Clinical Policy: Sofosbuvir (Sovaldi)

Reference Number: CP.PCH.20
Effective Date: 11.01.16
Last Review Date: 02.20
Line of Business: Commercial, HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sofosbuvir (Sovaldi®) is hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor.

FDA Approved Indication(s)

Sovaldi is indicated for the treatment of chronic HCV infection in:

- Adult patients without cirrhosis or with compensated cirrhosis:
  - Genotype 1 or 4 for use in combination with pegylated interferon and ribavirin (RBV)
  - Genotype 2 or 3 for use in combination with RBV
- Pediatric patients 3 years of age and older with genotype 2 or 3 without cirrhosis or with compensated cirrhosis in combination with RBV

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Sovaldi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Diagnosis of chronic HCV infection as evidenced by detectable serum HCV RNA levels by quantitative assay in the last 6 months;
2. Confirmed HCV genotype is one of the following (a or b):
   a. For adults (≥ 18 years): Genotypes 1, 2, 3, 4, 5, or 6;
   b. For pediatrics (age ≥ 3 years): Genotypes 2 or 3;
   **Chart note documentation and copies of lab results are required*
3. Documentation of treatment status of the member (treatment-naïve or treatment-experienced);
4. Documentation of cirrhosis status of the member (no cirrhosis, compensated cirrhosis, or decompensated cirrhosis);
5. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program (*see Appendix F*);
6. Must meet one of the following (a, b, c, d or e):
   a. For members ≥ 18 years with genotype 1: Member must use Harvoni® (*authorized generic or brand for 8 wees only*), sofosbuvir/velpatasvir (Epclusa®)

(*authorized generic preferred*), Mavyret™, or Zepatier® unless all are contraindicated or clinically significant adverse effects are experienced;
   b. For members ≥ 18 years with genotype 4: Member must use sofosbuvir/velpatasvir (Epclusa) (*authorized generic preferred*), Mavyret, or Zepatier unless all are contraindicated or clinically significant adverse effects are experienced;
   c. For members ≥ 18 years with genotype 2, 3, 5, or 6: Member must use sofosbuvir/velpatasvir (Epclusa) (*authorized generic preferred*) or Mavyret, unless all are contraindicated or clinically significant adverse effects are experienced;
   d. For pediatric patients (age ≥ 6 years or weight ≥ 17 kg) with genotype 2 or 3, one of the following (i or ii):
      i. If age between 6 and 11 years, or weight between 17 kg and 44 kg, member must use sofosbuvir/velpatasvir (Epclusa®) (*authorized generic preferred*), unless are contraindicated or clinically significant adverse effects are experienced
      ii. If age ≥ 12 years or weight ≥ 45 kg: member must use Mavyret™ or sofosbuvir/velpatasvir (Epclusa®) (*authorized generic preferred*), unless both are contraindicated or clinically significant adverse effects are experienced;
   e. For pediatric patients (age ≥ 3 years) with genotype 1: Member must use Harvoni (*authorized generic or brand for 8 weeks only*), unless contraindicated or clinically significant adverse effects are experienced;
7. For pediatric patients (age ≥ 3 years) with genotype 2 or 3: use is in combination with RBV;
8. Life expectancy ≥ 12 months with HCV treatment;
9. Member agrees to participate in a medication adherence program meeting both of the following components (a and b):
   a. Medication adherence monitored by pharmacy claims data or member report;
   b. Member's risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;
10. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V Dosage and Administration for reference)*;
11. Dose does not exceed 400 mg (1 tablet) per day.

Approval duration:
Adults: up to a total of 24 weeks*
*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*
Pediatrics: 12 weeks for genotype 2; 24 weeks for genotype 3

B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Must meet both of the following (i and ii):
      i. Documentation supports that member is currently receiving Sovaldi for chronic HCV infection and has recently completed at least 60 days of treatment with Sovaldi;
      ii. Confirmed HCV genotype is one of the following (1 or 2):
         1) For adults (> 18 years): Genotypes 1, 2, 3, 4, 5, or 6;
         2) For pediatrics (age ≥ 3 years): Genotypes 2 or 3;
2. Member is responding positively to therapy;
3. Dose does not exceed 400 mg (1 tablet) per day.

Approval duration:
Adults: up to a total of 24 weeks*
*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*
Pediatrics: up to 12 weeks for genotype 2; up to 24 weeks for genotype 3

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
FDA: Food and Drug Administration
HBV: hepatitis B virus
HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDSA: Infectious Diseases Society of America
RBV: ribavirin
RNA: ribonucleic acid

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Harvoni® (sofosbuvir/ ledipasvir)	Without cirrhosis, treatment-naïve, whose HCV viral load is less than 6 million IU/mL: **Genotypes 1** One tablet PO QD for 8	Harvoni: sofosbuvir 400 mg/ ledipasvir 90 mg (1 tablet) per day
Epclusa® (sofosbuvir/ velpatasvir)	Without cirrhosis or with compensated cirrhosis, treatment naïve or treatment experienced: **Genotypes 1 through 6** One tablet PO QD for 12 weeks	Epclusa: One tablet (Adult/Peds ≥ 30 kg: sofosbuvir 400 mg /velpatasvir 100 mg; Peds 17 to 29 kg: sofosbuvir 200 mg /velpatasvir 50 mg) per day
Epclusa® (sofosbuvir/ velpatasvir) plus RBV	With decompensated cirrhosis (Child-Pugh class B or C) treatment-naïve or treatment experienced: **Genotypes 1 through 6** One tablet PO QD plus weight-based RBV for 12 weeks	Epclusa: One tablet (Adult/Peds ≥ 30 kg: sofosbuvir 400 mg /velpatasvir 100 mg; Peds 17 to 29 kg: sofosbuvir 200 mg /velpatasvir 50 mg) per day
Mavyret™ (glecaprevir/ pibrentasvir)	Treatment-naïve: **Genotypes 1, 2, 3, 4, 5, or 6** Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 8 weeks	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day
Mavyret™ (glecaprevir/ pibrentasvir)	Treatment-experienced with IFN/pegIFN + RBV +/- sofosbuvir CHC infection: **Genotypes 1, 2, 4, 5, or 6** Without cirrhosis: Three tablets PO QD for 8 weeks With compensated cirrhosis: Three tablets PO QD for 12 weeks	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day
Mavyret™ (glecaprevir/ pibrentasvir)	Treatment-experienced with IFN/pegIFN + RBV +/- sofosbuvir CHC infection: **Genotype 3** Without cirrhosis or with compensated cirrhosis:	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Three tablets PO QD for 16 weeks	
Mavyret™ (glecaprevir/ pibrentasvir	Treatment-experienced with NS5A inhibitor without prior NS3/4A protease inhibitor CHC infection: **Genotype 1** Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 16 weeks	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day
Mavyret™ (glecaprevir/ pibrentasvir)	Treatment-experienced with NS3/4A protease inhibitor without prior NS5A inhibitor CHC infection: **Genotype 1** Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 12 weeks	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 1a:** Treatment-naïve or pegIFN/RBV-experienced with or without compensated cirrhosis without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 One tablet PO QD for 12 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 1a:** Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis with baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 One tablet PO QD plus weight-based RBV for 16 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 1b:** Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis One tablet PO QD for 12 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Zepatier® (grazoprevir/ elbasvir)	**Genotype 1a or 1b:** pegIFN/RBV/NS3 PI*‡ -experienced with or without compensated cirrhosis without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 One tablet PO QD plus weight-based RBV for 12 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 1a or 1b:** pegIFN/RBV/NS3 PI*‡ -experienced with or without compensated cirrhosis with baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 One tablet PO QD plus weight-based RBV for 16 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 3‡:** pegIFN/RBV-experienced with compensated cirrhosis One tablet PO QD plus sofosbuvir 400 mg for 12 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 4:** Treatment-naïve with or without compensated cirrhosis One tablet PO QD for 12 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day
Zepatier® (grazoprevir/ elbasvir)	**Genotype 4:** PegIFN/RBV-experienced with or without compensated cirrhosis with virologic relapse/failure Virologic relapse after prior pegIFN/RBV therapy: One tablet PO QD for 12 weeks Virologic failure while on pegIFN/RBV therapy: One tablet PO QD plus weight-based RBV for 16 weeks	One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): when used in combination with peginterferon alfa/RBV or RBV alone, all contraindications to peginterferon alfa and/or RBV also apply to Sovaldi combination therapy.
- Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV

Appendix D: Direct-Acting Antivirals for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Mavyret*	Pibrentasvir			Glecaprevir	
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Vosevi*	Velpatasvir	Sofosbuvir		Voxilaprevir	
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

Appendix E: General Information

- Hepatitis B Virus Reactivation (HBV) is a Black Box Warning for all direct-acting antiviral drugs for the treatment of HCV. HBV reactivation has been reported when treating HCV for patients co-infected with HBV, leading to fulminant hepatitis, hepatic failure, and death, in some cases. Patients should be monitored for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up, with treatment of HBV infection as clinically indicated.
- Gane et al. studied 10 patients treated with Sovaldi monotherapy for 12 weeks who had genotype 2 or 3 disease. The primary efficacy (sustained virologic response (SVR) at 12 weeks after therapy stopped) was much lower (60%) on monotherapy versus 100% on combination therapy.
- Child-Pugh Score:

	1 Point	2 Points	3 Points
Bilirubin	Less than 2 mg/dL Less than 34 umol/L	2-3 mg/dL 34-50 umol/L	Over 3 mg/dL Over 50 umol/L
Albumin	Over 3.5 g/dL Over 35 g/L	2.8-3.5 g/dL 28-35 g/L	Less than 2.8 g/dL Less than 28 g/L

	1 Point	2 Points	3 Points
INR	Less than 1.7	1.7 - 2.2	Over 2.2
Ascites	None	Mild / medically controlled	Moderate-severe / poorly controlled
Encephalopathy	None	Mild / medically controlled Grade I-II	Moderate-severe / poorly controlled. Grade III-IV

Child-Pugh class is determined by the total number of points: A = 5-6 points; B = 7-9 points; C = 10-15 points.

- The 2017 AASLD/IDSA guidelines no longer recommend Solvadi/RBV for the indication of Genotype 2 or 3 with decompensated cirrhosis (moderate or severe hepatic impairment; CTP class B or C) who may or may not be candidates for liver transplantation, including those with hepatocellular carcinoma) or for the indication of hepatocellular carcinoma patients awaiting liver transplantation.

Appendix F: Healthcare Provider HCV Training

Acceptable HCV training programs and/or online courses include, but are not limited to the following:

- Hepatitis C online course (https://www.hepatitisc.uw.edu/): University of Washington is funded by the Division of Viral Hepatitis to develop a comprehensive, online self-study course for medical providers on diagnosis, monitoring, and management of hepatitis C virus infection. Free CME and CNE credit available.
- Fundamentals of Liver Disease (https://liverlearning.aasld.org/fundamentals-of-liver-disease): The AASLD, in collaboration with ECHO, the American College of Physicians (ACP), CDC, and the Department of Veterans Affairs, has developed Fundamentals of Liver Disease, a free, online CME course to improve providers' knowledge and clinical skills in hepatology.
- Clinical Care Options: http://www.clinicaloptions.com/hepatitis.aspx
- CDC training resources: https://www.cdc.gov/hepatitis/resources/professionals/trainingresources.htm

V. Dosage and Administration

Indication: Adult patients with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
Sovaldi, Olysio	Genotype 1: Treatment-naive or treatment-experienced with peg-IFN/RBV patients without cirrhosis: Sovaldi 400 mg plus Olysio 150 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Olysio	Genotype 1 or 4: Treatment-naïve or treatment-experienced, liver transplant patients with or without	Sovaldi: 400 mg/day	AASLD-IDSA (updated May 2018)

Indication: Adult patients with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
	compensated cirrhosis: Sovaldi 400 mg plus Olysio 150 mg PO QD with or without weight-based RBV for 12 weeks		
Sovaldi, Daklinza	Genotype 1: Treatment-naïve or treatment-experienced without cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 1, 2, 3, or 4: Decompensated cirrhosis (including those with hepatocellular carcinoma): Daklinza 60 mg plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 1, 2, 3, or 4: Decompensated cirrhosis (including those with hepatocellular carcinoma) and intolerant to RBV: Daklinza 60 mg plus Sovaldi 400 mg PO QD for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 1-6‡: Treatment-naïve or treatment- experienced, post-liver transplantation with or without compensated cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 2: Treatment-naïve or treatment-experienced without cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 2: Treatment -naïve or treatment- experienced with	Sovaldi: 400 mg/day	AASLD-IDSA (updated May 2018)

Indication: Adult patients with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
	compensated cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD for 16 to 24 weeks		
Sovaldi, Daklinza	Genotype 2 or 3: Treatment-naïve or treatment-experienced, post-liver transplantation with decompensated cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 3: Treatment-naïve or treatment-experienced with peg IFN/RBV without cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD for 12 weeks (If NS5A Y93H is present, weight- based RBV should be added)	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)
Sovaldi, Daklinza	Genotype 3: Treatment-naïve with compensated cirrhosis: Daklinza 60 mg plus Sovaldi 400 mg PO QD with or without weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA (updated May 2018)
Sovaldi, Zepatier ǂ	Genotype 3: pegIFN/RBV-experienced with compensated cirrhosis: Sovaldi 400 mg PO QD plus Zepatier 1 tablet PO QD for 12 weeks	Sovaldi: 400 mg per day	AASLD-IDSA (updated May 2018)

AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen.
ǂ Off-label, AASLD-IDSA guideline-supported dosing regimen
Treatment-experienced refers to previous treatment with peginterferon/RBV unless otherwise stated
The use of Sovaldi in combination with peginterferon and ribavirin for the treatment of chronic HCV is no longer recommended by the AASLD/IDSA guidelines.

Indication: Pediatric patients (age ≥ 3 years) with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
Sovaldi, RBV	Genotype 2: • ≥ 35 kg: Sovaldi 400 mg + RBV for 12 weeks • 17 to < 35 kg: Sovaldi 200 mg + RBV for 12 weeks • < 17 kg: Sovaldi 150 mg + RBV for 12 weeks	Sovaldi: 400 mg/day	FDA-approved labeling
Sovaldi, RBV	Genotype 3: • ≥ 35 kg: Sovaldi 400 mg + RBV for 24 weeks • 17 to < 35 kg: Sovaldi 200 mg + RBV for 24 weeks • < 17 kg: Sovaldi 150 mg + RBV for 24 weeks	Sovaldi: 400 mg/day	FDA-approved labeling

VI. Product Availability

Tablets: 400 mg, 200 mg
Oral pellets: 200 mg, 150 mg

VII. References

1. Sovaldi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; August 2019. Available at: http://www.sovaldi.com/. Accessed September 5, 2019.
2. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated May 24, 2018. Available at: https://www.hcvguidelines.org/. Accessed April 30, 2019.
3. Wirth et al. Sofosbuvir-Containing Regimens are Safe and Effective in Adolescents with Chronic hepatitis C Infection. 26th Annual Meeting of the Asian pacific Association for the Study of the Liver (APASL) on February 15-19, 2017 in Shangahi, China [oral GT1-3].
4. El-Shabrawi MH, Kamal NM. Burden of pediatric hepatitis C. World J Gastroenterol. 2013 Nov 28;19(44):7880-8. doi: 10.3748/wjg.v19.i44.7880.
5. Wirth S. Current treatment options and response rates in children with chronic hepatitis C. World J Gastroenterol 2012 Jan 14; 18(2): 99-104. doi:10.3748/wjg.v18.i2.99.
6. Wolitski R. When it comes to curing hepatitis c, your health care provider may not need to be a specialist. U.S. Department of Health & Human Services. Last updated September 20, 2017. Available at: https://www.hhs.gov/hepatitis/blog/2017/09/20/study-calls-for-expansion-of-hepatitis-c-treatment.html. Accessed October 30, 2019.
7. CDC. Viral hepatitis: Q&As for health professionals. Last updated July 2, 2019. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed October 30, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; per SDC and prior clinical guidance added HIM line of business to existing Commercial policy (modified policy number to CP.PCH.20, retired HIM.PA.SP2 and CP.CPA.176); added requirement that life expectancy ≥ 12 months with HCV treatment and participation in a medication adherence program.	12.03.19	02.20
Added new prescriber requirement to include a "provider who has expertise in treating HCV based on a certified training program"; Appendix F (Healthcare Provider HCV Training) added. RT4: updated Sovaldi FDA-approved age (3 years), dosage forms, and pediatric dosing information; added pediatric redirection to Harvoni for members age ≥ 3 years in initial criteria; updated Mavyret dosing recommendations to 8 weeks total duration of therapy for treatment-naïve HCV with compensated cirrhosis across all genotypes (1-6).	11.07.19	02.20
RT4: updated redirection for pediatric patients with genotype 2 or 3 to reflect the pediatric extension for Epclusa to age 6 years or weight ≥ 17 kg.	04.02.20	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.