of intolerance to interferon • Autoimmune hepatitis or other autoimmune disorder • Hypersensitivity to PEG • Decompensated hepatic disease • History of depression or clinical features consistent with depression • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
Regence BCBS	Yes	Yes	No	**Treatment Regimens:**

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
3/14/2014 Coverage Policy				All FDA approved regimens **Treatment Criteria:** • No prior tx with PI • Disease Severity: Metavir ≥ F3 as documented by biopsy or non-invasive markers of fibrosis (ultrasound, CT scan, liver elastography, FibroScan, FIB-4 score, or other serum fibrosis marker panels) • SUD: o Documentation of no marijuana or IV drug use or alcohol abuse in past six months • Pt receives drug from pharmacy providing clinical support services o Patient intake to identify drug-drug interactions and patient specific needs or barriers to completion of HCV therapy o Issue refill reminders o Provide minimum necessary quantities while ensuring therapy is no interrupted o Demonstrate ability to dispense partial month fills o Medications must be supplied w/I 48 hours of receiving Rx order o Provide assistance to members in scheduling laboratory blood draws to measure viral response that can guide therapy and determine the need for continuing treatment o Monitor adverse effects through telephone consultation o Provide dedicated team of clinical pharmacists for 24 hr/7 day support

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Provide documentation to Rx of pt program enrollment and contacts. • SOF considered "investigational" for: ○ Monotherapy ○ Retreatment following tx failure with PI ○ Retreatment following liver transplantation **Interferon Ineligibility Criteria:** • Intolerance to IFN • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease • History of depression, or clinical features consistent with depression • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
Anthem BCBS 4/15/2014 Clinical Criteria PA Form	Yes	Yes	Yes	**Treatment Regimens:** • All FDA regimens listed • Also includes SOF + PEG + RBV for genotypes 5 & 6 • SOF + SIM for genotype 1 interferon ineligible or prior tx failure with PEG + RBV **Treatment Criteria:**

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Age ≥ 18 years • <u>Disease Severity:</u> ○ Pt must have compensated liver disease (CTP score ≤ 6, class A) ○ Biopsy proven fibrosis score ≥ F3 on Metavir, Batts-Ludwig, or IASL fibrosis staging scales ○ Biopsy proven fibrosis score ≥ F4 on Ishak staging scale ○ In absence of biopsy, fibrosis ≥ F3 on IASL, Batts-Ludwig or Metavir scales or ≥ F4 on Ishak scale based on medical imaging-proven fibrosis staging • <u>SUD:</u> ○ "Individual not actively abusing illicit drugs and/or alcohol," OR ○ "Individual receiving concurrent tx to facilitate cessation of drug and/or alcohol abuse" • Exclusions: ○ Severe renal impairment ○ Previous tx with any PI or other polymerase inhibitor (e.g., SOF) **Interferon Ineligibility Criteria:** • Intolerance to IFN • Autoimmune hepatitis and other autoimmune disorders • CTP score > 6 • Hypersensitivity to IFN

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Decompensated hepatic disease • History of uncontrolled major depression, clinical features consistent with depression or suicidal ideation • Uncontrolled epilepsy • Retinal disease • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
United Health Care	n/a	n/a	n/a	None identified

ALT= alanine aminotransferase; APRI= AST to platelet ratio index; ARFI= acoustic radiation force impulse imaging; AST= aspartate aminotransferase; CD4= cluster of differentiation 4; CLIA= Clinical Laboratory Improvement Act; COPD= chronic obstructive pulmonary disease; CrCl= Creatinine Clearance; CTP= Child-Turcotte-Pugh score; DAA= direct acting antiviral; DUR= drug utilization review; DVHA= Department of Vermont Health Access; dx= diagnosis; ESRD= end stage renal disease; FDA= U.S. Food and Drug Administration; FIB-4= fibrosis-4 clinical calculator; HBV= hepatitis B virus; HCC= hepato cellular carcinoma; HCV= hepatitis C virus; HIV= Human Immunodeficiency Virus; hx= history; IASL= International Association for Study of the Liver; IFN= interferon; INR= international normalized ratio; IU= international units; LLOQ= lower limit of quantification; MELD= Model End Stage Liver Disease; MRE= magnetic resonance elastography; MRI= magnetic resonance imaging; PA= prior authorization; PDL= preferred drug list; PEG= pegylated interferon; PI= protease inhibitor; pt= patient; RBV= ribavirin; RNA= ribonucleic acid; rx= prescription; SIM= simeprevir (Olysio™); SOF= sofosbuvir (Sovaldi™); SUD= substance use disorder; SVR= sustained virological response; tx= treatment; wk= week

*Treatment regimen not included in FDA approval or not for this population

[1]The SOF + SIM is an off-label combination that is currently under FDA review for approval. There are no studies on this combination treatment in HIV+ populations.

Table 2a.

State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ – Summary Findings

Methods

To identify states with policies for Harvoni® and Viekira Pak™, Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically available and accessible online at the time of our search (April 30-May 5, 2015). Information from state policies is summarized below and described in detail in the partner report (Center for Evidence-based Policy, 2015b). The state policies have been assessed by two Center staff members for accuracy. New or revised Harvoni® and Viekira Pak™ policies that became publically available after our search dates were excluded from our analysis.

Harvoni® and Viekira Pak™ and State Preferred Drug Lists

Preferred Drug List		
States where Harvoni® is the preferred agent	**States where Viekira Pak™ is the preferred agent**	**No stated preference between Harvoni® and Viekira Pak™**
12	**13**	**18**
AZ, CA, GA, IL, IA, NH, SD, UT, VT, VA, WA, WV	AK, AR, FL, KY, MN, MO, MT, NY, NC, SC, TN, TX, WI	AL, CO, CT, DE, ID IN, KS, ME, MD, MA, MS, NE, ND, OK, OR, PA, RI, WY

Summary of State Medicaid Medical Coverage Policies for Harvoni® and/or Viekira Pak™ Treatment of Hepatitis C

This analysis includes the 33 publicly available policies that contain detailed clinical coverage criteria for Harvoni® or Viekira Pak™ treatment for chronic hepatitis C virus (HCV) infection.

Policy Criteria		Number of States	States
Disease severity requirement			
	≥ F4	2	DE, IL
	≥ F3	17	AZ, AR, CO, FL, ID, IA, MO, NY, PA, OR, SD, TN, VT, VA, WA, WV, WI
	≥ F2	6	AK, IN, MD, NC, ND, OK
Disease severity is most often described through Metavir fibrosis scores. The scale runs from F0 to F4: F0 = no fibrosis ; F1 = portal fibrosis without septa; F2 = portal fibrosis with few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis. Even policies which generally restrict coverage based on Metavir fibrosis scores often include other disease severity criteria which would make patients eligible for treatment even with a low fibrosis score. For example, patients with extrahepatic manifestations or patients on a transplant list may be treated even if they do not meet fibrosis score criteria. See companion report (Center 2015b) for details on state policies.			
SUD criteria			
	≥ 3 months abstinence	4	AK, DE, IA, MO
	≥ 6 months abstinence	12	AZ*, CO, ID*, ME, OK, OR, PA, SD, TN, VT, WV, WI
	≥ 12 months abstinence	2	IL, ND
	States that require abstinence *OR* current enrollment in a treatment program	6	FL, GA, MN**, NC, WA**, WI
Some policies appear to require abstinence for all patients, some only for patients with a history of a SUD diagnosis, and some for patients who are currently assessed as misusing alcohol or drugs. Policies that request information on substance use but do not make clear coverage criteria are excluded from this table. *Criteria applies only to patients with a history of SUD **Patients in SUD treatment must be abstinent for at least 3 months before receiving HCV treatment			

Specialist physician requirement			
	Prescribe	8	IN, IA, MD, MS, PA, SD, TN, UT
	Prescribe or consult	16	AZ, CO, FL, ID, IL, ME, MN, NY, ND, OK, OR, VT, VA, WA , WV,WI
Once in a lifetime benefit/pt allowed only 1 treatment with DAA therapy *Once in a lifetime benefit applies to Viekira Pak only.		17	AL*, AZ, CO, FL, IL, IA, NY, NC, OK*, OR*, PA, TN, VT, VA, WV, WI, WY
Response-driven therapy (e.g., continuation dependent upon achieving early viral response)		15	AK, AZ, CO, FL, ID, MD, MA, MO, NY, NC, ND, TN, VA, WV, WI
Informed consent			
	Requires physician to certify patient has been educated on HCV treatment/other related issues	9	AL, FL, ID, ME, MN, NY, PA, VT, WA,
	Requires patient to sign formal informed consent form	7	DE, IL, NC, ND, OK, WV, WY
Require providers to collect efficacy data (SVR12, SVR24, and/or SVR52)		6	ID, IL, MN, OK, WA, WV
Requires that patient is vaccinated against Hepatitis A and B		4	AZ, CO, OK, WV

Reference

Center for Evidence-based Policy. (2015b). *State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Suggested citation: Center for Evidence-based Policy. (2015a). *State Medicaid Coverage Policies for Harvoni and Viekira Pak Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Table 2b.

State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ Treatment of Hepatitis C

Methods

To identify states with policies for Harvoni® and Viekira Pak™, Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically available and accessible online at the time of our search (April 30-May 5, 2015). Information from state policies is described in detail below and summarized in the partner report (Center for Evidence-based Policy, 2015a). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised Harvoni® and Viekira Pak™ policies that became publically available after our search dates were excluded from our analysis.

Suggested citation: Center for Evidence-based Policy. (2015b). *State Medicaid Coverage Policies for Harvoni and Viekira Pak Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

State Date of Policy Documentation Links	Notes
Alabama 2/18/2015 Harvoni PA Form Harvoni PA Instructions 2/18/2015 Viekira Pak PA Form Viekira Pak PA Instructions	**Treatment Regimens: Alabama has separate prior authorization forms and criteria for Harvoni and Viekira Pak.** General criteria for the2 drugs is the same (listed below) with only slight differences (see notes below). Alabama does not list Harvoni or Viekira Pak on its PDL. **No stated preference between Harvoni and Viekira Pak.** **Treatment Criteria:** PA form requests the following information but does not indicate approval criteria: • Clinical criteria: ○ Patient's genotype

State Date of Policy Documentation Links	Notes
	○ Cirrhosis status ○ Requested dose/duration of tx ○ For Harvoni: ▪ Indicate treatment experience ▪ For tx-naïve, non-cirrhotic patients, indicated pre-treatment HCV RNA level (*presumably for consideration of 8-wk tx)* ▪ Indicate pt's GFR ○ For Viekira Pak: ▪ Indicate if pt has known sensitivity to ritonavir ▪ Indicate if pt has decompensated liver disease or moderate to severe hepatic impairment (CTP class B or C) ▪ Review of contraindicated medications with Viekira Pak ▪ Indicate if patient has received a liver transplant w/ Metavir score ≤ 2 • <u>Disease severity:</u> "Applicable diagnostic measures for liver disease" (but no required values): ○ Metavir fibrosis score ○ CTP classification ○ ARFI ○ Abdominal imaging (ultrasound, CT, MRI) and evidence of surface abnormalities, features of portal hypertension, ascites ○ APRI ○ FibroScan value ○ FIB-4 score • <u>SUD:</u> ○ Indicate alcohol or drug use in past 6 months ○ Requires drug and alcohol screening lab report submitted with PA form • <u>Once in a lifetime benefit:</u> ○ Pt must be informed that AL policy is to cover only 1 tx regimen w/Sovaldi or Viekira Pak per

State Date of Policy Documentation Links	Notes
	lifetime • Informed consent: o Pt must be "counseled on the proposed regimen to include possible side effects that may occur" • HIV co-infection: o If co-infected, indicate whether the pt has been on a stable HIV Rx regimen for at least 8 wks o Report pt viral load & CD4 count
Alaska 1/16/2015 PA Criteria	**Treatment Regimens: Viekira Pak "first line preferred treatment."** Harvoni ("second line"), interferon-based regimens ("third line") and Olysio + Sovaldi ("fourth line") regimens allowed. **Treatment Criteria:** • Age: o 18+ years • Clinical criteria required: o Genotype and subtype o HCV viral load documented o Documentation of previous tx, whether it was completed, reasons for discontinuation, outcome of tx • Disease severity: o Metavir score F2-F4 • Specialists: o Pts with CTP score > 6, class B or C must be managed by liver disease specialist • SUD: o Abstention from illicit drugs and alcohol for minimum of 90 days as evidenced by negative urine confirmation test • HIV co-infection: o Must include CD4 count, HIV viral load, tx regimen

State Date of Policy Documentation Links	Notes
	○ For Viekira Pak, must be on stable antiretroviral regimen • Exclusions: ○ Diagnostic disease severity evidence not submitted ○ Pt not abstaining from alcohol or drugs ○ For regimens with RBV, pregnant or lactating ○ For regimens with SIM, pt not SIM-naïve ○ For regimens with SOF, pt has severe renal impairment or ESRD ○ Contraindicated drug reactions • Retreatment: Not authorized within 2 years • Authorization duration: Initial authorization 8 wks, subsequent authorization for 4 or 8 wks depending on duration of regimen • Response driven therapy: ○ For regimens longer than 8 wks, HCV RNA must be submitted for tx weeks 4 and 8 ○ HCV RNA must be < 25 IU/mL at tx wk 4, **OR** if HCV RNA detectable at wk 4, HCV RNA at wk 6 must be lower than at wk 4 or undetectable
Arizona 3/15/2015 Hepatitis C Drug PA Criteria (Sec 320-N)	**Treatment Regimens:** Sovaldi and Harvoni are the preferred agents for Hepatitis C. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ HCV genotype ○ HCV RNA level ○ Cardiac clearance for members with ischemic heart disease ○ Psychiatric clearance for pts with serious mental illness

State Date of Policy Documentation Links	Notes
	○ HIV specialist clearance for HIV coinfection ○ Lab results: ▪ Total bilirubin, albumin, INR, CL_{cr} or GFR, LFTs, and CBC within past 90 days ○ Prior tx results including HCV RNA levels at baseline, at the time of tx, and at tx discontinuation (if available) • Disease severity: ○ "Imaging evidence of cirrhosis or severe fibrosis based upon ultrasound, CT, or MRI of the abdomen describing a nodular-appearing liver, generally in combination with evidence of splenomegaly and portal hypertension," **OR** ○ MRE ≥ 11 kPa, **OR** ○ Liver biopsy w/ Metavir score ≥ F3, **OR** ○ FibroSURE ≥ 0.58, **OR** ○ Extraheaptic manifestations including leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease • Specialists: ○ Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Baseline alcohol/drug screen within 30 days ○ If member has a hx of SUD in past 12 months, must be in remission for at least 6 months prior to tx ○ Random drug/alcohol screens for pts with hx of SUD • Vaccinations: Pt must have hepatitis A and B vaccinations • Once in a lifetime benefit: ○ No prior tx with SOF or SIM ○ 1 course of therapy per lifetime • HIV co-infection:

State Date of Policy Documentation Links	Notes
	○ CD4 count > 500 cells/mm3 if member is not taking antiretroviral therapy, **OR** ○ CD4 count > 200 cells/mm3 if member is virologically suppressed (e.g., HIV RNA < 200 copies/mL) • Exclusions: ○ HCV-5 and -6 ○ Documented non-adherence to prior HCV tx ○ Member declines to participate in "treatment adherence program" ○ Decompensated liver disease (CTP > 9) ○ MRE score < 11 kPa ○ Metavir score < F3 ○ FibroSURE score < 0.58 ○ Current use of P-gp inducer drugs ○ Severe renal impairment or ESRD ○ Post-liver transplant tx • Adherence: ○ Members prescribed SOF or SIM "must participate in a treatment adherence program" • Response driven therapy: ○ HCV viral load testing at 4 wks for 12-wk regimen and 4 and 12 wks for 24-wk regimen ○ If viral load is undetectable, tx continues ○ If viral load is low but detectable, test again ○ If viral load is still detectable (>100 IUs), tx discontinued
Arkansas 3/12/15 PA Form PA Criteria	**Treatment Regimens:** Viekira Pak, Harvoni, or Sovaldi prescribed according to FDA criteria. **Harvoni is only an option for 8-week tx (when appropriate); otherwise, Viekira Pak is preferred for other HCV-1 pts. Sovaldi prescribed for HCV-2, -3, -4.** **Treatment Criteria:** • Clinical criteria

State Date of Policy Documentation Links	Notes
	○ Liver biopsy required for all requests ○ Patient's genotype and subgenotype ○ Prescribed medication dependent on: ▪ Cirrhosis status ▪ Prior treatment history • Disease severity: ○ Metavir ≥ F3 OR ○ Pre-liver transplant pt OR ○ Severe extrahepatic hepatitis C complications (case by case review) • HIV co-infection: ○ If co-infected, will receive Viekira Pak treatment ○ Should refer to drug interactions for dosage recommendations for concomitant HIV-1 antiviral drugs. • Exclusions: ○ Pts with HCV-5, -6
California 6/30/2014 Policy Web Page Tx Policy Tx Regimen Chart Tx Algorithm	**Treatment Regimen:** "Effective Jan 1, 2015 Sovaldi and Harvoni are on the Medi-Cal Contract Drugs List." *New policy issued July 1, 2015 and not described here. Link:* *http://www.dhcs.ca.gov/Documents/Hepatitis%20C%20Policy.pdf* **Clinical Criteria:** • Age: ○ 18+ years • Clinical criteria required (but no approval standards specified): ○ Tx history ○ RNA level and HCV genotype ○ Documentation of cirrhosis status

State Date of Policy Documentation Links	Notes
Colorado 3/1/2015 Viekira Pak PA Form Sovaldi/Harvoni PA Form 4/1/2015 PDL	**Treatment Regimen:** All treatments will continue to be approved on a "case by case basis" during an interim period until final criteria and treatment rollout go into effect October 2015. **No tx preference stated.** **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ HCV-1a or -1b ○ Physician attest to pt readiness for adherence ○ Physician attest to significant health impact if treatment is delayed ○ Tx-naïve with DAA ○ Baseline HCV RNA and ALT levels w/in 30 days of start date • Disease severity ○ Extrahepatic manifestation of HCV (leukocytoclasic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease), **OR** ○ Compensated cirrhosis defined by CTP class A; or CTP class B AND on transplant list with projected time to transplant < 1 year, **OR** ○ Transplant pt with fibrosing cholestatic HCV or a pt with cirrhosis from recurrent HCV who has been approved for re-transplantation, **OR** ○ Pt on the transplant list with a projected time to transplant of < 1 year, **OR** ○ Metavir ≥ F3 • Specialists: ○ Prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist

State Date of Policy Documentation Links	Notes
	• SUD: ○ 6 months free of alcohol, marijuana and other Schedule I controlled substances, cocaine, and opiate misuse ○ Monthly screens for pts with a prior history (2 years) of drug/alcohol/opioid abuse • Vaccinations: ○ Must have or plan to get hepatitis A and B vaccinations • Once in a lifetime benefit: ○ One course of DAA therapy per lifetime • HIV co-infection ○ Harvoni: Must be HIV-negative and hepatitis B-negative ○ Viekira Pak: May be HIV-positive • Exclusions ○ Pts not abstaining from alcohol or drugs ○ Pts with severe renal impairment (eGFR < 30 ml/min/1.73m2), ESRD, or on hemodialysis ○ Prior DAA treatment ○ Pts currently taking contraindicated medications • Birth control/pregnancy: ○ Women and their partners must use 2 forms of contraception ○ Pregnancy test required prior to beginning therapy • Adherence: ○ Adherence monitored based on prescription fills (must be filled w/in 7 days); treatment will be discontinued with non-adherence ○ Pts must receive refills within 1 week of completing the prior fill • Response-driven therapy ○ All approvals initially for an 8-week time period ○ Further approval dependent on RNA level testing at wks 4, 12, and 24 ○ If viral load is detectable while on Viekira Pak or Harvoni, test again in 2 weeks

State Date of Policy Documentation Links	Notes
	○ If viral load has increased, all treatment discontinued unless documentation provided to support therapy continuation ○ For Sovaldi regimens, if HCV RNA is above the lower limit at wks 4, 6 (if applicable), and 12 (if applicable), all treatment will be discontinued
Connecticut 1/2015 PDL 1/2015 Sovaldi PA Form	**Treatment Regimen:** Effective 7/1/2015, Harvoni, Peg-Intron, and Viekira Pak are additions to the PDL. No additional criteria found for approval of Harvoni and Viekira Pak. Sovaldi PA identified.
Delaware 05/2015 PA Criteria and Form 4/9/2015 PDL (pg 21)	**Treatment Regimen:** Both Harvoni and Viekira Pak are preferred; only FDA-approved regimens allowed. **Treatment Criteria:** • Clinical criteria: ○ HCV RNA level ○ Documentation of prior tx • Disease severity: For all DAAs ○ Metavir ≥ F4 based on liver biopsy or "other objective laboratory test," **OR** ○ Documented cirrhosis through ultrasound or CT scan with extrahepatic manifestations, or clinical findings such as the presence of ascites • SUD: ○ Documented abstinence from illegal substance or alcohol use for 90 days prior to therapy ○ Drug screen required • Informed consent:

State Date of Policy Documentation Links	Notes
	○ Pts sign informed consent addressing need for tx adherence, RBV side effects, commitment to contraception and risk of birth defects, avoidance of drugs and alcohol. • HIV co-infection: ○ Submit medication regimen ○ Undetectable viral load or CD4 count ≥ 350 cell/uL • Birth control/pregnancy: ○ Informed consent includes commitment to birth control without regard to tx regimen
Florida Drug Criteria Page 11/12/2014 Harvoni PA Form 4/21/2015 Harvoni PA Criteria 4/30/2014 Viekira Pak PA Form 4/28/2015 Viekira Pak PA Criteria	**Treatment Regimens:** Viekira Pak preferred; Harvoni approved when Viekira Pak is contraindicated. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria: ○ HCV genotype lab documentation ○ Quantitative viral load ○ Drug and alcohol test results, or medically documented addiction therapy or services. • Disease severity: ○ Treatment determined by the test results of : ▪ Metavir score (≥ F3) ▪ FibroScan score (≥ 9.5) ▪ FibroTest score (≥ .58) ▪ APRI score (≥ 1.5) • Specialists: ○ Prescribed by or in consultation with a hepatologist, gastroenterologist, infection disease specialist, or transplant physician • SUD:

State Date of Policy Documentation Links	Notes
	○ Drug test confirming no illicit drug or alcohol use in the previous month ○ Test results submitted with therapy request ○ Or, patient is receiving substance or alcohol abuse counseling services, or seeing an addiction specialist (medically documented) • Once in a lifetime benefit: ○ Harvoni: Tx-naïve to ledipasvir or Sovaldi ○ Viekira Pak: Tx-naïve to dasabuvir/ombitasvir/paritaprevir, Sovaldi with or without ledipasvir, and Olysio therapy. ○ Viekira Pak: Tx-experienced pts are those who tried and failed tx with PEG and RBV-based therapy. • Informed consent: ○ Patient must commit to course of treatment, blood test, and visits that will occur before and after treatment. • HIV co-infection: ○ Viekira Pak approved for HIV+ pts with HCV-1a or -1b • Exclusions: ○ Signs of risky behaviors ○ Decompensated cirrhosis (CTP score > 6) ○ HCV-2, -3, -4, -5, or -6 ○ For Harvoni: Post-liver transplant ○ For Viekira Pak: Positive pregnancy test • Birth control/pregnancy: ○ Viekira Pak (with RBV): Female pts required to have a negative pregnancy test w/in 30 days of starting therapy. • Authorization duration: ○ No early refills due to lost, stolen or vacation override • Adherence:

State Date of Policy Documentation Links	Notes
	○ Viekira patients have access to personalized adherence support system • Response-driven therapy: ○ Initial review: 1 month ○ For 8- and 12-week treatments, reauthorization occurs at 4 weeks to determine response to therapy For 24-week tx, reauthorization occurs at 4 and 12 wks ○ Lab results collected 2 or more weeks after the first prescription fill date must indicate a response to therapy (RNA < 25 IU/mL) for subsequent reauthorization ○ Continuation of treatment may be authorized for pts who are **100% compliant** as verified by the medication fill history
Georgia 2/25/2015 Hepatitis C Agents PA Criteria	**Treatment Regimens: Harvoni is preferred over Viekira Pak;** Viekira Pak or Sovaldi should only be prescribed when pts cannot take or tolerate Harvoni. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Must be diagnosed with chronic HCV; HCV-1 only, subtype recorded ○ Viekira Pak: to qualify for tx, must also have compensated liver disease • SUD: ○ Pts who abuse alcohol or IV drugs must be enrolled in a substance abuse program • Transplant: ○ Pts who are transplant recipients must have normal liver function and can have up to mild fibrosis • Exclusions: ○ HCV-2 through HCV-6
Hawaii	n/a

State Date of Policy Documentation Links	Notes
No information available	
Idaho 4/24/15 PA Criteria	**Treatment Regimens: Harvoni, Olysio, Sovaldi, Viekira Pak.** **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ HCV genotye 1,2,3 or 4 or hepatic carcinoma secondary to HCV awaiting liver transplantation ○ Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count and negative pregnancy test (if applicable) ○ Previous history of HCV treatment (tx-naïve or treatment experienced) ○ Healthcare provider must submit a SVR at week 12 and week 24 after successful completion of treatment • Disease severity: ○ Liver biopsy with a Metavir stage F3-F4, **OR** ○ Batts-Ludwig scale 3-4, **OR** ○ FibroScan measurement > 12.5 kPa, **OR** ○ ARFI value > 1.75, **OR** ○ Radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly, **OR** ○ APRI score > 1.5 OR FIB-4 > 3.25 and serious extrahepatic manifestations of hepatitis C ○ FibroSURE, FibroTest, and FIBROSpect are not recommended for routine use in the diagnosis of cirrhosis • Specialist: ○ Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or a liver transplant physician

State Date of Policy Documentation Links	Notes
	• SUD: ○ "Patient has no history of alcohol or substance abuse within the 6 months prior to treatment," **OR** ○ Patients with a history of intravenous drug/substance abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence ○ Negative urine toxicology and blood alcohol laboratory test within 1 month of request ○ Patients with a history of substance/alcohol abuse will require monthly random urine toxicology and blood alcohol screening while on treatment • Informed consent: ○ "Documentation that the provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment" • Exclusions: ○ Non-FDA approved combinations/dosing regimens ○ Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2) ○ Pt will be excluded if there is "documented ongoing non-adherence to prior medical treatment or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment" ○ History of intravenous drug abuse/alcohol dependency/substance abuse WITHOUT documented evidence of successful completion of 6 months of abstinence ○ Co-administration with drugs that are contraindicated with hepatitis C agent requested ○ Decompensated liver disease ○ Viekira Pak: moderate to severe hepatic impairment (CTP class B or C) for Viekira Pak ○ Sovaldi / Harvoni: Severe renal impairment or hemodialysis • Birth control: ○ Prescriptions with RBV: Pregnant women or those who may plan to become pregnant during the course of treatment are excluded • Adherence: ○ Adherence counseling performed; documented understanding by pt

State Date of Policy Documentation Links	Notes
	○ Pt will be excluded if there is documented ongoing non-adherence to prior medical treatment or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment ○ "Hepatitis C agents not recommended in patients with a history of relapse" ○ Failure to complete HCV disease evaluation appointments and procedures will result in discontinuation • Response-driven therapy: ○ Provider must submit viral count at 2, 4, and 8 weeks for 12- or 24-week tx regimens ○ Requests for renewal will be denied in pts who have not achieved RNA below the limit of detection after 4 weeks of therapy or who have not demonstrated a 1-log decrease in HCV RNA after 3 wks ○ All treatment must be discontinued if HCV RNA > 25 IU/ml at week 4 or any time after • Post-tx reporting: ○ Provider must submit SVR12 and SVR24 after completion of treatment
Illinois 1/2015 PA Criteria PA Form *Added Criteria: No Date* Harvoni PA Criteria Viekira Pak PA Criteria	**Treatment Regimens:** Harvoni and Sovaldi preferred. Viekira Pak is not preferred: "Patient must have documented clinical evidence supporting use of Viekira Pak over preferred agents." **Treatment Criteria:** • Age: ○ 18+ years • Clinical Criteria Required: ○ HCV-1, -2, -3, or -4 (including subtype for Viekira Pak) ○ Baseline HCV-RNA levels • Disease severity: ○ Stage 4 hepatic fibrosis documented by: ▪ Liver biopsy Metavir = F4, **OR** ▪ FibroScan score ≥ 12.5 kPa,**OR** ▪ FibroTest score ≥ 0.74, **OR**

State Date of Policy Documentation Links	Notes
	▪ APRI score > 2.0, **OR** ▪ Radiological imaging consistent w/cirrhosis (e.g., evidence of portal hypertension), **OR** ▪ Physical findings or clineical evidence consistent with cirrhosis • Specialists: o Prescribed by or in consultation within 3 months with a gastroenterologist, transplant hepatologist, infectious disease specialist • SUD: o Documented negative standard urine drug screen w/in 15 days of PA submission o No evidence of active SUD within 12 months; if existed, must submit 2 consecutive months of negative standard urine screen • Once in a lifetime benefit: o Once in a lifetime benefit for all newer DAAs • Informed consent: o Pt must sign tx plan showing commitment to dosing plan and schedule, schedule for refills, and information on how to reduce risk of exposure/transmission of disease • Exclusions: o Cancer, except HCC cleared for transplant o Pt with decompensated liver disease as defined by CTP class B or C. o Pts currently prescribed contraindicated medications o Terminal disease with life expectancy < 12 months or in hospice o Harvoni/Sovaldi: ▪ Pt with ESRD requiring dialysis ▪ Pt with GFR < 30 mL/min/1.73m2 • Birth control/pregnancy: o Viekira Pak: If taken with RBV, female pts must have a negative pregnancy test within the previous 30 days and monthly therefore during treatment, and male pts must not have a pregnant partner

State Date of Policy Documentation Links	Notes
	and must agree to use "adequate contraception" during treatment ○ Harvoni: In pregnant women, documentation is provided justifying potential benefits and risks to the fetus • Adherence: ○ Non-compliance or failure to fill Rx will result in termination of tx • Post-tx reporting: ○ Must submit HCV RNA levels w/l first 8 wks of tx, at completion, and SVR12 and SVR24
Indiana 4/1/2015 PDL PA Criteria PA Form	**Treatment Regimens:** Policy allows prescription of Harvoni, Viekira Pak, Sovaldi,, telaprevir, or boceprevir with criteria varying by medication. Criteria below applies to Harvoni and Viekira Pak. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria: ○ HCV-1 • Disease severity: ○ > stage 2 fibrosis, **OR** ○ co-infection with HIV or AIDS, **OR** ○ post-liver transplant • Specialists: ○ Prescription must be written by an infectious disease specialist or gastroenterologist • HIV co-infection: ○ Either Harvoni or Viekira Pak approved for HIV co-infection • Birth control/pregnancy: ○ Women must confirm negative pregnancy test prior to therapy • Authorization duration:

State Date of Policy Documentation Links	Notes
	○ Up to 12 wks • Adherence: ○ Re-approval contingent on confirmed compliance
Iowa 6/1/2015 PA Criteria (p.18) PA Form	**Treatment Regimens: Sovaldi w/ RBV (and when appropriate, PEG)** is the primary treatment for pts with HCV-1 through -4 and pts with HCC (awaiting liver transplant). **Harvoni** is only used if PEG is contraindicated in pts with G1. Viekira Pak is not mentioned. **Treatment Criteria:** • Age: ○ 18+ • Clinical criteria: ○ Prior tx history (tx naïve, prior null responder, partial null responder, relapse) ○ If prior tx failure is due to non-compliance, documentation that steps to address and correct the causes of non-compliance is required ○ Viral load within 6 months of beginning therapy • Disease severity: ○ Documentation of ≥ stage 3 fibrosis confirmed by a liver biopsy • Specialist: ○ Prescriber is an infectious disease specialist, gastroenterologist, hepatologist, or other hepatitis specialist • SUD: ○ Abstinence from illicit drugs or alcohol in the 3 preceding months, indicated by a negative urine test • Once in a lifetime benefit: ○ Excluded if previously received protease inhibitor treatment • HIV co-infection:

State Date of Policy Documentation Links	Notes
	○ Sovaldi prescribed if HIV + - • Birth control/pregnancy: ○ Female pts must not be pregnant, and male pts must not have a pregnant partner ○ Both men and women pts must use 2 forms of effective contraception during tx and for at least 6 months after tx has concluded ○ Documentation of monthly pregnancy tests • Quantity limit: ○ Lost or stolen medication replacement requests will be denied ○ 72-hour emergency supply rule does not apply • Exclusions: ○ Previous non-compliance, without documentation indicating this behavior has been addressed and corrected ○ Pt has previously tried or failed therapy with a protease inhibitor ○ Pt receiving dialysis ○ Pt has decompensated cirrhosis ○ HCV-5 or 6
Kansas DUR Agenda	**Treatment Regimens:** As of June 1, 2015, Harvoni and Viekira Pak are preferred, and Sovaldi is non-preferred for HCV-1. No prior authorization criteria available.
Kentucky PDL	**Treatment Regimens: Viekira Pak is the preferred DAA**; Harvoni is not preferred. Clinical PA is required, and there is a quantity limit. No prior authorization criteria identified
Louisiana P&T Agenda	**Treatment Regimens:** HCV drugs considered at May 6, 2015 Pharmaceutical and Therapeutics Committee; no prior authorization criteria identified.
Maine 3/23/2015	**Treatment Regimens: Harvoni, Viekira Pak and Sovaldi regimens allowed.** **Treatment Criteria:**

State Date of Policy Documentation Links	Notes
PA Form	• Clinical criteria required: ○ Active infection verified by viral load in the past year (must report genotype, Metavir score) • Disease severity: ○ Metavir score and method used (doesn't specify score criteria) ○ $CL_{cr} \geq 30mL/min$; creatinine levels taken within the past 6 mo • Specialist: ○ Prescriber is consulting, or has consulted with, a gastroenterologist, hepatologist, infectious disease specialist, or other hepatitis specialist. • Informed consent: ○ Counseling must be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission • SUD: ○ Documentation that the pt has not abused drugs or alcohol in the past 6 months ○ Must submit urine drug screen for members with history of drug abuse other than alcohol ○ Counseling must be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission • Birth control/pregnancy: ○ For any regimen that includes RBV: ▪ Patient is not pregnant (or, if male, does not have a pregnant female partner) and is not planning to become pregnant during treatment or within 6 months of stopping ▪ Agreement that partners will use 2 forms of effective contraception during treatment and for at least 6 months ▪ Verification that monthly pregnancy tests will be performed throughout treatment • Exclusions: ○ Pt not receiving dialysis ○ Pt currently taking a contraindicated medication • Authorization duration:

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	○ PA form covers up to 12 weeks of therapy; only a 14-day supply will be allowed for the first fill • Adherence: ○ Documentation of adherence (viral load changes or progress notes on compliance) are required for refill
Maryland 1/2015 PA Criteria Sample Treatment Plan PA Form	**Treatment Regimens:** Approved treatment includes Harvoni, Harvoni + RBV, Viekira Pak, and Viekira Pak + RBV, all for either 12 or 24 weeks; 8-week Harvoni may be permitted. Sovaldi-based regimens for HCV-2, -3, and -4. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Baseline HCV RNA level w/in 60 days of anticipated start • Disease severity: ○ Metavir score of ≥ 2 demonstrated by a liver biopsy or other accepted test • Specialist: ○ Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Form requires information on hx of drug/alcohol abuse, whether pt has been abstinent for 6 months or is currently in tx; coverage criteria not specified • Birth control/pregnancy: ○ If using RBV, pt or partner must use 2 forms of contraception ○ Viekira Pak w/ RBV for female pts who are pregnant or may become pregnant; male pts whose partners are pregnant are excluded • HIV co-infection: ○ Harvoni or Viekira Pak allowed ○ HIV+ pts treated with Viekira Pak should also be on suppressive ARV drugs to reduce risk of HIV

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	protease inhibitor drug resistance • Exclusions: o Pt receiving concomitant therapy w/ a hepatitis protease inhibitor o ESRD requiring hemodialysis o Viekira Pak : pt receiving concomitant therapy w/ HCV polymerase inhibitor or NS5A inhibitor o Viekira Pak : pts with severe hepatic impairment / CTP class C secondary to risk of potential toxicity; not recommended for pts with moderate hepatic impairment/CTP class B o Harvoni: pts using P-gp inducers o Harvoni: Severe renal impairment • Authorization duration: o 8 wks • Adherence: o Initial therapy approved for 8 weeks o Authorized for additional 8-week period at a time o Must receive refill within 7 days of completing prior supply • Response Driven Therapy: o Virologic response is measured at 4, 12, and 24 (if applicable) weeks of therapy, and 12 weeks after therapy ends o Treatment should be discontinued when: ▪ Treatment 4 weeks: < 2 log reduction in RNA from baseline ▪ Treatment 12 weeks: any detectable HCV RNA level ▪ Treatment 24 weeks: any detectable HCV RNA level
Massachusetts 3/2015 PA Form	**Treatment Regimens:** Both Harvoni and Viekira Pak used; **12 wk RBV + Harvoni preferred** to 24-wk Harvoni or 24-wk Viekira Pak for tx-experienced pts with compensated liver; **8-wk Harvoni preferred** to 12-week Viekira Pak (tx-naïve, no cirrhosis).

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Clinical Information Drug List	**Treatment Criteria:** • Age: ○ + 18 years • Clinical criteria required: ○ Diagnosis of chronic HCV-1 ○ Baseline viral load ○ Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, FibroScan, FibroSURE, FIB-4) • Disease severity: ○ Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, FibroScan, FibroSURE, FIB-4) ○ No exclusion based on Metavir score; states guidelines based on if Metavir score is 0-2 or 2-4. • Exclusions: ○ Excluded from Viekira Pak if pt previously treated with HCV protease inhibitor • Response-driven therapy: ○ Tx naïve pts: Tx discontinued if viral load is detectable at wk 4 and has increased by > 10-fold (> 1 $\log_{10}$ IU/mL) on repeat testing at wk 6 ○ Tx experienced pts: For continuation of treatment beyond 12 weeks, lab values at 4 weeks and 6 weeks (if detected at 4 wks) must support continued use
Michigan Drug Info Page	**Treatment Regimens:** As of May 5, 2015 search on Magellan's Michigan Medicaid Drug LLookup, neither Harvoni or Viekira Pak are covered.
Minnesota 4/2015 PA Form	**Treatment Regimens: Viekira Pak is preferred ;** Harvoni, Olysio, and Sovaldi are listed as "non-preferred drugs." Treatment with SIM + SOF not allowed. **Treatment Criteria:**

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PA Criteria	• Age: ○ 18+ years • Clinical criteria for Viekira Pak: ○ "At the time of treatment initiation, pt has evidence for FFS health insurance coverage for the duration of tx" ○ Documentation of genotype and subtype ○ Pre-treatment detectable RNA viral load measured w/in 1 year of tx start date. ○ Notes of specialist consultation attached to authorization request ○ Treating clinician attest patient has been evaluated for "readiness" of treatment, including potential impediments to effective treatment • Non-preferred drugs: Clinical criteria/severity required (Harvoni, Olysio, Sovaldi): ○ Pt has met the preferred drug authorization criteria, **AND** ○ Pt has HCV-1, -2, -3, -4 or HCV-1 with contraindication to Viekira Pak, **AND** ○ Pt has at least 1 condition listed below: 1. Decompensated liver disease (CTP class B/C and MELD ≤ 20) 2. Abdominal imaging suggestive of cirrhosis 3. Evidence from at least 1 non-invasive test a. APRI ≥ 1.5, b. FibroSURE ≥ 0.49, c. FibroScan ≥ 7.1, d. FIB-4 > 3.25 e. MRE ≥ 6 kPa f. FIBROSpect ≥ 42 4. Biopsy ≥ F3 5. HCV infection with post solid organ transplant, awaiting liver transplant, stage I-III HCC, post-liver transplant, severe complications from HCV of Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations, **OR** HCV-induced renal disease

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	• Disease severity: ○ None provided for preferred drug (Viekira Pak) • Specialist: ○ Prescribed by, or in documented consult with, a gastroenterologist, hepatologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis • SUD: ○ If pt has a history of alcohol abuse, must be abstinent 6 mo prior. Exceptions include: ▪ Pt is 3 mo abstinent, receiving treatment at an approved facility, and agrees to abstain during tx, **OR** ▪ Pt is under the care of an addiction medicine/chemical dependency treatment provider and provider attests pt agrees to abstain during tx ○ If pt has a history of IV drug use, must be abstinent 6 mo prior to starting tx. Exceptions include: ▪ Pts who have abstained for 3 mo and are receiving chemical dependency tx (addiction medicine specialist/buprenorphine waived provider), **AND** ▪ The chemical dependency provider can attest to 3 mo abstinence, **AND** ▪ Pt must agree to a urine tox screen w/I 30 days of starting tx • Informed consent: ○ Provider must attest pt is "ready" for tx "including identification of potential impediments to effective tx (e.g., difficulties with compliance, missing appointments, adequate social support, adequate control of mental health conditions, alcohol use disorder, IV drug use). Potential impediments to successful tx must be addressed in tx notes prior to initiating tx and submitted with authorization request." • Exclusions: ○ Pts deemed by treating clinician unable to adhere to tx ○ HCV-5 or -6 ○ Creatinine clearance (CL_{cr}) < 30 mL/min or on hemodialysis ○ Severe end organ disease and not eligible for transplant (liver, heart, lung, kidney)

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	○ Clinically significant illness or any other major medical disorder that may interfere with patient's ability to complete a course of tx ○ Pts determined by the primary clinician to "not achieve a long-term clinical benefit" (i.e. receiving palliative care, multisystem organ failure, etc.) ○ Viekira Pak: Decompensated liver disease CTP score > 12 or MELD > 20 ○ MELD <20 and either intrahepatic cholangiocarcinoma, HCC with metastatic spread, malignancy outside the liver not meeting oncologic criteria for cure, cardiopulmonary disease that cannot be corrected, hemangiosarcoma • Birth control/pregnancy: ○ Viekira Pak: Pregnant pts excluded • Adherence: ○ Treating clinician must assess pt ability to adhere (control of mental health illness, adequate social support, etc); impediments must be addressed in tx notes and submitted with authorization request • Post-treatment reporting: ○ Provider must submit SVR12 results to the Department
Mississippi 4/17/2015 PDL P&T Committee Minutes	**Treatment Regimen: Viekira Pak, Harvoni, and Sovaldi are all preferred agents.** Manual PA required; no detailed coverage criteria identified besides: • Specialist: ○ "Restricted to infectious disease and hepatologist specialsts."
Missouri 1/8/2015 PDL	**Treatment Regimen: Viekira Pak preferred** to Harvoni, Olysio, or Sovaldi**.** Viekira Pak prescribed for 12 or 24 weeks depending on prior tx history. Viekira Pak tx requires RBV for HCV-1a with or without cirrhosis and HCV-1b with cirrhosis

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	Treatment Criteria: • Age: o 18+ years • Clinical criteria required: o Viekira Pak and Harvoni: HCV-1 o Baseline viral load o For non-preferred medications: Trial and failure of Viekira Pak • Disease severity: o Fibrosis score ≥ F3 (for HCV-3, fibrosis ≥ F2) • SUD: o Negative urine alcohol and illicit drug screen results for 3 mo prior o Any evidence of alcohol or drug use during tx will result in discontinuation • Once in a lifetime benefit: o No: If pt fails Viekira Pak treatment, eligible for Harvoni tx • Birth control/pregnancy: o Pregnant pts excluded • Quantity limit: o 28-day supply, no more than a 7-day gap between prior and incoming claims • Exclusions: o Lack of approval criteria o Pregnant pts o HCV-5 or -6 o Metavir score < F3 o Viral load > 25 IU/mL at tx wk 4 or beyond • Adherence:

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	○ Tx withdrawn if there is a gap in therapy > 7 days from prior claim • Response-driven therapy: ○ Viral load submitted at wk 12 and 24; viral load at wk 12 must be < 25 IU/mL if tx duration is 24 weeks ○ Tx discontinued if viral load > 25 IU/mL at treatment week 4 or beyond
Montana 5/1/2015 PDL	**Treatment Regimen: Viekira Pak preferred** to Harvoni, Sovaldi, Olysio, and Victrelis. Prior authorization criteria not identified.
Nebraska Drug Lookup	**Treatment Regimen**: Nebraska Medicaid's Magellan Drug Lookup identifies both Harvoni and Viekira Pak as covered with required PA. Prior authorization criteria not identified.
Nevada 1/1/2015 PDL	**Treatment Regimen: Sovaldi, Olysio listed as preferred agents**. No mention of Viekira Pak or Harvoni.
New Hampshire 2/13/2015 PDL PA Form	**Treatment Regimen: Harvoni preferred to Sovaldi**; no mention of Viekira Pak on PDL. Prior authorization criteria not identified.
New Jersey	**Treatment Regimen:** New Jersey has managed care for pharmaceutical benefits. No information available.
New Mexico	**Treatment Regimen:** New Mexico is a managed care state. No information available.
New York	**Treatment Regimen: Viekira Pak preferred.**

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Approved Prescriber List 4/9/2015 PDL 1/2015 PA Checklist Harvoni PA Worksheet 2/2015 Viekira Pak Worksheet	**Treatment Criteria:** • Clinical criteria required: o HCV genotype test results o Baseline RNA within 3 months of initiating therapy o Liver fibrosis evaluation o Tx history o Documentation of extra-hepatic manifestations o Documentation of concomitant conditions/comorbidities • Disease severity: o Evidence of stage 3 or 4 hepatic fibrosis confirmed by liver biopsy, FibroScan ≥ 9.5, FibroSURE ≥ .58, APRI > 1.5, or radiological imaging consistent with cirrhosis o Liver transplant o Other coexistent liver disease o Type 2 diabetes mellitus (insulin resistant) o Debilitating fatigue impacting quality of life • Specialist: o Therapy must be prescribed by a specialist, or a health care practitioner experienced and trained in the treatment of HCV, or a practitioner under the supervision of a specialist ▪ Non-specialists must fill out additional Medicaid authorization forms and must have 1) experience managing and treating at least 10 pts with HCV in the past year and 2) 10 HCV-related CME credits in the past year • Once in a lifetime benefit: o Maximum 12 wks (or 24 wks, if 24-wk regimen is prescribed) over beneficiary lifetime • Informed consent: o Provider must use "scales/assessment tools to evaluate the readiness of the patient," including SAMHSA/HRSA Drug & Alcohol Screening Tools or Psychosocial Readiness Evaluation and

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	Preparation for Hepatitis C Treatment (http://prepc.org/) • Co-infection: ○ Test for HBV co-infection • Birth control/pregnancy: ○ Viekira Pak: a negative pregnancy test must be collected within 30 days of initiating tx • Response-driven therapy: ○ Viral load confirms no detectable HCV RNA levels (or a ≥ 2 log reduction) before week 4 (for 12-wk tx) or before week 12 (for 24-wk tx) and submitted prior to additional approval
North Carolina 3/23/2015 PA Criteria 4/27/2015 PDL	**Treatment Regimen: Viekira Pak is the preferred treatment.** **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Diagnosis chronic HCV with genotype and subtype ○ Baseline HCV RNA tested within the past 6 mo ○ Provider "must be reasonably certain tx will improve beneficiary's overall health status" • Disease severity: ○ Any one of these can be submitted as documentation: ▪ Metavir scores (≥F2) ▪ Batts-Ludwig scores (≥F2) ▪ IASL scores (≥F2) ▪ Ishak scores (≥F3) ▪ FibroScan score ▪ FibroSURE score ▪ APRI scores

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	▪ Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension) ▪ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician • SUD: o Pts with a history of alcohol or IV drug use must commit to abstinence o Pts with a recent history of alcohol or IV drug use (within1 year) requires enrollment in tx program **AND/OR** counseling **AND/OR** support group o Must agree to toxicology/alcohol screens (as needed) o Pts with signs of high-risk behavior (IV drug use, recurring alcoholism) will not be reauthorized • Informed consent: o Provider must complete a Beneficiary Readiness Evaluation with the pt ▪ The Beneficiary Readiness Evaluation includes directions for the provider to educate the pt about the risks of drug and alcohol abuse and includes 6 questions about drug use history, metal health, and social support ▪ In addition to SUD-related requirements, a mental health consult is required if mental health conditions are untreated ▪ Patient signs to indicate understanding of compliance expectations • Once in a lifetime benefit: o Pt will be denied coverage if the pt is requesting re-treatment and either failed to achieve a SVR (25 IU/mL) or relapsed after achieve a SVR during a previously completed Sovaldi regimen o Pt will be denied coverage if previously attempted a course of therapy with recommended drug • Transplant: o Viekira Pak approved for liver transplant recipients with fibrosis ≤ F2 • Exclusions: o Lab results indicate no response to therapy o Signs of high-risk behavior o Failure to complete HCV disease evaluation appointment and procedures

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	○ Non-compliance to regimen ○ Previously attempted therapy course ○ Viekira Pak: Pt requires dialysis ○ Viekira Pak: Used in combination with other protease inhibitors or with Sovaldi, or with another NS5A or NS5B inhibitor ○ Viekira Pak: Decompensated liver disease (CTP class B or C) • Authorization duration: ○ 8 wks • Adherence: ○ Provider must complete a Beneficiary Readiness Evaluation with the pt meeting ALL of the criteria (see informed consent) ○ Pts who show signs of high-risk behavior, fail to complete disease evaluation appointments and procedures, and are not compliant to regimen will be denied reauthorization • Response-driven therapy: ○ Lab results collected 4 or more wks after the first prescription fill date must indicate a response to therapy of ≥ 2 log reduction in HCR RNA or HCV RNA < 25 IU/mL
North Dakota Harvoni PA Form Harvoni Authorization Algorithm Viekira PA Form Viekira Pak Authorization Algorithm	**Treatment Regimens: Viekira Pak, Harvoni.** **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Viekira Pak: Diagnosis of HCV-1 chronic HCV with compensated liver disease • Disease severity: ○ Must have compensated liver disease ○ Liver biopsy, must show Metavir score ≥ 2 or Ishak score ≥ 3 or other accepted test demonstrating

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	liver fibrosis • Specialist: ○ Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • SUD: ○ Pt must be drug and alcohol free for past 12 mo • Informed consent: ○ State has hepatitis C patient consent form covering tx adherence, alcohol/drug use, education on reinfection, birth control requirements • Birth control: ○ Viekira Pak: Female pts must have a negative pregnancy test w/in 30 days prior to initiation of therapy and monthly tests during tx ○ Viekira Pak is contraindicated with oral contraceptives • Exclusions: ○ Severe renal impairment and ESRD ○ Any medications contraindicated with either Viekira Pak or Harvoni ○ Viekira Pak: Contraindicated in pts with severe hepatic impairment • Response-driven therapy: ○ Algorithm requires HCV RNA levels taken on week 4 and sent with renewal request
Ohio	**Treatment Regimens: Updated policy addressing Harvoni and Viekira Pak not identified.**
Oklahoma No date PA Criteria Harvoni Initiation Pt Intent to Treat Contract Pharmacist Contract	**Treatment Regimens: Both Viekira Pak and Harvoni are preferred.** "Use of Sovaldi (sofosbuvir) and Olysio (simeprevir) in combination or alone for treatment of HCV-1 will require patient-specific, clinically significant reasoning why Viekira Pak or Harvoni is not appropriate for the member." **Treatment Criteria:** • Age:

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PA Renewal	○ 18+ years • Clinical criteria required: ○ Approved diagnosis of chronic HCV-1 ○ Pre-treatment viral load must be confirmed and indicated on the petition; viral load should be from the previous 3 months ○ "All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease" ○ For Viekira Pak, providers must monitor ALT levels during first 4 wks, then as needed • Disease severity: ○ Metavir fibrosis score ≥ 2 • Specialist ○ Prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist, **OR** ○ The pt must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist w/in the last 3 months • Informed consent: ○ Pt must sign the Intent To Treat contact ○ Pharmacy must submit the Therapy Pharmacy Agreement for each pt • SUD: ○ Pt must have no illicit IV drug use or alcohol abuse in last 6 mo ○ Pt must agree to no IV drug or alcohol use during tx and post-therapy • Once in a lifetime benefit: ○ For Viekira Pak: Pt must not have previously failed tx with protease inhibitor (non-responder or relapsed) • Vaccinations:

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	○ Documentation of hepatitis A vaccines • Birth control/pregnancy: ○ Female pts must have a negative pregnancy test immediately before tx ○ Male and female pts must be willing to use 2 forms of non-hormonal birth control ○ For Viekira Pak, female partners of male pt should be "checked for pregnancy for informational purposes" • Exclusions: ○ Alcohol abuse or IV drug use in past 6 mo ○ Decompensated cirrhosis ○ Pregnancy ○ Current use of contraindicated medications ○ Failure to address clinically significant issues prior to starting therapy, including but not limited to: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease ○ Harvoni: Severe renal impairment ○ Viekira Pak: Pt must not have previously failed tx with protease inhibitor (non-responder or relapsed) • Authorization duration: ○ "Approval for 12 wks of tx will not be granted before the 10th of a month (for 24 wks, prior to the 15th of the month) to prevent prescription limit issues from affecting compliance" • Adherence: ○ Prescriber must verify they will work with the pt to ensure adherence ○ Tx gaps longer than 3 days/mo will result in denial of subsequent request for continued therapy • Post-treatment reporting: ○ "The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12)."

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Oregon 4/2015 PA Criteria	**Treatment Regimens: Harvoni and Viekira Pak both preferred.** **Treatment Criteria:** • Clinical criteria required: ○ Expected survival from non-HCV associated morbidity > 5 years ○ A baseline HCV RNA level ○ Reported genotype • Disease severity: ○ Test (FibroSURE, FibroScan, FibroTest) indicates Metavir ≥ F3, **OR** ○ Cirrhosis w/o ongoing progressive decompensation (MELD score 8-11), **OR** ○ Extrahepatic manifestation due to HCV, **OR** ○ Pt listed for transplant, and tx is essential to prevent infection post-transplant, **OR** ○ Post-transplant pt with stage 4 fibrosis, **OR** ○ Post-transplant pt with fibrosing cholesteric hepatitis • Specialist: ○ 2014 PA criteria required prescription or consultation with a gastroenterologist or hepatologist • SUD: ○ Pt must be abstinent from IV drugs, illicit drugs, marijuana use, and alcohol abuse for > 6 mo ○ If pt has a history of alcohol abuse, has the pt been abstinent from alcohol > 6 mo • Once in a lifetime benefit: ○ Viekira Pak: Pt denied tx if previously failed DAA therapy • HIV co-infection: ○ HIV+ pts on Viekira Pak must not be on suppressive antiretroviral therapy or therapy with significant ARV drug interactions • Transplant:

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	○ Approved if: ▪ Pt listed for transplant, and tx is essential to prevent post-transplant infection, **OR** ▪ Post-transplant pt with stage 4 fibrosis, **OR** ▪ Post-transplant pt with fibrosing cholesteric hepatitis • Birth control/pregnancy: ○ Viekira Pak: Pt must be off ethinyl estradiol birth control for at least 1 wk prior to starting tx • Exclusions: ○ Decompensated liver ○ Renal impairment or ESRD ○ Pts on medications contraindicated with tx ○ Viekira Pak: Pt previously failed DAA therapy
Pennsylvania 1/21/2015 PDL 12/9/2014 PA Bulletin PA Criteria PA Form	**Treatment Regimens: Olysio, Sovaldi are preferred;** Harvoni and Viekira Pak are not listed on PDL but discussed in prior authorization criteria **Treatment Criteria:** • Age: ○ 18 + years • Clinical criteria required: ○ Diagnosis with documented genotype ○ Disease severity/liver fibrosis documented by non-invasive test, FibroScan, or liver biopsy ○ Documented HCV RNA at baseline tested within past 3 months • Disease severity: ○ Metavir fibrosis ≥ F3 documented by recent noninvasive test, FibroScan, or liver biopsy • Specialist: ○ Prescribed by a physician specialist (infectious disease, gastroenterology, hepatology, transplant)

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	• SUD: ○ Documented pattern of abstinence from alcohol and drugs for 6 months prior to treatment ○ Pts with a history of substance dependence: Lab testing (blood alcohol level and urine drug screen) that support abstinence ○ Pt is compliant with substance dependence tx if currently being treated • Once in a lifetime benefit: ○ Pt has not previously failed tx with requested DAA • Informed consent: ○ Pt counseled on risks of medication interactions • Birth control/pregnancy: ○ Tx w/ RBV: Negative pregnancy test prior to initiating therapy; agree to use 2 or more forms of contraception and take monthly pregnancy tests during therapy • Exclusions: ○ Life expectancy < 12 months due to non-liver-related comorbid conditions ○ Previously failed tx with requested DAA ○ A history of an incomplete course of DAA therapy due to non-compliance with medications ○ For combination therapy (ex: Harvoni, Sofobuvir), pt has renal impairment or ESRD • Re-treatment: ○ Pt will be denied treatment if pt has a history of an incomplete course of DAA therapy due to non-compliance with medications ○ Other requests for re-treatment will depend if the pt meets the medical necessity guidelines; has addressed issues of non-compliance (if previously a problem); or, in the judgement of the physician reviewer, the services are medically necessary
Rhode Island 1/2015	**Treatment Regimens: Viekira Pak, Harvoni, and Sovaldi** are included on a list of hepatitis C drugs to which "clinical criteria applies to this class / requires manual prior authorization." No prior authorization criteria identified.

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PDL	
South Carolina 2014 PA Form	**Treatment Regimens: Viekira Pak is preferred; Harvoni, Sovaldi, and Olysio are not preferred.** Prior authorization form asks for patient information but does not describe criteria used to determine coverage.
South Dakota No date Harvoni PA Form Algorithm	**Treatment Regimens: Harvoni,** no mention of Viekira Pak. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Diagnosis chronic hepatitis C, HCV-1 • Disease severity: ○ Liver biopsy confirming a Metavir score ≥ F3, unless medical contraindicated, or documentation of severe extrahepatic manifestations • Specialist: ○ Prescribed by hepatologist, gastroenterologist, or infectious disease specialist • SUD: ○ Drug and alcohol free for past 6 mo • Exclusions: ○ Renal impairment or ESRD ○ Concominent use of Harvoni and P-gp inducers, certain anticonvulsants, certain antiretrovirals, and rosuvastatin are not recommended.
Tennessee	**Treatment Regimens: Viekira Pak preferred; Harvoni, Sovaldi, and Olysio are non-preferred.** Non-preferred agents require pt have a contraindication or clinically significant drug-drug interaction with preferred agent.

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5/1/2015 PDL PA Criteria (p. 49) Viekira Pak PA Form Harvoni PA Form	**Treatment Criteria:** • Clinical criteria required: ○ Documentation of disease severity ○ Documentation of risk for severe complications • Disease severity: must have evidence of 1 of the following: ○ Medical documentation of Metavir score ≥ F3 through ▪ Liver biopsy showing Metavir score ≥ F3, **OR** ▪ FibroTest score ≥ .59, **OR** ▪ FibroScan score ≥ 9.5, **OR** ▪ FIB-4 index > 3.25, **OR** ○ Documentation showing pt at the highest risk for severe complications: ▪ "Evidence of essential mixed bryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, perifpheral neuropathy, central nervous system vasculitis), **OR** ▪ Evidence of proteinuria, **OR** ▪ Evidence of nephrotic syndrome, **OR** ▪ Evidence of membranoproliferative glomerulonephritis • Specialist: ○ Prescribed by a provider with a Tennessee Medicaid Provider ID ○ PA requested by physician specialist with experience in the treatment of hepatitis C infection (e.g., hepatology, infectious disease, or gastroenterology) • SUD: ○ Pt is not currently participating in illicit substance or alcohol abuse attested by the physician **AND** ○ Confirmed by: ▪ Validated screening tools (CAGE alcohol screen, NIDA's drug screening tool). **OR** ▪ An acceptable alcohol consumption test (serum gamma-glutamyl transpeptidase, mean

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	corpuscular volume, carbohydrate-deficient transferrin, and urine ethylglucuronide) and a urine toxicology screen in lieu of laboratory drug screen report ▪ Screens completed w/in 14 days of PA; results documented in medical file o Prescriber can submit a clinical rationale if a false-positive test is suspected o If pt has a prior history of substance or alcohol abuse, pt must be free of substance or alcohol use for 6 mo AND be participating in or have completed a recovery program, be receiving counseling, or be seeing an addiction specialist • Once in a lifetime benefit: o Pts previously treated with Harvoni or Viekira Pak are ineligible for re-treatment • Birth control/pregnancy: o Viekira Pak: Pts must not be pregnant or have concomitant therapy with ethyl estradiol-containing contraceptives • Exclusions: o Decompensated cirrhosis (CTP score > 6) o Pt receiving concomitant therapy with any contraindicated medications o Harvoni: Severe renal failure o Viekira Pak: Pt receiving concomitant therapy with a hepatitis C protease inhibitor o • Authorization duration: o 8 wks • Adherence: o Compliance must be confirmed based on pharmacy paid claims history for authorization renewal • Response-driven therapy: o RNA levels must be < 25 IU/mL at pre-defined treatment weeks o For 12-week therapy, reauthorization occurs at week 8 for the final 4 weeks of treatment, based on RNA levels tested at 4 weeks

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	○ For 24-week therapy, reauthorization occurs at weeks 8 and 16, based on RNA levels tested at 4 and 12 weeks
Texas 1/22/2015 PDL/PA Criteria	**Treatment Regimen: Viekira Pak is preferred**; Harvoni, Olysio, Sovaldi are non-preferred. • Non-preferred treatments may be authorized if there is contraindication, allergic reaction, or treatment failure with preferred drugs • Other prior authorization criteria not identified
Utah 10/17/2014 Harvoni PA Form 1/6/2015 Viekira Pak PA Form 5/1/2015 PDL	**Treatment Regimen: Harvoni, Olysio, and Sovaldi all preferred drugs. Viekira Pak not on PDL, but there is a separate PA form for VP.** **Treatment Criteria:** • Clinical criteria required: ○ A copy of HCV genotype testing results (must be HCV-1) ○ A copy of pre-treatment viral load test results ○ Documentation of previous tx (although prior tx failure is not a requirement for approval) • Specialist: ○ Prescribed by gastroenterologist or hepatologist • Response-driven therapy: ○ None: Initial authorization period is for fill treatment course (12 weeks for Harvoni, 24 weeks for VP)
Vermont 1/2015 PA Form 2/2015	**Treatment Regimens: Harvoni is preferred for HCV1; Sovaldi is preferred for HCV-2 through HCV-6.** No mention of Viekira Pak. **PDL states** "these drugs must be obtained and billed through our specialty pharmacy vendor, Briova." **Treatment Criteria:** • Clinical criteria required:

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PDL 1/2015 Pharmacy Benefit Manual	○ Documentation of active HCV infectious verified by viral load ○ Documentation of HCV genotype ○ CL_{cr} ≥ 30 mL/min (verified by lab results w/ creatinine level in last 6 months) ○ "DVHA Medical Director will review case details to determine eligibility for requested medication" • Disease severity: ○ Metavir stage ≥ F3 • Specialist: ○ Prescriber is, or has consulted with, a gastroenterologist, hepatologist, infectious disease specialist, or other hepatitis specialist in the past year • Informed consent: ○ Counselling must be provided and documented regarding abstaining from alcohol and drugs and preventing HCV transmission • SUD: ○ Documentation showing pt has abstained from alcohol and drug abuse for 6 mo prior; pt must receive counselling on abstaining from alcohol and drug abuse ○ Pts with history of drug abuse (other than alcohol) must submit urine drug screenings • Once in a lifetime benefit: ○ "Treatment experienced" coverage applicable ONLY IF previously treated with PEG + IFN + RBV or PEG + IFN + RBV + (in some cases) a protease inhibitor or, in some cases, Sovaldi. • Birth control/pregnancy: ○ For tx with RBV: ▪ Female pt not pregnant, and won't be during tx or 6 mo after ▪ Male pt does not have a pregnant partner, and she won't become pregnant during tx or 6 mo after ▪ Pt agrees to use 2 forms of non-hormonal contraception during tx and for 6 months after ▪ Verification pregnancy tests will be performed throughout tx

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	• Exclusions: ○ Pt receiving dialysis ○ Pt taking any contraindicated medications • Authorization duration: ○ Initial Rx for 14 days ○ Authorization for up to 12 wks of tx • Adherence: ○ Initial prescription fill covers a 14-day supply ○ Documentation of adherence (viral load changes, progress notes) required to continue therapy beyond 12 weeks
Virginia 1/1/2015 PA Criteria 8/2014 PA Form	**Treatment Regimens: Harvoni, Olysio, and Sovaldi are on preferred drug list.** No mention of Viekira Pak. **Treatment Criteria (for Harvoni):** • Age: ○ 18+ years • Clinical criteria required: ○ Baseline HCV RNA • Disease severity: ○ Metavir score ≥ F3, and/or ○ Highest risk for disease progression (not defined) • Specialist: ○ Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Pt must be evaluated for current history of substance and alcohol abuse

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	• Once in a lifetime benefit: o Tx-experienced pts eligible only if prior tx was PEG + RBV w/ or w/o protease inhibitor o One course of ledipasvir and/or sofobuvir per lifetime • Exclusions: o Pts receiving concomitant therapy with a HCV protease inhibitor o Pts with decompensated cirrhosis (CTP score ≥ 6 [B or C class]) o Pts with severe renal impairment or ESRD o HCV-2, -3, -4, -5, -6 (*HCV-2 and -3 have option for Sovaldi-based treatment)* o At tx week 4 (and tx week 12, if applicable), tx will be discontinued if RNA levels ≥ 25 IU/mL • Adherence: o Initial approval is 8 weeks, renewal is based on compliance with drug regimen (based on paid claims history) • Response-driven therapy: o Initial approval is for 8 weeks o 12-week treatment: Continue tx for 4 more weeks if RNA < 25 IU/mL (test at 4 wks) o 24-week treatment: Continue tx for 8 more weeks if RNA < 25 IU/mL; re-authorize again at 16 weeks if RNA < 25 IU/mL (test at 4 wks; 12 wks)
Washington 1/15/2015 PA Criteria	**Treatment Regimens: Harvoni, Sovaldi-based regimens.** No record of Viekira Pak. Effective Jan. 1, 2015, HCV treatments carved out of Washington's Apple Health Managed Care Organization and covered by Apple Health Fee-For-Service program. **Treatment Criteria:** • Clinical criteria required: o Baseline detectable viral load

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	○ Provider must agree to submit viral load after completion of full course of treatment upon request to track tx success. • <u>Disease severity</u>: ○ At least 1 of the 3 following conditions: ▪ Metavir ≥ F3 measured by • APRI ≥ 1.5 **AND** FibroSURE ≥ 0.49, **OR** • FibroScan ≥ 7.1 **AND** FibroSURE ≥ 0.49, **OR** • FibroScan ≥ 7.1 **AND** APRI ≥ 1.5, **OR** • Biopsy ≥ F3, **OR** • Abdominal imaging, in which radiologist determines findings are suggestive of cirrhosis (e.g., nodules; enlarged liver, especially the left lobe; tortuous hepatic arteries; ascites; or portal hypertension), **OR** ▪ HIV or HBV coinfection with Metavir ≥ F2 measured by • FibroScan ≥ 7.1, **OR** • APRI ≥ 1.5, **OR** • APRI = 0.5 – 1.5 **AND** FibroSURE ≥ 0.49, **OR** • Biopsy ≥ F2 **OR** ▪ Metavir = F0-F4 with 1 of the following: • Post solid organ transplant • Awaiting liver transplant • Stage I-III HCC meeting Milan Criteria • HCV infection post-liver transplant • Severe complications (cryoglobulinemia or HCV-induced renal disease) • Decompensated liver disease (CTP score 7-12 class B/C and MELD ≤ 20[6]) • <u>Specialist:</u> ○ Prescriber is a gastroenterologist, hepatologist, or infectious disease specialist, OR prescriber

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	participates and consults with Project ECHO o Exceptions may be made for other non-specialist providers who work in coordination with an organized system of care, have received training in hepatitis C diagnosis, staging, and treatment protocols, and have ready access to specialists who treat HCV • Informed consent: o Pt must attend a medical care visit with the treating clinician to discuss the pros and cons of antiviral therapy, the importance of adherence to tx, and risk factors for fibrosis progression o Clinician must attest that the pt has been evaluated for "psychosocial readiness," including identifying potential impediments to adherence that must be addressed prior to initiating tx • SUD: o Pts satisfying inclusion criterion 1 and 2 (see disease severity) with a history of alcohol use disorder must be abstinent for 6 mo or longer ▪ Exceptions will be considered if, for at least 3 months, a pt is receiving treatment from an approved facility or under the care of an addiction medicine specialist and abstaining from alcohol during tx; documentation supporting an exception is required o Pts satisfying inclusion criterion 1 and 2 with a history of IV drug use must be abstinent from IV drugs for at least 3 months ▪ Exceptions will be considered for pts with IV drug use in the past 3 mo if receiving opiate substitution therapy or medication-assisted treatment from an approved facility or an addiction medicine specialist; documentation supporting an exception is required • Birth Control/Pregnancy o Excluded if pregnant or planning to become pregnant • Exclusions: o CL_{cr} < 30 mL/min or on hemodialysis o Pregnant or planning on becoming pregnant o Severe end organ disease and not eligible for transplant (e.g., liver, heart, lung, kidney) o Clinically significant illness or any other major medical disorder that may interfere with pt's ability

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	to complete a course of treatment ○ Pts who, in the professional judgment of the primary clinician, would not achieve a long-term clinical benefit from HCV treatment (pt with multisystem organ failure, receiving palliative care, etc) ○ Decompensated liver disease with CTP score > 12 or MELD > 20[6] ○ MELD < 20[6] and one of the following: Cardiopulmonary disease that cannot be corrected; malignancy outside the liver; HCC with metastatic spread; intrahepatic cholangiocarcinoma; hemangiosarcoma; uncontrolled sepsis • Authorization duration: ○ Approved antiviral regimens may be limited to 7 days or a 14-day supply with exceptions for members with limited transportation to retail pharmacies; plans may limit dispensing to a single specialty pharmacy with exceptions for members without stable mailing addresses • Adherence: ○ Pt must participate in case management or adherence monitoring if required by the plan • Post-treatment reporting: ○ Providers must submit HCV RNA "after completion of full course of antiviral treatment"
West Virginia 3/2015 Prior Authorization Page Harvoni PA Criteria Pt Consent Form Viekira Pak PA Criteria Hep C Generic PA Form Hep C Continuation PA	**Treatment Regimen: Harvoni preferred.** Other regimens considered on a case-by-case basis."Viekira Pak criteria includes documented failure or contraindication to preferred HCV therapy." **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Patient must be diagnosed with HCV-1 for Harvoni or Viekira Pak • Disease sSeverity: ○ Patient must have a documented diagnosis of cirrhosis or a fibrosis level ≥ F3 ○ Cirrhosis may be substantiated either through biopsy or the presence of **at least 2** of the following

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Form	clinical features: Cirrhotic features on imaging; ascites; esophageal varices; reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2) o Fibrosis level must be substantiated via biopsy or other accepted method (e.g., FibroSURE) • Specialist: o Prescribed by, or in conjunction with, a gastroenterologist, hepatologist, or infectious disease physician • SUD: o Patient has abstained from the use of illicit drugs and alcohol for a minimum of 6 months, as indicated by the patient's signature on the Patient Consent form • Vaccinations: o Patient must be vaccinated against hepatitis A B • Once in a lifetime benefit: o Coverage is for 1 successful course of therapy in a lifetime; reinfection will not be covered Exceptions may be allowed on a case-by-case basis o For Harvoni, pt must be SOF tx-naïve • Informed consent: o Patient has abstained from the use of illicit drugs and alcohol for a minimum of 6 months, as indicated by the patient's signature on the Patient Consent form o Patient must consent to full 12- or 24-week treatment • HIV coinfection: o Harvoni: "Pt must not be co-infected with HIV" • Transplant: o Pt must not be awaiting liver transplant ("Harvoni is not indicated in this population") • Quantity Limit: o Lost/stolen medication replacement request will not be honored • Exclusions: o Harvoni: Pt is awaiting or post-liver transplant (Harvoni is not indicated in this population)

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	○ Harvoni: Pt has severe renal impairment or ESRD ○ Viekira Pak: Pt is on dialysis ○ Viekira Pak: CTP class of B or C ○ Prescription for any other HCV anti-viral medication ○ Prescriber has determined that the pt has not abstained from illicit drugs and/or alcohol for 6 months prior to the start of treatment ○ Pt has a HIV co-infection ○ Pt takes a concomitant medication that may have a significant clinical interaction ○ Coverage will be discontinued if a pt's RNA level > 25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at wk 4 • Authorization duration: ○ Initial 6-wk authorization • Adherence: ○ Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4, documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. Failure to obtain and report RNA load will result in denial of further coverage • Response-driven therapy: ○ Initial approval is for 6 weeks; submission of RNA levels is required at the start of therapy and at week 4 ○ Continued coverage after week 6 depends upon receipt of a HCV RNA level at treatment week 4, documentation of patient compliance, continued abstinence and a HCV RNA < 25 IU/ml. Failure to obtain and report the pt's RNA viral load will result in denial of further coverage • Post-treatment reporting: ○ Pt and provider must agree to collect and submit SVR12 and SVR24
Wisconsin	**Treatment Regimens: Viekira Pak is preferred;** Harvoni, Olysio, and Sovaldi are not preferred. Only pts ineligible for Viekira Pak due to medical or medication contraindication will be considered for Harvoni.

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12/2014 PA Form PA Instructions PA Form Renewal No date Viekira Pak PA Criteria Harvoni PA Criteria 12/2014 PDL	Prior authorization for HCV agents requires paper processing only. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Chronic HCV-1 infection ○ Lab data within last 6 months, including the following: ▪ HCV-RNA level ▪ LFTs ▪ CBC ▪ serum creatinine test ▪ albumin test ▪ INR ○ Test results (if performed) from liver biopsy, scan, or ultrasound ○ HCV clinical data, including: ▪ Likely source of the HCV infection ▪ Current medical records for HCV assessment and treatment ▪ History of liver transplant, or documentation if the pt is on the liver transplant wait list ○ Assessment of the presence or absence of cirrhosis. If cirrhotic, documentation of the following: ▪ CTP score ▪ HCC status based on liver CT, ultrasound, or MRI ▪ Presence and treatment of ascites, esophageal varices, hepatic encephalopathy, jaundice, and portal hypertension ▪ FibroScan results may be provided as 1 component of cirrhosis assessment ○ Fibrosis stage or score

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	▪ Staging calculators (APRI, FIB-4, NAFLD), blood assays (FibroSURE, FIBROSpect), and liver biopsies are not accepted as ways to differentiate between F2 and F3 Metavir scores. o Hepatitis C medication treatment history, including details of the following: ▪ When treatment occurred ▪ Medications taken and compliance ▪ Treatment results (e.g., null response, partial response, or relapse) o Relevant medical history not related to hepatitis C from the pt's primary care provider, including: ▪ Current medication list ▪ Current hx and physical ▪ Current and past psychosocial history, including alcohol and illicit drug use ▪ Other liver disease ▪ Transplant history ▪ Hepatitis A, hepatitis B, or HIV co-infection ▪ Autoimmune disease ▪ Other significant or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, CVD, pulmonary disease) • Disease severity: o Compensated cirrhosis (i.e. CTP class A) o Metavir score ≥ F3 or evidence of bridging fibrosis ▪ "Note: ForwardHealth does not accept fibrosis staging as determined by calculators or blood assays to differentiate between F2 and F3 or greater Metavir scores. Some examples of fibrosis staging calculators may include APRI, FIB-4, and NAFLD. Some examples of blood assays may include FibroSUREand FIBROSpect. ForwardHealth does accept liver biopsy to determine a Metavir score or to determine fibrosis staging." o Serious extrahepatic manifestations of HCV o Liver transplant recipients w/ normal hepatic function and mile fibrosis (Metavir ≤ F2). • Specialist:

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	○ Prescribed by board-certified gastroenterologist or infectious disease specialist or by "mid-level practitioner" who has a collaborative relationship with a board-certified specialist • SUD: ○ Past and current alcohol abuse or illicit drug use must be documented ○ Documentation of at least 6 months of abstinence from alcohol abuse or illicit drug use is required ○ Pts currently abusing drugs or alcohol will be denied tx ○ Active participation in a recovery program is required for members with a recent hx of alcohol or drug abuse • Once in a lifetime benefit: ○ Denied tx if past or current use of Viekira Pak, Sovaldi, Harvoni, Olysio, Incivek, or Victrelis • HIV co-infection: ○ Harvoni: pts co-infected with HIV will be denied tx • Transplant: ○ Harvoni not covered for post-liver transplant tx • Exclusions: ○ Pt has autoimmune hepatitis or another condition that is contraindicated for RBV ○ The pt has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, CVD, pulmonary disease) ○ Pt has cirrhosis with moderate or severe liver functional compromise (i.e. CTP class B or C). "If member is currently on a liver transplant wait list with an elevated MELD score, individual circumstances will be considered for review." ○ Harvoni: member has received a liver transplant ○ The pt has decompensated cirrhosis ○ The pt has acute hepatitis C ○ The pt is currently abusing drugs or alcohol ○ The pt has taken or is currently taking Sovaldi, Harvoni, Olysio, Incivek, or Victrelis ○ Non-compliance with approved hepatitis C treatment regimen (for renewals only)

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	○ Use of contraindicated medications • Authorization duration: ○ 8 wks • Response-driven rherapy: ○ Treatment approved for 8 weeks; renewal if RNA < 25 IU/ml
Wyoming 05/2015 PA Form	**Treatment Regimens:** Viekira Pak, Harvoni both preferred agents subject to criteria. **Treatment Criteria:** • Clinical criteria required: ○ HCV genotype ○ Cirrhosis status ○ Any other medications given concurrently with HCV medication ○ Tx history • Disease severity: ○ Pt's cirrhosis status • Informed consent: ○ Pt must complete PREP-C (Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment) https://prepc.org ○ Pt and the prescriber must complete the Wyoming Medicaid Client Disclosure and Commitment to Take Hepatitis C Medications form (attached to PA form) • SUD: ○ A drug screen in the last month is required ○ If positive for illicit drugs, prior authorization will be denied • Once in a lifetime benefit: ○ Only 1 course of tx per pt will be covered

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	• HIV co-infection: ○ HIV and hepatitis B tests must be performed within 1 month of tx • Adherence: ○ All approved pts will be preferred to WYHealth nurses for case management

Abbreviations: ALT = alanine aminotransferase; APRI = AST:platelet ratio index; ARFI = acoustic radiation force impulse imaging; ARV = antiretroviral; AST = aspartate aminotransferase; CBC = complete blood count; CD4 = cluster of differentiation 4; CL_{cr} = creatinine clearance; CLIA = Clinical Laboratory Improvement Act; COPD = chronic obstructive pulmonary disease; CT = computed tomography; CTP = Child-Turcotte-Pugh score; CVD = cardiovascular disease; DAA = direct-acting antiviral; DUR = drug utilization review; DVHA = Department of Vermont Health Access; dx = diagnosis; ESRD = end-stage renal disease; FDA = U.S. Food and Drug Administration; FFS = fee-for-service; FIB-4 = fibrosis-4 clinical calculator; GFR = glomerular filtration rate (and estimated GFR); HBV = hepatitis B virus; HCC = hepatocellular carcinoma; HCV = hepatitis C virus; HCV-1 = HCV genotype 1 (and equivalents for genotypes 2, 3, 4, 5, 6); HIV = human immunodeficiency virus; HRSA = Health Resources and Services Administration; hx = history; IASL = International Association for Study of the Liver; IFN = interferon; INR = international normalized ratio; IU = international units; IV = intravenous; LFT = liver function test; LLOQ = lower limit of quantification; MELD = model end-stage liver disease; mo = month(s); MRE = magnetic resonance elastography; MRI = magnetic resonance imaging; PA = prior authorization; pt = patient; P-gp = permeability glycoprotein; NALFD = non-alcoholic fatty liver disease; NIDA = National Institute on Drug Abuse; NS5A = nonstructural protein 5A (and equivalent for 5B); PDL = preferred drug list; PEG = pegylated interferon alpha; PI = protease inhibitor; pt = patient; RBV = ribavirin; RNA = ribonucleic acid; Rx = prescription; SAMHSA = Substance Abuse and Mental Health Services Administration; SIM = simeprevir (Olysio™); SOF = sofosbuvir (Sovaldi™); SUD = substance use disorder; SVR = sustained virological response; tx = treatment; wk = week