

<b>Clinical Policy Title:</b>	ledipasvir/sofosbuvir
<b>Policy Number:</b>	RxA.161
<b>Drug(s) Applied:</b>	Harvoni®
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	09/14/2021
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Sofosbuvir/ledipasvir (Harvoni®) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.

Harvoni® is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV:

- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

## Dosing Information

Drug Name	Indication	Dosing Regimen *,**	Maximum Dose
ledipasvir/sofosbuvir (Harvoni®)	HCV Genotype 1	<p><b>Pediatric (age 3+): Weight-based</b></p> <ul style="list-style-type: none"> <li>• &lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>• 17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>• ≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p><b>Adult (age 18+):</b></p> <ul style="list-style-type: none"> <li>• ledipasvir 90mg/sofosbuvir 400mg orally once daily.</li> </ul> <p><b>Treatment duration:</b></p>	<p><b>Pediatric (age 3+):</b></p> <ul style="list-style-type: none"> <li>• &lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>• 17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>• ≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p><b>Adult:</b></p> <ul style="list-style-type: none"> <li>• 1 Oral tablet/day (sofosbuvir 400 mg/ ledipasvir 90 mg)</li> </ul>

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Dosing Information			
Drug Name	Indication	Dosing Regimen*,**	Maximum Dose
		<ul style="list-style-type: none"> <li>Treatment-naïve without cirrhosis, HIV uninfected or whose HCV viral load is less than 6 million IU/mL: for 8 weeks</li> <li>Treatment-naïve with compensated cirrhosis (Child-Pugh A): for 12 weeks (includes HIV coinfecting patients)</li> <li>Treatment-experienced with PegIFN/RBV without cirrhosis: for 12 weeks</li> <li>Treatment-experienced with compensated cirrhosis (Child-Pugh A): for 24 weeks</li> <li>Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child-Pugh B or C): for 12 weeks with RBV</li> </ul>	
ledipasvir/sofosbuvir (Harvoni®)	HCV Genotype 1 or 4	<p>Pediatric (age 3+): Weight-based</p> <ul style="list-style-type: none"> <li>&lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p>Adult (age 18+):</p> <ul style="list-style-type: none"> <li>ledipasvir 90mg/sofosbuvir 400 mg orally once daily</li> </ul> <p>Treatment Duration:</p>	<p>Pediatric:</p> <ul style="list-style-type: none"> <li>&lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p>Adult:</p> <ul style="list-style-type: none"> <li>ledipasvir 90mg/sofosbuvir 400 mg</li> </ul>

Dosing Information			
Drug Name	Indication	Dosing Regimen*,**	Maximum Dose
		<ul style="list-style-type: none"> <li>Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A): for 12 weeks with RBV</li> </ul>	
ledipasvir/sofosbuvir (Harvoni®)	HCV Genotype 4, 5, or 6	<p><b>Pediatric (age 3+): Weight-based</b></p> <ul style="list-style-type: none"> <li>&lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p><b>Adult (age 18+):</b></p> <ul style="list-style-type: none"> <li>ledipasvir 90mg/sofosbuvir 400 mg orally once daily</li> </ul> <p><b>Treatment duration:</b></p> <ul style="list-style-type: none"> <li>Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A): for 12 weeks</li> </ul>	<p><b>Pediatric:</b></p> <ul style="list-style-type: none"> <li>&lt;17 kg - Oral pellets: 33.75 mg ledipasvir/150 mg sofosbuvir once daily</li> <li>17 to &lt;35 kg - Oral pellets, tablets: 45 mg ledipasvir/200 mg sofosbuvir once daily</li> <li>≥35 kg - Oral pellets, tablets: 90 mg ledipasvir/400 mg sofosbuvir once daily</li> </ul> <p><b>Adult:</b></p> <ul style="list-style-type: none"> <li>sofosbuvir 400 mg/ ledipasvir 90 mg</li> </ul>

\*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.

\*\* Treatment-experienced refers to previous treatment with peginterferon/RBV unless otherwise stated.

### Dosage Forms

- Tablets: 90 mg of ledipasvir and 400 mg of sofosbuvir; 45 mg of ledipasvir and 200 mg of sofosbuvir
- Oral pellets: 45 mg of ledipasvir and 200 mg of sofosbuvir; 33.75 mg of ledipasvir and 150 mg of sofosbuvir

### Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting

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that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

## **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. Documentation of treatment status of the member (treatment-naïve or treatment experienced);
3. Documentation of cirrhosis status of the member (no cirrhosis, compensated cirrhosis, or decompensated cirrhosis);
4. Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease specialist; or provider who has expertise in treating HCV based on a certified training program.
5. Age  $\geq$  3 years;
6. Member meets one of the following (a, b)
  - a. HCV genotype is 1 and documentation of baseline viral load is provided;\*
  - b. HCV genotype is 4, 5, or 6;\*Chart note documentation and copies of lab results are required.
7. Life expectancy is 12 months or greater with HCV treatment;
8. Member must try generic ledipasvir-sofosbuvir 90-100 mg tablets before brand Harvoni 90-400 mg tablets;
9. Member meets one of the following (a or b):
  - a. Age  $<$ 6 years;
  - b. For ages 6 years or older, or weight 17 kg or greater, member meets one of the following (i or ii):
    - i. Request is for 8 weeks of therapy only;
    - ii. If request is for greater than 8 weeks of therapy, member must use one of the following (unless contraindicated or clinically significant adverse effects are experienced) (a or b):
      - a. If age is between 6 and 11 years, or weight between 17 kg and 44 kg, member must use sofosbuvir/velpatasvir (Epclusa®) at up to maximally indicated doses;
      - b. If age is 12 years or older, or weight is greater than 44 kg, member must use Mavyret® or sofosbuvir/velpatasvir (Epclusa®) at up to maximally indicated doses;
10. 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;
11. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (see Background for reference);
12. Dose does not exceed ledipasvir/sofosbuvir 90 mg/400 mg per day.

#### **Approval Duration:**

**Commercial:** 6 months

**Medicaid:** 6 months

## **II. Continued Therapy Approval**

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

1. Member meets one of the following (a or b):

- a. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
- b. Must meet both of the following (i and ii):
  - i. Documentation supports that member is currently receiving Harvoni® for chronic HCV infection and has recently completed at least 60 days of treatment with Harvoni®;
  - ii. Confirmed HCV genotype is 1, 4, 5, or 6;
2. Member is responding positively to therapy;
3. Dose does not exceed ledipasvir/sofosbuvir 90 mg/400 mg per day.

**Approval Duration:**

**Commercial:** 6 months

**Medicaid:** 6 months

**III. Appendices**

**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

IDSA: Infectious Diseases Society of America

NS3/4A, NS5A/B: nonstructural protein

RBV: ribavirin

PegIFN: pegylated interferon

**APPENDIX B: Therapeutic Alternatives**

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
sofosbuvir/velpatasvir (Epclusa®)	<p><b>HCV Genotype 1, 2, 3, 4, 5, or 6:</b></p> <p>Without cirrhosis, with compensated cirrhosis, treatment-naïve or -experienced patient</p> <ul style="list-style-type: none"> <li>• sofosbuvir 400 mg/velpatasvir 100 mg orally once daily for 12 weeks</li> </ul> <p>With decompensated cirrhosis treatment-naïve or -experienced patient</p> <ul style="list-style-type: none"> <li>• sofosbuvir 400 mg/velpatasvir 100 mg orally once daily for 12 weeks AND RBV</li> <li>• If ineligible for RBV, then 1 tablet orally once daily for 24 weeks ‡</li> </ul> <p>With decompensated cirrhosis in whom prior sofosbuvir- or NS5A-based treatment experienced failed</p> <ul style="list-style-type: none"> <li>• 1 tablet orally once daily for 24 weeks AND RBV</li> </ul> <p><b>HCV Genotype 1b:</b></p>	sofosbuvir 400 mg/velpatasvir 100 mg

Drug Name	Dosing Regimen	Maximum Dose
	<p>With compensated cirrhosis or without cirrhosis and non-NS5A inhibitor, sofosbuvir-containing regimen experienced</p> <ul style="list-style-type: none"> <li>sofosbuvir 400 mg/velpatasvir 100 mg orally once daily for 12 weeks</li> </ul>	
<p>glecaprevir/ pibrentasvir (Mavyret®)</p>	<p><b>HCV Genotype 1,2, 3, 4, 5, or 6:</b></p> <p>Treatment-naive</p> <ul style="list-style-type: none"> <li>Without cirrhosis or with compensated cirrhosis: <ul style="list-style-type: none"> <li>3 tablets orally once daily for 8 weeks</li> </ul> </li> <li>With compensated cirrhosis and HIV coinfection: <ul style="list-style-type: none"> <li>3 tablets orally once daily for 12 weeks</li> </ul> </li> </ul> <p>Treatment-experienced (with IFN/pegIFN + RBV)</p> <ul style="list-style-type: none"> <li>Without cirrhosis: <ul style="list-style-type: none"> <li>3 tablets orally once daily for 8 weeks</li> </ul> </li> <li>With compensated cirrhosis <ul style="list-style-type: none"> <li>3 tablets orally once daily for 12 weeks</li> </ul> </li> </ul> <p><b>HCV Genotype 1:</b></p> <p>Treatment-experienced with sofosbuvir</p> <ul style="list-style-type: none"> <li>Without cirrhosis or with compensated cirrhosis: <ul style="list-style-type: none"> <li>3 tablets orally once daily for 16 weeks</li> </ul> </li> </ul> <p><b>HCV Genotype 4, 5, or 6:</b></p> <p>Treatment-experienced with sofosbuvir</p> <ul style="list-style-type: none"> <li>Without cirrhosis or with compensated cirrhosis: <ul style="list-style-type: none"> <li>3 tablets orally once daily for 16 weeks</li> </ul> </li> </ul>	<p>3 tablets/day (glecaprevir 300 mg/ pibrentasvir 120 mg)</p>
<p>grazoprevir/ elbasvir (Zepatier®)</p>	<p><b>Genotype 1a:</b></p> <p>Treatment-naïve or pegIFN/RBV-experienced with or without compensated cirrhosis WITHOUT baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 and HIV coinfection</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily for 12 weeks</li> </ul> <p>Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis WITH baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily AND RBV for 16 weeks</li> </ul> <p><b>Genotype 1b:</b></p> <p>Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis and HIV coinfection</p>	<p>1 tablet/day (grazoprevir 100 mg/ elbasvir 50 mg)</p>

Drug Name	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> <li>1 tablet orally once daily for 12 weeks</li> </ul> <p><b>Genotype 1a or 1b:</b> Treatment-experienced with or without compensated cirrhosis WITHOUT baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily AND RBV for 12 weeks</li> </ul> <p>Treatment-experienced with or without compensated cirrhosis WITH baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily AND RBV for 16 weeks</li> </ul> <p><b>Genotype 4:</b> Treatment-naïve with or without compensated cirrhosis and HIV coinfection</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily for 12 weeks</li> </ul> <p>Virologic relapse after prior pegIFN/RBV therapy:</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily for 12 weeks</li> </ul> <p>Virologic failure after receiving pegIFN/RBV therapy:</p> <ul style="list-style-type: none"> <li>1 tablet orally once daily AND RBV for 16 weeks</li> </ul>	

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

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - If used in combination with RBV, all contraindications to RBV also apply to Harvoni® combination therapy.
- Boxed Warning(s):
  - Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV.

**APPENDIX D: Pharmacologic Categories for Alternate Therapies listed in Appendix B**

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor

			NS5B Palm Polymerase Inhibitor		
Epclusa®*	velpatasvir	sofosbuvir			
Harvoni®*	ledipasvir	sofosbuvir			
Mavyret®*	pibrentasvir			glecaprevir	
Sovaldi®		sofosbuvir			
Technivie®*	ombitasvir			paritaprevir	ritonavir
Viekira XR®/PAK®*	ombitasvir		dasabuvir	paritaprevir	ritonavir
Vosevi®*	velpatasvir	sofosbuvir		voxilaprevir	
Zepatier®*	elbasvir			grazoprevir	

\*Combination drug

#### 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.
- Treatment with Harvoni® for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL. In the ION-3 trial, patients with a baseline HCV viral load of < 6 million IU/mL and were treated with Harvoni® for 8 weeks achieved SVR-12 at a rate of 97% versus 96% of those treated with Harvoni® for 12 weeks.
- 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
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
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Child-Pugh class is determined by the total number of points: A = 5-6 points; B = 7-9 points; C = 10-15 points

**References**

1. Harvoni® Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; March 2020. Available at <http://www.harvoni.com/>. Accessed June 2, 2021.
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 August 27, 2020. Available at: <https://www.hcvguidelines.org/>. Accessed June 2, 2021.
3. Wirth S, Gonzalez-Peralta R, Rosenthal P, et al. Sofosbuvir-Containing Regimens are Safe and Effective in Adolescents with Chronic hepatitis C Infection. The 26th Annual Meeting of the Asian pacific Association for the Study of the Liver (APASL) in February 15-19, 2017 in Shanghai, China. Accessed June 2, 2021.
4. Squires JE, Balisteri WF. Hepatitis C Virus Infection in Children and Adolescents. Hepatology Communications 2017; 1(2): 87-98. Accessed June 2, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Background was updated to include updates in indication.</li> <li>3. Dosing information updated.</li> <li>4. Dosage Forms section updated.</li> <li>5. Therapeutic alternatives section updated.</li> <li>6. Added age and weight-based criteria to initial approval criteria.</li> <li>7. Updated initial approval duration.</li> <li>8. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance...".</li> <li>9. Updated abbreviations section.</li> <li>10. QD was updated to "once daily" in document.</li> <li>11. References were updated.</li> </ol>	08/26/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Continued Therapy criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by..."</li> <li>2. Therapeutic alternative verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance..".</li> <li>3. Appendix D was updated to remove Daklinza,</li> </ol>	5/28/2021	09/14/2021

<p>Olysio. 4. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Dosing Information dosing regimen for indication HCV Genotype 1 was updated to include “ledipasvir 90mg/sofosbuvir 400mg orally once daily” under Adult (age 18+).</li> <li>2. Dosing Information dosing regimen treatment duration for indication HCV Genotype 1 was updated from “Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) whose HCV viral load is less than 6 million IU/mL: For 8 weeks (12 weeks for black and/or HIV-coinfected patients)” to “Treatment-naïve without cirrhosis, HIV uninfected or whose HCV viral load is less than 6 million IU/mL: for 8 weeks.”</li> <li>3. Dosing Information dosing regimen for indication HCV Genotype 1 or 4 was updated to include “ledipasvir 90mg/sofosbuvir 400 mg orally once daily” under Adult (age 18+).</li> <li>4. Dosing Information dosing regimen for indication HCV Genotype 4, 5, or 6 was updated to include “ledipasvir 90mg/sofosbuvir 400 mg orally once daily” under Adult (age 18+).</li> <li>5. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy.</li> <li>6. Initial Approval Criteria and Continued Therapy Approval Criteria Approval Duration units were updated from days/weeks to “6 months”.</li> <li>7. Initial approval criteria I.A.8 was updated to add, “Member must try.....90-400 mg tablets.”</li> <li>8. Continued Therapy Approval Criteria II.A.1.a was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>9. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..".</li> <li>10. Appendix B: Therapeutic Alternatives primary indication listed for both Eplclusa and Mavyret</li> </ol>	<p>6/02/2021</p>	<p>09/14/2021</p>

was updated from “HCV Genotype 1, 4, 5, or 6” to “HCV Genotype 1,2, 3, 4, 5, or 6”.

11. Appendix B: Therapeutic Alternatives dosing regimen for Mavyret was updated from “Treatment-naïve: [Without cirrhosis: 3 tablets PO once daily for 8 weeks] / [With compensated cirrhosis: 3 tablets PO once daily for 12 week]” to “Treatment-naïve: [Without cirrhosis or with compensated cirrhosis: 3 tablets orally once daily for 8 weeks] / [With compensated cirrhosis and HIV coinfection: 3 tablets orally once daily for 12 weeks]”.
12. Appendix B: Therapeutic Alternatives dosing regimen for Zepatier was updated to include “...and HIV coinfection” to indications Genotype 1a, Genotype 1b, and Genotype 4.
13. Appendix B: Therapeutic Alternatives dosing regimen for Zepatier was updated from “Virologic failure while on pegIFN/RBV therapy” to “Virologic failure after receiving pegIFN/RBV therapy”.
14. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".
15. Appendix D was updated to remove inactive/unavailable drug names Daklinza, daclatasvir, Olysio, and simeprevir.
16. Appendix D was updated to include footnote “\*Combination drug”.
17. References were reviewed and updated.