



Hepatitis C Direct Acting Antivirals Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Zepatier	elbasvir-grazoprevir tab	50-100 MG	M ; N ; O ; Y	N		
Mavyret	glecaprevir-pibrentasvir pellet pack ; glecaprevir-pibrentasvir tab	100-40 MG ; 50-20 MG	M ; N ; O ; Y	N		
Harvoni ; Ledipasvir/sofosbuvir	ledipasvir-sofosbuvir pellet pack ; ledipasvir-sofosbuvir tab	33.75-150 MG ; 45-200 MG ; 90-400 MG	M ; N ; O ; Y	M ; N		
Sovaldi	sofosbuvir pellet pack ; sofosbuvir tab	150 MG ; 200 MG ; 400 MG	M ; N ; O ; Y	N		
Epclusa ; Sofosbuvir/velpatasvir	sofosbuvir-velpatasvir pellet pack ; sofosbuvir-velpatasvir tab	150-37.5 MG ; 200-50 MG ; 400-100 MG	M ; N ; O ; Y	M ; N		
Vosevi	sofosbuvir-velpatasvir-voxilaprevir tab	400-100-100 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Epclusa	sofosbuvir-velpatasvir pellet pack	150-37.5 MG ; 200-50 MG	28	Packs	28	DAYS			
Epclusa ; Sofosbuvir/velpatasvir	sofosbuvir-velpatasvir tab	200-50 MG ; 400-100 MG	28	Tablets	28	DAYS			
Harvoni	ledipasvir-sofosbuvir pellet pack	33.75-150 MG ; 45-200 MG	28	Packs	28	DAYS			
Harvoni ; Ledipasvir/sofosbuvir	ledipasvir-sofosbuvir tab	45-200 MG ; 90-400 MG	28	Tablets	28	DAYS			
Mavyret	glecaprevir-pibrentasvir pellet pack	50-20 MG	140	Packs	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Mavyret	glecaprevir-pibrentasvir tab	100-40 MG	90	Tablets	30	DAYS			
Sovaldi	sofosbuvir pellet pack	150 MG ; 200 MG	28	Packs	28	DAYS			
Sovaldi	sofosbuvir tab	200 MG ; 400 MG	30	Tablets	30	DAYS			
Vosevi	sofosbuvir-velpatasvir-voxilaprevir tab	400-100-100 MG	30	Tablets	30	DAYS			
Zepatier	elbasvir-grazoprevir tab	50-100 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Eplclusa ; Sofosbuvir/velpatasvir	sofosbuvir-velpatasvir pellet pack ; sofosbuvir-velpatasvir tab	150-37.5 MG ; 200-50 MG ; 400-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Harvoni ; Ledipasvir/sofosbuvir	ledipasvir-sofosbuvir pellet pack ; ledipasvir-sofosbuvir tab	33.75-150 MG ; 45-200 MG ; 90-400 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mavyret	glecaprevir-pibrentasvir pellet pack ; glecaprevir-pibrentasvir tab	100-40 MG ; 50-20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sovaldi	sofosbuvir pellet pack ; sofosbuvir tab	150 MG ; 200 MG ; 400 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vosevi	sofosbuvir-velpatasvir-voxilaprevir tab	400-100-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Zepatier	elbasvir-grazoprevir tab	50-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Epclusa	sofosbuvir-velpatasvir pellet pack	150-37.5 MG ; 200-50 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Epclusa ; Sofosbuvir/velpatasvir	sofosbuvir-velpatasvir tab	200-50 MG ; 400-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Harvoni	ledipasvir-sofosbuvir pellet pack	33.75-150 MG ; 45-200 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Harvoni ; Ledipasvir/sofosbuvir	ledipasvir-sofosbuvir tab	45-200 MG ; 90-400 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mavyret	glecaprevir-pibrentasvir pellet pack	50-20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mavyret	glecaprevir-pibrentasvir tab	100-40 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sovaldi	sofosbuvir pellet pack	150 MG ; 200 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sovaldi	sofosbuvir tab	200 MG ; 400 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vosevi	sofosbuvir-velpatasvir-voxilaprevir tab	400-100-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Zepatier	elbasvir-grazoprevir tab	50-100 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
Epclusa and Sofosbuvir/Velpatasvir	Preferred Agents	Non-Preferred Agents
	Genotype 1	
	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 2	Genotype 2
	Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir)	Sovaldi (sofosbuvir)

Module	Clinical Criteria for Approval	
	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
	Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 3 Sovaldi (sofosbuvir)
	Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 5
	Genotype 6 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 6
<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient is treatment naive OR B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor OR C. The patient has decompensated cirrhosis AND 3. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for the use of the requested agent for the patient's age for the requested indication [medical records required] AND 4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND 5. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND 6. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following: 		

Module	Clinical Criteria for Approval
	<p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. The requested agent is a preferred agent for the patient’s specific factors OR</p> <p>C. The patient has been treated with the requested non-preferred agent in the past 30 days OR</p> <p>D. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested non-preferred agent [chart notes required] OR</p> <p>E. The patient has tried and had an inadequate response to ALL preferred agents for the patient’s specific factors [chart notes required] OR</p> <p>F. ALL preferred agents for the patient’s specific factors were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>G. The patient has an intolerance or hypersensitivity to ALL preferred agents for the patient’s specific factors [chart notes required] OR</p> <p>H. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient’s specific factors [chart notes required] OR</p> <p>I. ALL of the preferred agent(s) for the patient’s specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>J. ALL of the preferred agent(s) for the patient’s specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL preferred agents for the patient’s specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>L. There is clinical support for the use of the requested non-preferred agent over the preferred agent(s) AND</p> <p>7. ONE of the following:</p> <p>A. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient’s diagnosis OR</p> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patients Eligible for or Excluded from Simplified HCV Treatment tables below)) AND <div data-bbox="272 1499 987 1938" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Patients Eligible for Simplified HCV Treatment</p> <p>Adults with chronic HCV infection, including persons living with HIV:</p> <ul style="list-style-type: none"> • Infected with any genotype • Have NOT previously received HCV treatment • Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by: <ul style="list-style-type: none"> ○ Liver stiffness > 12.5 kPa by FibroScan ○ FIB-4 > 3.25 ○ Noninvasive serologic test ○ Liver biopsy ○ Liver nodularity or splenomegaly on imaging </div>

Module	Clinical Criteria for Approval												
	<div data-bbox="272 184 987 258" style="border: 1px solid black; padding: 5px;"> <ul style="list-style-type: none"> ○ Platelet count < 150,000/mm³ </div> <div data-bbox="272 264 987 296" style="border: 1px solid black; padding: 5px;"> <p>Patients Excluded from Simplified HCV Treatment</p> </div> <div data-bbox="272 302 987 720" style="border: 1px solid black; padding: 5px;"> <p>Adults with chronic HCV infection:</p> <ul style="list-style-type: none"> • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation </div> <p>1. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>2. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 1 (FDA labeling) or 2 (AASLD/IDSA guidelines for decompensated cirrhosis) AND</p> <p>3. The requested length of therapy does NOT exceed the length of therapy noted in Table 1 (FDA labeling) or 2 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient's treatment regimen</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Tables 1 or 2 (at least 12 weeks for BCBSNM)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Table 1: Epclusa or Sofosbuvir/Velpatasvir Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 1459 1128 1869"> <thead> <tr> <th data-bbox="235 1459 457 1549">Genotype</th> <th data-bbox="457 1459 682 1549">Patients 3 years of age and older*</th> <th data-bbox="682 1459 906 1549">Treatment</th> <th data-bbox="906 1459 1128 1549">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1549 457 1707">1, 2, 3, 4, 5, or 6</td> <td data-bbox="457 1549 682 1707">Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="682 1549 906 1707">Epclusa Sofosbuvir/Velpat asvir</td> <td data-bbox="906 1549 1128 1707">12 weeks</td> </tr> <tr> <td data-bbox="235 1707 457 1869">1, 2, 3, 4, 5, or 6</td> <td data-bbox="457 1707 682 1869">Patients with decompensated cirrhosis (Child-Pugh B and C)</td> <td data-bbox="682 1707 906 1869">Epclusa + ribavirin Sofosbuvir/Velpat asvir + ribavirin</td> <td data-bbox="906 1707 1128 1869">12 weeks</td> </tr> </tbody> </table> <p>*HCV/HIV-1 co-infection, follow recommendation in table above</p>	Genotype	Patients 3 years of age and older*	Treatment	Duration	1, 2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa Sofosbuvir/Velpat asvir	12 weeks	1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + ribavirin Sofosbuvir/Velpat asvir + ribavirin	12 weeks
Genotype	Patients 3 years of age and older*	Treatment	Duration										
1, 2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa Sofosbuvir/Velpat asvir	12 weeks										
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + ribavirin Sofosbuvir/Velpat asvir + ribavirin	12 weeks										

Table 2: Epclusa or Sofosbuvir/Velpatasvir Decompensated Cirrhosis Treatment Recommendations based on AASLD/IDSA Guidelines for unique populations

Genotype	Patient Population*	Treatment	Duration
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) who are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Epclusa Sofosbuvir/Velpat asvir	24 weeks
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) - based treatment failed	Epclusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis) Sofosbuvir/Velpat asvir with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis)	24 weeks

*HCV/HIV-1 co-infection, follow recommendation in table above

The requested agent will also be approved when the following are met:

1. The member resides in Ohio **AND**
2. The plan is Fully Insured or HIM Shop (SG) **AND** BOTH of the following
 - A. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
 - B. ONE of the following:
 1. The patient has another FDA labeled indication for the requested agent and route of administration **OR**
 2. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**
 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted

Module	Clinical Criteria for Approval													
	<p>study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>													
Harvoni and Ledipasvir/Sofosbuvir	<table border="1"> <thead> <tr> <th data-bbox="232 674 732 707">Preferred Agents</th> <th data-bbox="732 674 1414 707">Non-Preferred Agents</th> </tr> </thead> <tbody> <tr> <td data-bbox="232 707 732 989"> Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </td> <td data-bbox="732 707 1414 989"> Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir) </td> </tr> <tr> <td data-bbox="232 989 732 1209"> Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </td> <td data-bbox="732 989 1414 1209"> Genotype 2 Sovaldi (sofosbuvir) </td> </tr> <tr> <td data-bbox="232 1209 732 1430"> Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </td> <td data-bbox="732 1209 1414 1430"> Genotype 3 Sovaldi (sofosbuvir) </td> </tr> <tr> <td data-bbox="232 1430 732 1707"> Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </td> <td data-bbox="732 1430 1414 1707"> Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir) </td> </tr> <tr> <td data-bbox="232 1707 732 1976"> Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </td> <td data-bbox="732 1707 1414 1976"> Genotype 5 </td> </tr> </tbody> </table>		Preferred Agents	Non-Preferred Agents	Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)	Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 2 Sovaldi (sofosbuvir)	Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 3 Sovaldi (sofosbuvir)	Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)	Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 5
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Module	Clinical Criteria for Approval		
	<table border="1" data-bbox="235 184 1227 464"> <tr> <td data-bbox="235 184 732 464"> <p>Genotype 6</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 184 1227 464"> <p>Genotype 6</p> </td> </tr> </table> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of hepatitis C genotype 1, 4, 5, or 6 AND 2. The prescriber has provided the patient's baseline HCV RNA level if the patient has genotype 1 AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient is treatment naive OR B. The patient was previously treated (i.e., treatment experienced) with peg-interferon and ribavirin with or without an HCV protease inhibitor OR C. The patient has decompensated cirrhosis AND 4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND 5. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND 6. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 7. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The requested agent is a preferred agent for the patient's specific factors OR C. The patient has been treated with the requested non-preferred agent in the past 30 days OR D. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested non-preferred agent [chart notes required] OR E. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR F. ALL of the preferred agent(s) for the patient's specific factors were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR G. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR H. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient's specific factors OR I. ALL of the preferred agent(s) for the patient's specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR J. ALL of the preferred agent(s) for the patient's specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR L. There is support for the use of the requested non-preferred agent over the preferred agent(s) AND 8. ONE of the following: <ol style="list-style-type: none"> A. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient's diagnosis OR B. ALL of the following: 	<p>Genotype 6</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 6</p>
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Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patients Eligible for or Excluded from Simplified HCV Treatment tables below) AND <div data-bbox="235 422 950 464" style="border: 1px solid black; padding: 5px;"> <p>Patients Eligible for Simplified HCV Treatment</p> <p>Adults with chronic HCV infection, including persons living with HIV:</p> <ul style="list-style-type: none"> ▪ Infected with any genotype ▪ Have NOT previously received HCV treatment ▪ Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by: <ul style="list-style-type: none"> ▪ Liver stiffness > 12.5 kPa by FibroScan ▪ FIB-4 > 3.25 ▪ Noninvasive serologic test ▪ Liver biopsy ▪ Liver nodularity or splenomegaly on imaging ▪ Platelet count < 150,000/mm³ </div> <div data-bbox="235 1213 950 1255" style="border: 1px solid black; padding: 5px;"> <p>Patients Excluded from Simplified HCV Treatment</p> <p>Adults with chronic HCV infection:</p> <ul style="list-style-type: none"> ▪ Previously received HCV treatment ▪ Hepatitis B surface antigen-positive ▪ Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) ▪ Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 ▪ Current pregnancy ▪ Known or suspected hepatocellular carcinoma ▪ Prior liver transplantation </div> <ol style="list-style-type: none"> 9. The patient does NOT have any FDA labeled contraindications to the requested agent AND

Module	Clinical Criteria for Approval																							
	<p>10. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 3 (FDA labeling) or 4 (AASLD/IDSA guidelines for decompensated cirrhosis) AND</p> <p>11. The requested length of therapy does NOT exceed the length of therapy noted in Table 3 (FDA labeling) or 4 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient's treatment regimen</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 3 or 4 (at least 12 weeks for BCBSNM)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>																							
	<p>Table 3: Harvoni or Ledipasvir/Sofosbuvir Treatment Recommendations based on FDA labeling</p>																							
	<table border="1"> <thead> <tr> <th data-bbox="232 825 456 921">Genotype</th> <th data-bbox="456 825 680 921">Patients 3 years of age and older*</th> <th data-bbox="680 825 904 921">Treatment</th> <th data-bbox="904 825 1128 921">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="232 921 456 1207">1</td> <td data-bbox="456 921 680 1207">Treatment-naive with initial viral load of less than 6 M IU/mL</td> <td data-bbox="680 921 904 1207">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="904 921 1128 1207">12 weeks** **NOTE approve 8 weeks length of therapy ONLY if prescriber is requesting 8 weeks of therapy</td> </tr> <tr> <td data-bbox="232 1207 456 1388">1</td> <td data-bbox="456 1207 680 1388">Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="680 1207 904 1388">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="904 1207 1128 1388">12 weeks</td> </tr> <tr> <td data-bbox="232 1388 456 1833">1</td> <td data-bbox="456 1388 680 1833">Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis</td> <td data-bbox="680 1388 904 1833">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="904 1388 1128 1833">12 weeks</td> </tr> <tr> <td data-bbox="232 1833 456 1988">1</td> <td data-bbox="456 1833 680 1988">Treatment-experienced (i.e., patients who have failed therapy with</td> <td data-bbox="680 1833 904 1988">Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin</td> <td data-bbox="904 1833 1128 1988">12 weeks</td> </tr> </tbody> </table>				Genotype	Patients 3 years of age and older*	Treatment	Duration	1	Treatment-naive with initial viral load of less than 6 M IU/mL	Harvoni Ledipasvir/Sofosbuvir	12 weeks** **NOTE approve 8 weeks length of therapy ONLY if prescriber is requesting 8 weeks of therapy	1	Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir	12 weeks	1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis	Harvoni Ledipasvir/Sofosbuvir	12 weeks	1	Treatment-experienced (i.e., patients who have failed therapy with	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin	12 weeks
Genotype	Patients 3 years of age and older*	Treatment	Duration																					
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1	Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir	12 weeks																					
1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis	Harvoni Ledipasvir/Sofosbuvir	12 weeks																					
1	Treatment-experienced (i.e., patients who have failed therapy with	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin	12 weeks																					

Module	Clinical Criteria for Approval			
		either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and eligible for ribavirin		
1		Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and ineligible for ribavirin (i.e., patients with a history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni Ledipasvir/Sofosbuvir	24 weeks
1		Treatment-naive and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with decompensated cirrhosis (Child-Pugh B or C)	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin	12 weeks
1 or 4		Treatment-naive and treatment-experienced (i.e.,	Harvoni + ribavirin	12 weeks

Module	Clinical Criteria for Approval			
		patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Ledipasvir/Sofosbuvir + ribavirin	
4, 5, or 6		Treatment-naive and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir	12 weeks

*HCV/HIV-1 co-infection, follow recommendation in table above

Table 4: Harvoni or Ledipasvir/Sofosbuvir Decompensated Cirrhosis Treatment Recommendations based on AASLD Guidelines for unique populations

Genotype	Patients 3 years of age and older*	Treatment	Duration
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) AND are ribavirin ineligible (i.e., patients with history of intolerance,	Harvoni Ledipasvir/Sofosbuvir	24 weeks

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		contraindication, or hypersensitivity to ribavirin)		
	1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) previously treated with sofosbuvir-based treatment failure	Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated Ledipasvir/Sofosbuvir + low initial dose of ribavirin (600 mg); increase as tolerated	24 weeks
*HCV/HIV-1 co-infection, follow recommendations in table above				
The requested agent will also be approved when the following are met:				
<ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] 				
Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)				
Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature				
Length of Approval: 12 months				
NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria				

Mavyret	Preferred Agents		Non-Preferred Agents	
	Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir		Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)	

Module	Clinical Criteria for Approval	
	Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
	Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 2 Sovaldi (sofosbuvir)
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	Genotype 6 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 6
	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for the use of the requested agent for the patient's age for the requested indication AND 3. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND 	

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	<p>4. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND</p> <p>5. If the client has preferred agent(s) for the patient’s specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment), then ONE of the following:</p> <ul style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The requested agent is a preferred agent for the patient’s specific factors OR C. The patient has been treated with the requested non-preferred agent in the past 30 days OR D. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested non-preferred agent [chart notes required] OR E. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient’s specific factors [chart notes required] OR F. ALL of the preferred agent(s) for the patient’s specific factors were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR G. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient’s specific factors [chart notes required] OR H. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient’s specific factors [chart notes required] OR I. ALL of the preferred agent(s) for the patient’s specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR J. ALL of the preferred agent(s) for the patient’s specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient’s specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR L. The prescriber has provided clinical information supporting the use of the requested non-preferred agent over the preferred agent(s) AND <p>6. ONE of the following:</p> <ul style="list-style-type: none"> A. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient’s diagnosis OR B. The requested agent is being used for acute HCV treatment and BOTH of the following: <ul style="list-style-type: none"> A. The patient is treatment naïve AND B. The patient does NOT have cirrhosis or has compensated cirrhosis OR C. The requested agent is being used for chronic HCV treatment AND ALL of the following: <ul style="list-style-type: none"> 1. The patient is treatment naïve AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patients Eligible for or Excluded from Simplified HCV Treatment tables below) AND <div data-bbox="235 1640 950 1978" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Patients Eligible for Simplified HCV Treatment Algorithm</p> <p>Adults with chronic HCV infection, including persons living with HIV:</p> <ul style="list-style-type: none"> ▪ Infected with any genotype ▪ Have NOT previously received HCV treatment ▪ Without cirrhosis OR with compensated cirrhosis </div>

Module	Clinical Criteria for Approval
	<p>(Child-Pugh A) as determined by:</p> <ul style="list-style-type: none"> ▪ Liver stiffness > 12.5 kPa by FibroScan ▪ FIB-4 > 3.25 ▪ Noninvasive serologic test ▪ Liver biopsy ▪ Liver nodularity or splenomegaly on imaging ▪ Platelet count < 150,000/mm³ <p>Patients Excluded from Simplified HCV Treatment Algorithm</p> <p>Adults with chronic HCV infection:</p> <ul style="list-style-type: none"> ▪ Previously received HCV treatment ▪ Hepatitis B surface antigen-positive Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) ▪ Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 ▪ Current pregnancy ▪ Known or suspected hepatocellular carcinoma ▪ Prior liver transplantation <p>7. The patient has not been previously treated with the requested agent AND</p> <p>8. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>9. The patient meets all requirements and will use the requested agent will in a treatment regimen noted in Table 5 (FDA labeling) AND</p> <p>10. The requested length of therapy does NOT exceed the length of therapy noted in Table 5 (FDA labeling) for the patient’s treatment regimen</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 5 (At least 12 weeks for BCBSNM)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

Module	Clinical Criteria for Approval				
Table 5: Mavyret Treatment Recommendations based on FDA labeling					
Genotype	Patient Population - adults and pediatric patients 3 years of age and older*†	Treatment	Duration - No Cirrhosis	Duration - Compensated Cirrhosis (Child-Pugh A)	
1, 2, 3, 4, 5, or 6	Liver or kidney transplant recipients	Mavyret	12 weeks	12 weeks	
1	Liver or kidney transplant recipients who are treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks	
3	Liver or kidney transplant recipients who are treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or	Mavyret	16 weeks	16 weeks	

Module	Clinical Criteria for Approval				
		NS5A inhibitor)			
	1, 2, 3, 4, 5, or 6	Treatment naive	Mavyret	BCBSNM: 12 weeks ALL other plans: 8 weeks	BCBSNM: 12 weeks ALL other plans: 8 weeks
	1	Treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks
	1	Treatment experienced with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, telaprevir) but without prior treatment with an NS5A inhibitor	Mavyret	12 weeks	12 weeks
	1, 2, 4, 5, or 6	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	BCBSNM: 12 weeks ALL other plans: 8 weeks	12 weeks

Module	Clinical Criteria for Approval				
	3	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	16 weeks	16 weeks
<p>*HCV/HIV-1 co-infection, follow recommendations in the table above</p>					
<p>+ Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendations in the table above</p>					
<p>The requested agent will also be approved when the following are met:</p>					
<ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] 					
<p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>					
<p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p>					
<p>Length of Approval: 12 months</p>					
<p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>					

Module	Clinical Criteria for Approval	
Sovaldi	Preferred Agents	Non-Preferred Agents
	Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 2 Sovaldi (sofosbuvir)
	Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 3 Sovaldi (sofosbuvir)
	Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 5
	Genotype 6 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 6
	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: 	

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> A. The patient is a pediatric patient with a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 2 or 3 AND if the patient has an FDA labeled indication, ONE of the following: <ul style="list-style-type: none"> 1. The patient's age is within FDA labeling for the requested agent for the requested indication OR 2. There is support for using the requested agent for the patient's age for the requested indication OR B. The patient is a pediatric patient with a diagnosis of hepatitis C genotype 2 or 3 AND ALL of the following: <ul style="list-style-type: none"> 1. If the patient has an FDA labeled indication, then ONE of the following: <ul style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested agent for the requested indication OR B. There is support for using the requested agent for the patient's age for the requested indication AND 2. ONE of the following: <ul style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes required] OR C. The patient has an intolerance or hypersensitivity to BOTH Epclusa and Mavyret [chart notes required] OR D. The patient has an FDA labeled contraindication to BOTH Epclusa and Mavyret OR E. BOTH Epclusa and Mavyret are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR F. BOTH Epclusa and Mavyret are not in the best interest of the patient based on medical necessity [chart notes required] OR G. There is support for the use of the requested agent over BOTH Epclusa and Mavyret (e.g., the patient is currently taking the requested agent) AND 3. ONE of the following: <ul style="list-style-type: none"> A. The patient is treatment naive OR B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin OR C. The patient is an adult and has a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 1, 2, 3, or 4 OR D. The patient is an adult with a diagnosis of hepatitis C genotype 1, 2, 3, or 4 AND BOTH of the following: <ul style="list-style-type: none"> 1. ONE of the following: <ul style="list-style-type: none"> A. The patient is treatment naive OR B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin AND 2. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following: <ul style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient has been treated with the requested non-preferred agent in the past 30 days OR C. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested non-preferred agent [chart notes required] OR D. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR E. ALL of the preferred agent(s) for the patient's specific factors were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR F. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR

Module	Clinical Criteria for Approval
	<p>G. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR</p> <p>H. ALL of the preferred agent(s) for the patient's specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>I. ALL of the preferred agent(s) for the patient's specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>K. There is support for the use of the requested non-preferred agent over the preferred agent(s) AND</p> <p>2. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND</p> <p>3. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND</p> <p>4. ONE of the following:</p> <p>A. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, infectious disease), or has consulted with a specialist in the area of the patient's diagnosis OR</p> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Eligible for or Excluded from Simplified HCV Treatment tables below) AND <div data-bbox="289 1220 1003 1724" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p>Patients Eligible for Simplified HCV Treatment</p> <p>Adults with chronic HCV infection, including persons living with HIV:</p> <ul style="list-style-type: none"> • Infected with any genotype • Have NOT previously received HCV treatment • Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by: <ul style="list-style-type: none"> ○ Liver stiffness > 12.5 kPa by FibroScan ○ FIB-4 > 3.25 ○ Noninvasive serologic test ○ Liver biopsy ○ Liver nodularity or splenomegaly on imaging ○ Platelet count < 150,000/mm³ </div> <div data-bbox="289 1730 1003 1990" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Patients Excluded from Simplified HCV Treatment</p> <p>Adults with chronic HCV infection:</p> <ul style="list-style-type: none"> • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) </div>

Module	Clinical Criteria for Approval														
	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <ul style="list-style-type: none"> Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 Current pregnancy Known or suspected hepatocellular carcinoma Prior liver transplantation </div> <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. The patient meets all requirements and will use the requested agent will in a treatment regimen noted in Table 6 or 7 (FDA labeling) AND 3. The requested length of therapy does NOT exceed the length of therapy noted in Table 6 or 7 (FDA labeling) for the patient’s treatment regimen <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 6 or 7 (at least 12 weeks for BCBSNM)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Table 6: Sovaldi Treatment Recommendations in Adult Patients with Genotype 1, 2, 3, or 4 Based on FDA Labeling</p>														
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Genotype</th> <th style="text-align: left;">Patient population*</th> <th style="text-align: left;">Treatment</th> <th style="text-align: left;">Duration</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;">1 or 4</td> <td style="vertical-align: top;">Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td style="vertical-align: top;">Sovaldi + Peg-interferon alfa + ribavirin</td> <td style="vertical-align: top;">12 weeks</td> </tr> <tr> <td style="vertical-align: top;">1</td> <td style="vertical-align: top;"> Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A) and are interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> Intolerance to interferon Autoimmune hepatitis and other autoimmune disorders Hypersensitivity to PEG interferon or any of its components </td> <td style="vertical-align: top;">Sovaldi + ribavirin</td> <td style="vertical-align: top;">24 weeks</td> </tr> </tbody> </table>	Genotype	Patient population*	Treatment	Duration	1 or 4	Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Peg-interferon alfa + ribavirin	12 weeks	1	Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A) and are interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> Intolerance to interferon Autoimmune hepatitis and other autoimmune disorders Hypersensitivity to PEG interferon or any of its components 	Sovaldi + ribavirin	24 weeks		
Genotype	Patient population*	Treatment	Duration												
1 or 4	Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Peg-interferon alfa + ribavirin	12 weeks												
1	Treatment naive without cirrhosis or with compensated cirrhosis (Child-Pugh A) and are interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> Intolerance to interferon Autoimmune hepatitis and other autoimmune disorders Hypersensitivity to PEG interferon or any of its components 	Sovaldi + ribavirin	24 weeks												

Module	Clinical Criteria for Approval			
		<ul style="list-style-type: none"> • Decompensated hepatic disease • Major uncontrolled depressive illness • A baseline neutrophil count below 1500/μL • A baseline platelet count below 90,000/μL • A baseline hemoglobin below 10 g/dL • A history of preexisting cardiac disease) 		
2		Treatment naive or treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	12 weeks
3		Treatment naive or treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	24 weeks
1-4		With hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 48 weeks BCBSNM: at least 12 weeks)
*HCV/HIV-1 co-infection, follow recommendations in table above				

Table 7: Sovaldi and Ribavirin with or without Peg-interferon Treatment Recommendations for Pediatric Patients 3 Years of Age and Older Based on FDA Labeling

Genotype	Patient population*	Treatment	Duration
2	Treatment naive and treatment experienced (i.e., patients who have failed an interferon-based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	12 weeks
3	Treatment naive and treatment experienced (i.e., patients who have failed an interferon-based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	24 weeks
2 or 3	Pediatric patients with hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	48 weeks

*HCV/HIV-1 co-infection, follow recommendations in table above

The requested agent will also be approved when the following are met:

1. The member resides in Ohio **AND**
2. The plan is Fully Insured or HIM Shop (SG) **AND** BOTH of the following
 - A. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
 - B. ONE of the following:
 1. The patient has another FDA labeled indication for the requested agent and route of administration **OR**
 2. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**
 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double

Module	Clinical Criteria for Approval												
	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>												
Vosevi	<table border="1"> <thead> <tr> <th data-bbox="232 646 732 680">Preferred Agents</th> <th data-bbox="732 646 1414 680">Non-Preferred Agents</th> </tr> </thead> <tbody> <tr> <td data-bbox="232 680 732 961"> <p>Genotype 1</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 680 1414 961"> <p>Genotype 1</p> <p>Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)</p> </td> </tr> <tr> <td data-bbox="232 961 732 1182"> <p>Genotype 2</p> <p>Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 961 1414 1182"> <p>Genotype 2</p> <p>Sovaldi (sofosbuvir)</p> </td> </tr> <tr> <td data-bbox="232 1182 732 1402"> <p>Genotype 3</p> <p>Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 1182 1414 1402"> <p>Genotype 3</p> <p>Sovaldi (sofosbuvir)</p> </td> </tr> <tr> <td data-bbox="232 1402 732 1680"> <p>Genotype 4</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 1402 1414 1680"> <p>Genotype 4</p> <p>Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)</p> </td> </tr> <tr> <td data-bbox="232 1680 732 1948"> <p>Genotype 5</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p> </td> <td data-bbox="732 1680 1414 1948"> <p>Genotype 5</p> </td> </tr> </tbody> </table>	Preferred Agents	Non-Preferred Agents	<p>Genotype 1</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 1</p> <p>Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)</p>	<p>Genotype 2</p> <p>Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 2</p> <p>Sovaldi (sofosbuvir)</p>	<p>Genotype 3</p> <p>Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 3</p> <p>Sovaldi (sofosbuvir)</p>	<p>Genotype 4</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 4</p> <p>Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)</p>	<p>Genotype 5</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 5</p>
Preferred Agents	Non-Preferred Agents												
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<p>Genotype 4</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 4</p> <p>Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)</p>												
<p>Genotype 5</p> <p>Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</p>	<p>Genotype 5</p>												

Module	Clinical Criteria for Approval
	<p data-bbox="237 184 396 216">Genotype 6</p> <p data-bbox="237 254 688 453"> Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) </p> <p data-bbox="735 306 891 338" style="text-align: center;">Genotype 6</p> <p data-bbox="277 499 1130 531">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="277 569 1417 1955" style="list-style-type: none"> 1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 AND 2. If genotype 1, the prescriber has provided the patient's subtype AND 3. The patient is NOT treatment naive AND 4. The patient has NOT been previously treated with the requested agent AND 5. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for the use of the requested agent for the patient's age for the requested indication AND 6. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND 7. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND 8. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient has been treated with the requested non-preferred agent in the past 30 days OR C. The requested agent is a preferred agent for the patient's specific factors OR D. The patient has been treated with the requested non-preferred agent in the past 30 days OR E. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested non-preferred agent [chart notes required] OR F. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR G. ALL of the preferred agent(s) for the patient's specific factors was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR H. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR I. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR J. ALL of the preferred agent(s) for the patient's specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR K. ALL of the preferred agent(s) for the patient's specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR L. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR M. There is support for the use of the requested non-preferred agent over the preferred agent(s) AND 9. ONE of the following: <ol style="list-style-type: none"> A. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient's diagnosis OR B. ALL of the following: <ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND

Module	Clinical Criteria for Approval
	<p data-bbox="469 180 1370 323"> 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below) AND </p> <p data-bbox="285 369 919 396">Patients Eligible for Simplified HCV Treatment</p> <p data-bbox="285 407 1058 464">Adults with chronic HCV infection, including persons living with HIV:</p> <ul data-bbox="574 501 1118 905" style="list-style-type: none"> ▪ Infected with any genotype ▪ Have NOT previously received HCV treatment ▪ Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by: <ul style="list-style-type: none"> ▪ Liver stiffness > 12.5 kPa by FibroScan ▪ FIB-4 > 3.25 ▪ Noninvasive serologic test ▪ Liver biopsy ▪ Liver nodularity or splenomegaly on imaging ▪ Platelet count < 150,000/mm³ <p data-bbox="285 955 967 982">Patients Excluded from Simplified HCV Treatment</p> <p data-bbox="285 993 704 1020">Adults with chronic HCV infection:</p> <ul data-bbox="574 1058 1118 1404" style="list-style-type: none"> ▪ Previously received HCV treatment ▪ Hepatitis B surface antigen-positive ▪ Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) ▪ Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 ▪ Current pregnancy ▪ Known or suspected hepatocellular carcinoma ▪ Prior liver transplantation <p data-bbox="285 1486 1406 1661"> 10. The patient does NOT have any FDA labeled contraindications to the requested agent AND 11. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 9 AND 12. The requested length of therapy does NOT exceed the length of therapy noted in Table 9 (FDA labeling) for the patient's regimen </p> <p data-bbox="285 1696 547 1724">Length of Approval:</p> <p data-bbox="285 1766 667 1793">BCBSIL and BCBSMT: 6 months</p> <p data-bbox="285 1833 1406 1890">ALL other plans: Up to the duration of treatment as determined in Table 9 (at least 12 weeks for BCBSNM)</p>

Module	Clinical Criteria for Approval			
<p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>				
<p>Table 9: Vosevi Treatment Recommendations based on FDA labeling</p>				
Genotype	Patient Population*	Patients Previously Treated with an HCV Regimen containing:	Duration	
1, 2, 3, 4, 5, or 6	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	An NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)	12 weeks	
1a or 3	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sofosbuvir without an NS5A inhibitor**	12 weeks	
<p>*HCV/HIV-1 co-infection, follow recommendations in table above</p>				
<p>**Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)</p>				
<p>The requested agent will also be approved when the following are met:</p>				
<ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] 				
<p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>				
<p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p>				
<p>Length of Approval: 12 months</p>				
<p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>				

Module	Clinical Criteria for Approval	
Zepatier	Preferred Agents	Non-Preferred Agents
	Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 2 Sovaldi (sofosbuvir)
	Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 3 Sovaldi (sofosbuvir)
	Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 5
	Genotype 6 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 6
	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of hepatitis C genotype 1 or 4 AND 2. BOTH of the following: 	

Module	Clinical Criteria for Approval		
	<p>A. If genotype 1, the prescriber has provided the patient's subtype AND</p> <p>B. If the subtype 1a, the prescriber has tested the patient for NS5A polymorphisms AND</p> <p>3. ONE of the following:</p> <p>A. The patient is treatment naive OR</p> <p>B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor AND</p> <p>4. If the patient has an FDA approved indication, ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for the use of the requested agent for the patient's age for the requested indication AND</p> <p>5. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection AND</p> <p>6. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND</p> <p>7. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient has been treated with the requested non-preferred agent in the past 30 days OR 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 4. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR 5. ALL of the preferred agent(s) for the patient's specific factors was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 6. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR 7. The patient has FDA labeled contraindication to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR 8. ALL of the preferred agent(s) for the patient's specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR 9. ALL of the preferred agent(s) for the patient's specific factors are not in the best interest of the patient based on medical necessity [chart notes required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 11. There is support for the use of the requested non-preferred agent over the preferred agent(s) AND <p>8. ONE of the following:</p> <p>A. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient's diagnosis OR</p> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Eligible for or Excluded for Simplified HCV Treatment tables below) AND 		
	<table border="1" style="width: 100%;"> <tr> <td data-bbox="232 1797 1128 1864" style="background-color: #e0e0e0;">Patients Without Cirrhosis Who Qualify for Simplified Treatment</td> </tr> <tr> <td data-bbox="232 1864 1128 1953"> <ul style="list-style-type: none"> ▪ Hepatitis B surface antigen (HBsAg) negative ▪ NOT currently pregnant </td> </tr> </table>	Patients Without Cirrhosis Who Qualify for Simplified Treatment	<ul style="list-style-type: none"> ▪ Hepatitis B surface antigen (HBsAg) negative ▪ NOT currently pregnant
Patients Without Cirrhosis Who Qualify for Simplified Treatment			
<ul style="list-style-type: none"> ▪ Hepatitis B surface antigen (HBsAg) negative ▪ NOT currently pregnant 			

Module	Clinical Criteria for Approval												
	<ul style="list-style-type: none"> ▪ No known or suspected hepatocellular carcinoma ▪ No prior liver transplantation <p>Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment</p> <ul style="list-style-type: none"> ▪ Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) ▪ Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) ▪ HBsAg negative ▪ NOT currently pregnant ▪ No known or suspected hepatocellular carcinoma ▪ No prior liver transplantation <p>9. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>10. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 10 (FDA labeling) AND</p> <p>11. The requested length of therapy does NOT exceed the length of therapy noted in Table 10 (FDA labeling) for the patient’s treatment regimen</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 10 (BCBSNM: at least 12 weeks)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Table 10: Zepatier Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="233 1545 1128 1974"> <thead> <tr> <th data-bbox="233 1545 456 1612">Genotype</th> <th data-bbox="456 1545 683 1612">Patient Population*</th> <th data-bbox="683 1545 906 1612">Treatment</th> <th data-bbox="906 1545 1128 1612">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="233 1612 456 1881">1a</td> <td data-bbox="456 1612 683 1881">Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</td> <td data-bbox="683 1612 906 1881">Zepatier</td> <td data-bbox="906 1612 1128 1881">12 weeks</td> </tr> <tr> <td data-bbox="233 1881 456 1974">1a</td> <td data-bbox="456 1881 683 1974">Treatment-naïve or PegIFN/RBV-experienced <u>with</u></td> <td data-bbox="683 1881 906 1974">Zepatier + ribavirin</td> <td data-bbox="906 1881 1128 1974">16 weeks</td> </tr> </tbody> </table>	Genotype	Patient Population*	Treatment	Duration	1a	Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier	12 weeks	1a	Treatment-naïve or PegIFN/RBV-experienced <u>with</u>	Zepatier + ribavirin	16 weeks
Genotype	Patient Population*	Treatment	Duration										
1a	Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier	12 weeks										
1a	Treatment-naïve or PegIFN/RBV-experienced <u>with</u>	Zepatier + ribavirin	16 weeks										

Module	Clinical Criteria for Approval			
		baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93		
1b		Treatment-naive or PegIFN/RBV-experienced	Zepatier	12 weeks
1a or 1b		PegIFN/RBV/protase inhibitor-experienced	Zepatier + ribavirin	12 weeks
4		Treatment-naive	Zepatier	12 weeks
4		PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks
<p>*HCV/HIV-1 co-infection, follow dosage recommendations in the table above</p> <p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>				

ZZZ New to Market Hepatitis C Agents	Preferred Agents	Non-Preferred Agents
	Genotype 1 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir)	Genotype 1 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)

Module	Clinical Criteria for Approval	
	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
	Genotype 2 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 2 Sovaldi (sofosbuvir)
	Genotype 3 Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 3 Sovaldi (sofosbuvir)
	Genotype 4 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 4 Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
	Genotype 5 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 5
	Genotype 6 Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Genotype 6
<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has an FDA labeled diagnosis for the requested agent AND 2. The requested agent is FDA labeled for treatment of the patient's genotype AND 3. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for the use of the requested agent for the patient's age for the requested indication AND 4. If FDA labeling for the requested agent requires patients are tested for hepatitis B viral (HBV) infection prior to starting treatment with the requested agent BOTH of the following <ol style="list-style-type: none"> A. The prescriber has screened the patient for current or prior HBV AND 		

Module	Clinical Criteria for Approval
	<p>B. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. ONE of the following:</p> <p>A. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease), or has consulted with a specialist in the area of the patient’s diagnosis OR</p> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient is treatment naive AND 2. The patient does NOT have cirrhosis or has compensated cirrhosis AND 3. The requested agent is supported in AASLD guidelines for simplified treatment AND 4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below) AND <p>Patients Eligible for Simplified HCV Treatment</p> <p>Adults with chronic HCV infection, including persons living with HIV:</p> <ul style="list-style-type: none"> • Infected with any genotype • Have NOT previously received HCV treatment • Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by: <ul style="list-style-type: none"> ○ Liver stiffness > 12.5 kPa by FibroScan ○ FIB-4 > 3.25 ○ Noninvasive serologic test ○ Liver biopsy ○ Liver nodularity or splenomegaly on imaging ○ Platelet count < 150,000/mm³ <p>Patients Excluded from Simplified HCV Treatment</p> <p>Adults with chronic HCV infection:</p> <ul style="list-style-type: none"> • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m²) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation <p>1. If the client has preferred agent(s) for the patient’s specific factors (e.g., age, genotype, cirrhosis status, treatment naive vs treatment experienced, previous treatment), then ONE of the following:</p> <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The requested agent is a preferred agent for the patient’s specific factors OR C. The patient has been treated with the requested non-preferred agent in the past 30 days OR D. The patient is currently being treated with the requested non-preferred agent and the patient is currently stable on the requested agent [chart notes required] OR E. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the patient’s specific factors [chart notes required] OR F. ALL of the preferred agent(s) for the patient’s specific factors were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR

Module	Clinical Criteria for Approval																																				
	<p>G. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR</p> <p>H. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) for the patient's specific factors [chart notes required] OR</p> <p>I. ALL of the preferred agent(s) for the patient's specific factors are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>J. ALL of the preferred agent(s) for the patient's specific factors is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agent(s) for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>L. There is support for the use of the requested non-preferred agent over the preferred agent(s) AND</p> <p>2. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 11 (FDA labeling) AND</p> <p>3. The requested length of therapy does NOT exceed the length of therapy noted in Table 11 (FDA labeling) for the patient's treatment regimen</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 11. (at least 12 weeks for BCBSNM)</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Table 11: Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 1129 1128 1417"> <thead> <tr> <th data-bbox="235 1129 381 1255">Agent(s)</th> <th data-bbox="381 1129 527 1255">FDA labeled indication(s)</th> <th data-bbox="527 1129 673 1255">Genotype</th> <th data-bbox="673 1129 820 1255">Treatment Regimen</th> <th data-bbox="820 1129 966 1255">FDA labeled dose</th> <th data-bbox="966 1129 1128 1255">Duration</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> <p>The requested agent will also be approved when the following are met:</p> <p>1. The member resides in Ohio AND</p> <p>2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following</p> <p>A. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>B. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double 	Agent(s)	FDA labeled indication(s)	Genotype	Treatment Regimen	FDA labeled dose	Duration																														
Agent(s)	FDA labeled indication(s)	Genotype	Treatment Regimen	FDA labeled dose	Duration																																

Module	Clinical Criteria for Approval
	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval												
<p>Epclusa and Sofosbuvir/Velpatasvir</p>	<p>Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. The requested length of therapy does NOT exceed the length of therapy noted in Table 1 (FDA labeling) or 2 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient’s treatment regimen AND 2. ONE of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the program quantity limit OR B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> 1. The requested agent is Epclusa 200 mg/50 mg packets AND BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed 2 packets per day AND B. There is support for why the patient cannot take 1 tablet of the 400 mg/100 mg tablet OR 2. The requested agent is Epclusa 200 mg/50 mg tablet AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed 2 tablets per day AND 2. There is support for why the patient cannot take 1 tablet of the 400 mg/100mg tablet <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Tables 1 or 2.</p> <p>Table 1: Epclusa or Sofosbuvir/Velpatasvir Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 1659 1226 1974"> <thead> <tr> <th data-bbox="235 1659 479 1722">Genotype</th> <th data-bbox="479 1659 730 1722">Patients 3 years of age and older*</th> <th data-bbox="730 1659 982 1722">Treatment</th> <th data-bbox="982 1659 1226 1722">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1722 479 1879">1,2, 3, 4, 5, or 6</td> <td data-bbox="479 1722 730 1879">Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="730 1722 982 1879">Epclusa Sofosbuvir/Velpatasvir</td> <td data-bbox="982 1722 1226 1879">12 weeks</td> </tr> <tr> <td data-bbox="235 1879 479 1974">1, 2, 3, 4, 5, or 6</td> <td data-bbox="479 1879 730 1974">Patients with decompensated</td> <td data-bbox="730 1879 982 1974">Epclusa + ribavirin Sofosbuvir/Velpatasvir + ribavirin</td> <td data-bbox="982 1879 1226 1974">12 weeks</td> </tr> </tbody> </table>	Genotype	Patients 3 years of age and older*	Treatment	Duration	1,2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa Sofosbuvir/Velpatasvir	12 weeks	1, 2, 3, 4, 5, or 6	Patients with decompensated	Epclusa + ribavirin Sofosbuvir/Velpatasvir + ribavirin	12 weeks
Genotype	Patients 3 years of age and older*	Treatment	Duration										
1,2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa Sofosbuvir/Velpatasvir	12 weeks										
1, 2, 3, 4, 5, or 6	Patients with decompensated	Epclusa + ribavirin Sofosbuvir/Velpatasvir + ribavirin	12 weeks										

Module	Clinical Criteria for Approval															
	<div style="border: 1px solid black; padding: 2px; display: inline-block;">cirrhosis (Child-Pugh B and C)</div>															
	*HCV/HIV-1 co-infection, follow recommendations in table above															
	Table 2: Eplusa or Sofosbuvir/Velpatasvir Decompensated Cirrhosis Treatment Recommendations based on AASLD/IDSA Guidelines for Unique populations															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="232 384 483 443">Genotype</th> <th data-bbox="483 384 732 443">Patient population*</th> <th data-bbox="732 384 980 443">Treatment</th> <th data-bbox="980 384 1229 443">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="232 443 483 800">1, 2, 3, 4, 5, or 6</td> <td data-bbox="483 443 732 800">Patients with decompensated cirrhosis (Child-Pugh B and C) who are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)</td> <td data-bbox="732 443 980 800">Eplusa Sofosbuvir/Velpatasvir</td> <td data-bbox="980 443 1229 800">24 weeks</td> </tr> <tr> <td data-bbox="232 800 483 1327">1, 2, 3, 4, 5, or 6</td> <td data-bbox="483 800 732 1327">Patients with decompensated cirrhosis (Child-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) -based treatment failed</td> <td data-bbox="732 800 980 1327">Eplusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis) Sofosbuvir/Velpatasvir with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis)</td> <td data-bbox="980 800 1229 1327">24 weeks</td> </tr> </tbody> </table>				Genotype	Patient population*	Treatment	Duration	1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) who are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Eplusa Sofosbuvir/Velpatasvir	24 weeks	1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) -based treatment failed	Eplusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis) Sofosbuvir/Velpatasvir with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis)	24 weeks
Genotype	Patient population*	Treatment	Duration													
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) who are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Eplusa Sofosbuvir/Velpatasvir	24 weeks													
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) -based treatment failed	Eplusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis) Sofosbuvir/Velpatasvir with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Pugh class C cirrhosis)	24 weeks													
	*HCV/HIV-1 co-infection, follow recommendations in table above															
Harvoni and Ledipasvir/Sofosbuvir	<p>Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. The requested length of therapy does NOT exceed the length of therapy noted in Table 3 (FDA labeling) or 4 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient's treatment regimen AND 2. ONE of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the program quantity limit OR B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> 1. The requested agent is Harvoni 45 mg/200 mg oral pellets AND BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed 2 packets daily AND B. There is support for why the patient cannot take 1 tablet of Harvoni 90 mg/400 mg strength OR 2. The requested agent is Harvoni 45 mg/200 mg tablet AND BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed 2 tablets daily AND 															

Module	Clinical Criteria for Approval																							
	<p>B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit</p> <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 3 or 4.</p> <p>Table 3: Harvoni or Ledipasvir/Sofosbuvir Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 636 1227 1980"> <thead> <tr> <th data-bbox="235 636 483 705">Genotype</th> <th data-bbox="483 636 732 705">Patients 3 years of age and older*</th> <th data-bbox="732 636 980 705">Treatment</th> <th data-bbox="980 636 1227 705">Treatment Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 705 483 915">1</td> <td data-bbox="483 705 732 915">Treatment-naïve with initial viral load of less than 6 M IU/mL</td> <td data-bbox="732 705 980 915">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="980 705 1227 915">12 weeks** **NOTE approve 8 weeks length of therapy only if prescriber is requesting 8 weeks of therapy</td> </tr> <tr> <td data-bbox="235 915 483 1068">1</td> <td data-bbox="483 915 732 1068">Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="732 915 980 1068">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="980 915 1227 1068">12 weeks</td> </tr> <tr> <td data-bbox="235 1068 483 1482">1</td> <td data-bbox="483 1068 732 1482">Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis</td> <td data-bbox="732 1068 980 1482">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="980 1068 1227 1482">12 weeks</td> </tr> <tr> <td data-bbox="235 1482 483 1980">1</td> <td data-bbox="483 1482 732 1980">Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and eligible for ribavirin</td> <td data-bbox="732 1482 980 1980">Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin</td> <td data-bbox="980 1482 1227 1980">12 weeks</td> </tr> </tbody> </table>				Genotype	Patients 3 years of age and older*	Treatment	Treatment Duration	1	Treatment-naïve with initial viral load of less than 6 M IU/mL	Harvoni Ledipasvir/Sofosbuvir	12 weeks** **NOTE approve 8 weeks length of therapy only if prescriber is requesting 8 weeks of therapy	1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir	12 weeks	1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis	Harvoni Ledipasvir/Sofosbuvir	12 weeks	1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and eligible for ribavirin	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin	12 weeks
Genotype	Patients 3 years of age and older*	Treatment	Treatment Duration																					
1	Treatment-naïve with initial viral load of less than 6 M IU/mL	Harvoni Ledipasvir/Sofosbuvir	12 weeks** **NOTE approve 8 weeks length of therapy only if prescriber is requesting 8 weeks of therapy																					
1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir	12 weeks																					
1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis	Harvoni Ledipasvir/Sofosbuvir	12 weeks																					
1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and eligible for ribavirin	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin	12 weeks																					

Module	Clinical Criteria for Approval		
1	1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Pugh A) and ineligible for ribavirin (i.e., patients with a history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni Ledipasvir/Sofosbuvir 24 weeks
1	1	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with decompensated cirrhosis (Child-Pugh B or C)	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin 12 weeks
1 or 4	1 or 4	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Harvoni + ribavirin Ledipasvir/Sofosbuvir + ribavirin 12 weeks

Module	Clinical Criteria for Approval														
	4, 5, or 6	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni Ledipasvir/Sofosbuvir 12 weeks												
*HCV/HIV-1 co-infection, follow recommendation in table above															
Table 4: Harvoni or Ledipasvir/Sofosbuvir Decompensated Cirrhosis Treatment Recommendations based on AASLD Guidelines for unique populations															
<table border="1"> <thead> <tr> <th data-bbox="232 957 483 1016">Genotype</th> <th data-bbox="483 957 732 1016">Patients 3 years of age and older*</th> <th data-bbox="732 957 980 1016">Treatment</th> <th data-bbox="980 957 1414 1016">Treatment Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="232 1016 483 1373">1, 4, 5, or 6</td> <td data-bbox="483 1016 732 1373">Patients with decompensated cirrhosis (Child-Pugh B or C) AND are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)</td> <td data-bbox="732 1016 980 1373">Harvoni Ledipasvir/Sofosbuvir</td> <td data-bbox="980 1016 1414 1373">24 weeks</td> </tr> <tr> <td data-bbox="232 1373 483 1709">1, 4, 5, or 6</td> <td data-bbox="483 1373 732 1709">Patients with decompensated cirrhosis (Child-Pugh B or C) previously treated with sofosbuvir-based treatment failure</td> <td data-bbox="732 1373 980 1709">Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated Ledipasvir/Sofosbuvir + low initial dose of ribavirin (600 mg); increase as tolerated</td> <td data-bbox="980 1373 1414 1709">24 weeks</td> </tr> </tbody> </table>				Genotype	Patients 3 years of age and older*	Treatment	Treatment Duration	1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) AND are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni Ledipasvir/Sofosbuvir	24 weeks	1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) previously treated with sofosbuvir-based treatment failure	Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated Ledipasvir/Sofosbuvir + low initial dose of ribavirin (600 mg); increase as tolerated	24 weeks
Genotype	Patients 3 years of age and older*	Treatment	Treatment Duration												
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) AND are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni Ledipasvir/Sofosbuvir	24 weeks												
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Pugh B or C) previously treated with sofosbuvir-based treatment failure	Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated Ledipasvir/Sofosbuvir + low initial dose of ribavirin (600 mg); increase as tolerated	24 weeks												

Mavyret

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. The requested length of therapy does NOT exceed the length of therapy noted in Table 5 (FDA labeling) for the patient’s treatment regimen **AND**
2. ONE of the following:
 - A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
 - B. The requested quantity (dose) exceeds the program quantity limit **AND ALL** of the following:

Module	Clinical Criteria for Approval			
	<ol style="list-style-type: none"> 1. The requested agent is Mavyret 50 mg/20 mg packets AND 2. The requested quantity (dose) does NOT exceed 6 packets per day AND 3. There is support for why the patient cannot take 3 tablets of the 100 mg/40 mg tablet <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 5.</p>			
	<p>Table 5: Mavyret Treatment Recommendations based on FDA labeling</p>			
	<p>Patient Population - adults and pediatric patients 3 years of age and older*+</p>	<p>Treatment</p>	<p>Duration - No Cirrhosis</p>	<p>Duration - Compensated Cirrhosis (Child-Pugh A)</p>
<p>1, 2, 3, 4, 5, or 6</p>	<p>Liver or kidney transplant recipients</p>	<p>Mavyret</p>	<p>12 weeks</p>	<p>12 weeks</p>
<p>1</p>	<p>Liver or kidney transplant recipients who are treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)</p>	<p>Mavyret</p>	<p>16 weeks</p>	<p>16 weeks</p>
<p>3</p>	<p>Liver or kidney transplant recipients who are treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with</p>	<p>Mavyret</p>	<p>16 weeks</p>	<p>16 weeks</p>

Module	Clinical Criteria for Approval				
		an HCV NS3/4A PI or NS5A inhibitor)			
	1, 2, 3, 4, 5, or 6	Treatment naïve	Mavyret	8 weeks	8 weeks
	1	Treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks
	1	Treatment experienced with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, telaprevir) but without prior treatment with an NS5A inhibitor	Mavyret	12 weeks	12 weeks
	1, 2, 4, 5, or 6	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	8 weeks	12 weeks
	3	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon,	Mavyret	16 weeks	16 weeks

Module	Clinical Criteria for Approval			
		ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)		
<p>*HCV/HIV-1 co-infection, follow recommendations in the table above +Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendations in the table above</p>				

Sovaldi

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. The requested length of therapy does NOT exceed the length of therapy noted in Table 6 or 7 (FDA labeling) for the patient’s treatment regimen **AND**
2. ONE of the following:
 - A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
 - B. The requested agent is Sovaldi 200 mg oral pellets AND BOTH of the following:
 1. The requested quantity (dose) does NOT exceed 2 packets daily **AND**
 2. There is support for why the patient cannot take 1 tablet of Sovaldi 400 mg strength **OR**
 - C. The requested agent is Sovaldi 200 mg tablets AND BOTH of the following:
 1. The requested quantity (dose) does NOT exceed 2 tablets daily **AND**
 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit

Length of Approval:

BCBSIL: 12 months

ALL other plans: Up to the duration of treatment as determined in Table 6 or 7.

Table 6: Sovaldi Treatment Recommendations in Adult Patients with Genotype 1, 2, 3, or 4 Based on FDA Labeling

Genotype	Patient population*	Treatment	Duration
1 or 4	Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Peg-interferon alfa + ribavirin	12 weeks
1	Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) and are interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> • Intolerance to interferon 	Sovaldi + ribavirin	24 weeks

Module	Clinical Criteria for Approval			
		<ul style="list-style-type: none"> • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to PEG interferon or any of its components • Decompensated hepatic disease • Major uncontrolled depressive illness • A baseline neutrophil count below 1500/μL • A baseline platelet count below 90,000/μL • A baseline hemoglobin below 10 g/dL • A history of preexisting cardiac disease) 		
2		Treatment naïve or treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	12 weeks
3		Treatment naïve or treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated	Sovaldi + ribavirin	24 weeks

Module	Clinical Criteria for Approval			
		cirrhosis (Child-Pugh A)		
1-4		With hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 48 weeks
*HCV/HIV-1 co-infection, follow recommendations in table above				
Table 7: Sovaldi and Ribavirin with or without Peg-interferon Treatment Recommendations for Pediatric Patients 3 years of Age and Older Based on FDA labeling				
	Genotype	Patient population*	Treatment	Duration
2		Treatment naïve and treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	12 weeks
3		Treatment naïve and treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	24 weeks
2 or 3		Pediatric patients with hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	48 weeks
*HCV/HIV-1 co-infection, follow recommendations in table above				
Vosevi	<p>Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. The requested length of therapy does NOT exceed the length of therapy noted in Table 9 (FDA labeling) for the patient’s regimen AND 2. The requested quantity (dose) does NOT exceed the program quantity limit <p>Length of Approval:</p> <p>BCBSIL: 12 months</p>			

Module	Clinical Criteria for Approval												
	<p>ALL other plans: Up to the duration of treatment as determined in Table 9.</p> <p>Table 9: Vosevi Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 315 1230 745"> <thead> <tr> <th data-bbox="235 315 483 472">Genotype</th> <th data-bbox="483 315 732 472">Patient Population*</th> <th data-bbox="732 315 980 472">Patients Previously Treated with an HCV Regimen Containing:</th> <th data-bbox="980 315 1230 472">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 472 483 619">1, 2, 3, 4, 5, or 6</td> <td data-bbox="483 472 732 619">Without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="732 472 980 619">An NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)</td> <td data-bbox="980 472 1230 619">12 weeks</td> </tr> <tr> <td data-bbox="235 619 483 745">1a or 3</td> <td data-bbox="483 619 732 745">Without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td> <td data-bbox="732 619 980 745">Sofosbuvir without an NS5A inhibitor^</td> <td data-bbox="980 619 1230 745">12 weeks</td> </tr> </tbody> </table> <p data-bbox="235 787 1417 871">*HCV/HIV-1 co-infection, follow recommendations in table above ^Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)</p>	Genotype	Patient Population*	Patients Previously Treated with an HCV Regimen Containing:	Duration	1, 2, 3, 4, 5, or 6	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	An NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)	12 weeks	1a or 3	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sofosbuvir without an NS5A inhibitor^	12 weeks
Genotype	Patient Population*	Patients Previously Treated with an HCV Regimen Containing:	Duration										
1, 2, 3, 4, 5, or 6	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	An NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)	12 weeks										
1a or 3	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sofosbuvir without an NS5A inhibitor^	12 weeks										
Zepatier	<p>Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:</p> <ol data-bbox="276 1039 1417 1134" style="list-style-type: none"> The requested length of therapy does NOT exceed the length of therapy noted in Table 10 (FDA labeling) for the patient’s treatment regimen AND The requested quantity (dose) does NOT exceed the program quantity limit <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Up to the duration of treatment as determined in Table 10.</p> <p>Table 10: Zepatier Treatment Recommendations based on FDA labeling</p> <table border="1" data-bbox="235 1428 1230 1942"> <thead> <tr> <th data-bbox="235 1428 483 1501">Genotype</th> <th data-bbox="483 1428 732 1501">Patient Population*</th> <th data-bbox="732 1428 980 1501">Treatment</th> <th data-bbox="980 1428 1230 1501">Duration</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1501 483 1774">1a</td> <td data-bbox="483 1501 732 1774">Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</td> <td data-bbox="732 1501 980 1774">Zepatier</td> <td data-bbox="980 1501 1230 1774">12 weeks</td> </tr> <tr> <td data-bbox="235 1774 483 1942">1a</td> <td data-bbox="483 1774 732 1942">Treatment-naïve or PegIFN/RBV-experienced <u>with</u> baseline NS5A polymorphisms at amino acid</td> <td data-bbox="732 1774 980 1942">Zepatier + ribavirin</td> <td data-bbox="980 1774 1230 1942">16 weeks</td> </tr> </tbody> </table>	Genotype	Patient Population*	Treatment	Duration	1a	Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier	12 weeks	1a	Treatment-naïve or PegIFN/RBV-experienced <u>with</u> baseline NS5A polymorphisms at amino acid	Zepatier + ribavirin	16 weeks
Genotype	Patient Population*	Treatment	Duration										
1a	Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier	12 weeks										
1a	Treatment-naïve or PegIFN/RBV-experienced <u>with</u> baseline NS5A polymorphisms at amino acid	Zepatier + ribavirin	16 weeks										

Module	Clinical Criteria for Approval			
		positions 28, 30, 31, or 93		
1b		Treatment-naïve or PegIFN/RBV-experienced	Zepatier	12 weeks
1a or 1b		PegIFN/RBV/protease inhibitor-experienced	Zepatier + ribavirin	12 weeks
4		Treatment-naïve	Zepatier	12 weeks
4		PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks

*HCV/HIV-1 co-infection, follow dosage recommendations in the table above

ZZZ New to Market Hepatitis C Agents

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

- The requested length of therapy does NOT exceed the length of therapy noted in Table 11 (FDA labeling) for the patient's treatment regimen **AND**
- ONE of the following:
 - The requested quantity (dose) does NOT exceed the program quantity limit **OR**
 - BOTH of the following:
 - The requested quantity (dose) is greater than the program quantity limit **AND**
 - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit

Length of approval:

BCBSIL 12 months

ALL other plans: Up to the duration of treatment as determined in Table 11.

Table 11: Treatment Recommendations based on FDA labeling

Agent(s)	FDA labeled indication (s)	Genotype	Treatment Regimen	FDA labeled dose	Treatment Duration