

Generic Name: Daclatasvir

Preferred: N/A

Therapeutic Class or Brand Name: Daklinza®

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class): N/A.

Date of Origin: 9/22/2015

GPI Code: 1235302510

Date Last Reviewed / Revised: 12/11/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

- I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, 4, 5, or 6 infection.
- II. Documentation that patient meets ONE of the following criteria A through E:
 - A. Patient has genotype 1 AND meets ONE of criteria 1 through 3:
 1. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®.
 2. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria a and b:
 - a) Patient has a documented contraindication to Epclusa® and Harvoni®.
 - b) Patient meets ONE of criteria (1) or (2):
 - (1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (2) Patient has a documented intolerance or contraindication to ribavirin.
 3. Patient is post-liver transplant and meets ONE of criterion a or b:
 - a) Patient does not have cirrhosis or has compensated cirrhosis and criterion (1) is met:
 - (1) Patient has a documented contraindication to Mavyret™ and Harvoni®.
 - b) Patient has decompensated cirrhosis, and criterion (1) is met:
 - (1) Patient has a documented contraindication to Harvoni®.
 - B. Patient has genotype 2 and meets ONE of criteria 1 through 3:
 1. Patient has a documented contraindication to Mavyret™ and Epclusa®.
 2. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria a and b:
 - a) Patient has a documented contraindication to Epclusa®.
 - b) Patient meets ONE of criteria (1) or (2):
 - (1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (2) Patient has a documented intolerance or contraindication to ribavirin.
 3. Patient is post-liver transplant and meets ONE of criteria a through c:

- a) Patient does not have cirrhosis and criterion (1) is met:
 - (1) Patient has a documented contraindication to Mavyret™.
- b) Patient has compensated cirrhosis, and criterion (1) is met:
 - (1) Patient has a documented contraindication to Mavyret™ and Epclusa®.
- c) Patient has decompensated cirrhosis, and criterion (1) is met:
 - (1) Patient has a documented contraindication to Epclusa®.

C. Patient has genotype 3 AND meets ONE of criteria 1 through 3:

- 1. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®.
- 2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets BOTH of criteria a and b:
 - a) Patient has a documented contraindication to Epclusa®.
 - b) Patient meets ONE of criteria (1) or (2):
 - (1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (2) Patient has a documented intolerance or contraindication to ribavirin.
- 3. Patient is post-liver transplant and criterion a is met:
 - a) Patient has a documented contraindication to Mavyret™ and Epclusa®.

D. Patient has genotype 4 and meets ONE of criteria 1 or 2:

- 1. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria a and b:
 - a) Patient has a documented contraindication to Epclusa® and Harvoni®.
 - b) Patient meets ONE of criteria (1) or (2):
 - (1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (2) Patient has a documented intolerance or contraindication to ribavirin.
- 2. Patient is post-liver transplant and criterion a is met:
 - a) Patient has a documented contraindication to Mavyret™ and Harvoni®.

E. Patient has genotypes 5 or 6 and criterion 1 is met:

- 1. Patient has a documented contraindication to Mavyret™ and Harvoni®.

III. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section.

IV. Documentation of patient's Hepatitis C treatment history and baseline viral load.

V. Minimum age requirement: 18 years old.

VI. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

EXCLUSION CRITERIA

- As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza® (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier™ (elbasvir/grazoprevir).
- Coadministration of Daklinza® with strong inducers of CYP3A or any of the drugs listed in the table below:

Drug Class	Drugs within class
Antiarrhythmics	Amiodarone
Anticonvulsants	Carbamazepine, phenytoin
Antimycobacterials	Rifampin
Herbal Supplements	St. John’s Wort (<i>Hypericum perforatum</i>)
Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection	Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)

OTHER CRITERIA

- The recommended dose of Daklinza® is one 60 mg tablet taken once daily. However, the dose must be adjusted when coadministered with strong CYP3A inhibitors and certain HIV antiviral agents (the dose must be decreased to one 30 mg tablet taken once daily) or moderate CYP3A inducers and nevirapine (the dose must be increased to one 90 mg tablet taken once daily).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 28 tablets per 28 days.

APPROVAL LENGTH

- Authorization:** Insert content here. See table directly below:

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Daklinza® + Sovaldi®	No	12w	12w ¹	12w	12w ¹	12w	12w ¹
	Comp	12w		12w		16-24w	16-24w ¹
	Decomp	24w		24w		24w	
Daklinza® + Sovaldi® + RBV	No						
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp						
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w	
	Decomp & Post Transplant [^]					12w [^]	12w [^]

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

Drug Therapy	Cirrhosis	G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE
Daklinza® + Sovaldi®	No	12w	12w ¹						
	Comp	24w [~]							
	Decomp	24w		24w					
Daklinza® + Sovaldi® + RBV	No								
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp	12w, 24w [~]							
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w					
	Decomp & Post Transplant [^]	12w [^]	12w [^]						

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

-RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.

^For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

- **Re-Authorization:** N/A

APPENDIX

N/A

REFERENCES

1. <http://hcvguidelines.org/full-report-view> .
2. http://packageinserts.bms.com/pi/pi_daklinza.pdf.
3. Medi-Span® .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/11/2018	<p>1. Deleted under Prior Authorization Criteria:</p> <p>II. Documentation that patient meets ONE of the following criteria A, B, or C:</p> <p>A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis).</p> <p>B. Is post-liver transplant.</p> <p>1. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2:pe 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis)</p> <p>2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephrit</p>
11/2/2017	<p>1. Changed "I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, or 4 infection" to "I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, 4, 5, or 6 infection" under Prior Authorization Criteria.</p> <p>2. Changed "III. A. 1. Patient has a documented contraindication to Zepatier™ and Epclusa®" to "III. A. 1. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®" under Prior Authorization Criteria.</p> <p>3. Changed "III. A. 2. Patient has decompensated cirrhosis (Child-Pugh B or C)..." to "III. A. 2. Patient has decompensated cirrhosis (Child-Pugh B or C)..." under Prior Authorization Criteria.</p> <p>Changed "III. A. 3. Patient is post-liver transplant and meets BOTH of criteria a and b: a. Patient has a documented contraindication to Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" to "III. A. 3. Patient is post-liver transplant and meets ONE of criterion a or b: a. Patient does not have cirrhosis or has compensated cirrhosis and criterion i is met: i. Patient has a documented contraindication to Mavyret™ and Harvoni®; b. Patient has decompensated cirrhosis, and criterion i is met: i. Patient has a documented contraindication to Harvoni®" under Prior Authorization Criteria.</p>

4. **Changed** "III. B. 1. Patient has a documented contraindication to Epclusa®" to "III. B. 1. Patient has a documented contraindication to Mavyret™ and Epclusa®" **under Prior Authorization Criteria.**
5. **Added** "III. B. 2. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria a and b: a. Patient has a documented contraindication to Epclusa®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
6. **Changed** "III. B. 2. Patient is post-liver transplant and meets ONE of criteria a or b: a. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin" to "III. B. 3. Patient is post-liver transplant and meets ONE of criteria a through c: a. Patient does not have cirrhosis and criterion i is met: i. Patient has a documented contraindication to Mavyret™; b. Patient has compensated cirrhosis, and criterion i is met: i. Patient has a documented contraindication to Mavyret™ and Epclusa®; c. Patient has decompensated cirrhosis, and criterion i is met: i. Patient has a documented contraindication to Epclusa®" **under Prior Authorization Criteria.**
7. **Changed** "III. C. 1. Patient has a documented contraindication to Epclusa® and Zepatier™" to "III. C. 1. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®" **under Prior Authorization Criteria.**
8. **Changed** "III. C. 2. Patient has decompensated cirrhosis (Child-Pugh B or C) and criterion a is met: a. Patient has a documented contraindication to Epclusa®" to "III. C. 2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets BOTH of criteria a and b: a. Patient has a documented contraindication to Epclusa®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
9. **Changed** "III. C. 3. Patient is post-liver transplant and meets ONE of criteria a or b: a. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin" to "III. C. 3. Patient is post-liver transplant and criterion a is met: a. Patient has a documented contraindication to Mavyret™" **under Prior Authorization Criteria.**
10. **Changed** "III. D. 1. Patient has decompensated cirrhosis (Child-Pugh B)..." to "III. D. 1. Patient has decompensated cirrhosis (Child-Pugh B or C)..." **under Prior Authorization Criteria.**
11. **Changed** "III. D. 2. Patient is post-liver transplant and meets BOTH of criteria a and b: a. Patient has a documented contraindication to Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" to "III. D. 2. Patient is post-liver transplant and criterion a is met: a. Patient has a documented contraindication to Mavyret™ and Harvoni®" **under Prior Authorization Criteria.**
12. **Added** "III. E. Patient has genotypes 5 or 6 and criterion 1 is met: 1. Patient has a documented contraindication to Mavyret™ and Harvoni®" **under Prior Authorization Criteria.**
13. **Added** "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" to list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..." **under Exclusion Criteria.**
14. **Removed** "Child-Pugh C" from **Exclusion Criteria.**
15. **Added** "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" **under Exclusion Criteria** to table under

“Coadministration of Daklinza® with...”, line entitled “Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection”.

16. **Changed table below Authorization under Approval Length from (changes made highlighted in yellow):**

Drug Therapy	Cirrhosis	Authorization Duration									
		G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Daklinza® + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w ¹		
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Comp	24w	24w ⁵	24w	24w ⁵	16-24w	16-24w ¹ , 24w ²	24w			
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Decomp	24w	24w	24w	24w					24w	24w
Daklinza® + Sovaldi® + RBV	No								24w ²		
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ^{1,2}		
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

to:

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Daklinza® + Sovaldi®	No	12w	12w ¹	12w	12w ¹	12w	12w ¹
	Comp	12w		12w		16-24w	16-24w ¹
	Decomp	24w		24w		24w	
Daklinza® + Sovaldi® + RBV	No						
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp						
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w	

	Decomp & Post Transplant [^]					12w [^]	12w [^]
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TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

Drug Therapy	Cirrhosis	G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE
Daklinza® + Sovaldi®	No	12w	12w ¹						
	Comp	24w [~]							
	Decomp	24w		24w					
Daklinza® + Sovaldi® + RBV	No								
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp	12w, 24w [~]							
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w					
	Decomp & Post Transplant [^]	12w [^]	12w [^]						

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

-RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

8/11/2016

- Changed** "Daklinza™" to "Daklinza®" throughout policy.
- Changed** "III. A. 1. Patient has a documented contraindication to Zepatier™" to "III. A. 1. Patient has a documented contraindication to Zepatier™ and Eplclusa®" **under Prior Authorization Criteria.**
- Changed** " "III. A. 2. Patient has decompensated cirrhosis (Child-Pugh B or C)" to "III. A. 2. Patient has decompensated cirrhosis (Child-Pugh B) AND meets BOTH of criteria a and b: a. Patient has a documented contraindication to Eplclusa® and Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
- Changed** "III. A. 3. Patient is post-liver transplant" to "III. A. 3. Patient is post-liver transplant and meets BOTH of criteria a and b: a. Patient has a documented contraindication to Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**

5. **Changed** "III. B. Patient has genotype 2" to "III. B. Patient has genotype 2 and meets ONE of criteria 1 or 2: 1. Patient has a documented contraindication to Epclusa®; 2. Patient is post-liver transplant and meets ONE of criteria a or b: a. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
6. **Changed** "III. C. Patient has genotype 3 AND meets ONE of criteria 1 through 4" to "Patient has genotype 3 AND meets ONE of criteria 1 through 3", **and removed** "4. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin" **under Prior Authorization Criteria.**
7. **Changed** "III. C. 1. Patient has a documented contraindication to Zepatier™" to "Patient has a documented contraindication to Epclusa® and Zepatier™" **under Prior Authorization Criteria.**
8. **Changed** "III. C. 2. Patient has decompensated cirrhosis (Child-Pugh B or C)" to "III. C. 2. Patient has decompensated cirrhosis (Child-Pugh B) and criterion a is met: a. Patient has a documented contraindication to Epclusa®" **under Prior Authorization Criteria.**
9. **Changed** "III. C. 3. Patient is post-liver transplant" to "III. C. 3. Patient is post-liver transplant and meets ONE of criteria a or b: a. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
10. **Changed** "III. D. 1. Patient has decompensated cirrhosis (Child-Pugh B or C)" to "III. D. 1. Patient has decompensated cirrhosis (Child-Pugh B) AND meets BOTH of criteria a and b: a. Patient has a documented contraindication to Epclusa® and Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
11. **Changed** "III. D. 2. Patient is post-liver transplant" to "III. D. 2. Patient is post-liver transplant and meets BOTH of criteria a and b: a. Patient has a documented contraindication to Harvoni®; b. Patient meets ONE of criteria i or ii: i. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ii. Patient has a documented intolerance or contraindication to ribavirin" **under Prior Authorization Criteria.**
12. **Added** "Epclusa® (sofosbuvir/velpatasvir)" **under Exclusion Criteria** to: 1) List of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..."; 2) table under "Coadministration of Daklinza® with...", line entitled "Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection".
13. **Changed** "Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" to "Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" in list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..." **under Exclusion Criteria.**
14. **Added** "Child-Pugh C" **under Exclusion Criteria.**
15. **Changed** "Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" to "Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" **and added** "(elbasvir/grazoprevir)" following Zepatier™ **under Exclusion Criteria** to table under "Coadministration of Daklinza® with...", line entitled "Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection".
16. **Changed** "Daklinza™ dose must be adjusted when coadministered with strong CYP3A inhibitors or moderate CYP3A inducers. Exceptions may be made for higher doses (up to one 60 mg tablet and one 30 mg tablet for a total dose of 90 mg once daily) when Daklinza™ must be coadministered with moderate CYP3A inducers (i.e. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine)." to "The recommended dose of Daklinza® is one 60 mg tablet taken once daily. However, the

dose must be adjusted when coadministered with strong CYP3A inhibitors and certain HIV antiviral agents (the dose must be decreased to one 30 mg tablet taken once daily) or moderate CYP3A inducers and nevirapine (the dose must be increased to one 90 mg tablet taken once daily)" **under Other Criteria.**

- 17. **Changed** "28 tablets per 28 days (see under Other Criteria for possible exceptions for higher doses); The quantity is limited to a maximum of a 28 day supply per fill" **to** "28 tablets per 28 days" **under Quantity/Days Supply Restrictions.**
- 18. **Changed the followings rows on the table below Authorization under Approval Length from (changes made highlighted in yellow):**

Drug Therapy	Cirrhosis	Authorization Duration										
		G1a		G1b		G2		G3		G4		
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	
Daklinza® + Sovaldi®	Decomp	24w		24w							24w	
Daklinza® + Sovaldi® + RBV	Decomp	12w		12w		12w		12w		12w		

to:

Drug Therapy	Cirrhosis	Authorization Duration										
		G1a		G1b		G2		G3		G4		
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	
Daklinza® + Sovaldi®	Decomp	24w	24w	24w	24w						24w	24w
Daklinza® + Sovaldi® + RBV	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w

3/21/2016

- 1. **Changed** "member" **to** "patient" **throughout policy.**
- 2. **Changed** "I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, or 3 infection;...III. Must be used in combination with Sovaldi® and ONE of criteria A, B, or C must be met: A. Genotype 1 AND one of criteria 1 or 2 is met: 1. Member is treatment-naïve and criterion a is met: a. Member has a documented contraindication to both Harvoni® AND Viekira Pak™; 2. Member is treatment-experienced and criterion a is met: a. Member has failed prior treatment with one of the following i, ii, or iii AND meets criteria listed under applicable failed treatment: i Peginterferon + ribavirin AND criterion aa is met: aa Member has a documented contraindication to both Harvoni® AND Viekira Pak™; ii Sovaldi® + Olysio® AND criterion aa is met: aa Member has a documented contraindication to Harvoni®; iii Protease inhibitor + peginterferon alfa + ribavirin AND criterion aa is met: aa Member has a documented contraindication to Harvoni®; B. Genotype 2 AND one of criteria 1 or 2 is met: 1. Member is treatment-naïve and criterion a is met: a. Member has a documented intolerance or contraindication to ribavirin; 2. Member is treatment-experienced and criteria a and b are met: a. Member has documented intolerance or contraindication to peginterferon; b. Member has failed prior treatment with Sovaldi® + ribavirin; C. Genotype 3 AND one of criteria 1 or 2 is met: 1. Member is treatment-naïve and criterion a is met: a. Member has documented intolerance or contraindication to peginterferon; 2. Member is treatment-experienced and criteria a and b are met: a. Member has documented intolerance or contraindication to peginterferon; b. Member has failed prior treatment with one of the

- following i or ii: i Peginterferon + ribavirin; ii Sovaldi® + ribavirin; IV. Documentation of member's Hepatitis C treatment history" **to** "I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, or 4 infection;...III. Documentation that patient meets ONE of the following criteria A through D: A. Patient has genotype 1 AND meets ONE of criteria 1 through 3: 1. Patient has a documented contraindication to Zepatier™; 2. Patient has decompensated cirrhosis (Child-Pugh B or C); 3. Patient is post-liver transplant; B. Patient has genotype 2; C. Patient has genotype 3 AND meets ONE of criteria 1 through 4: 1. Patient has a documented contraindication to Zepatier™; 2. Patient has decompensated cirrhosis (Child-Pugh B or C); 3. Patient is post-liver transplant; 4. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin; D. Patient has genotype 4 and meets ONE of criteria 1 or 2: 1. Patient has decompensated cirrhosis (Child-Pugh B or C); 2. Patient is post-liver transplant; IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section; V. Documentation of patient's Hepatitis C treatment history and baseline viral load" **under Prior Authorization Criteria.**
3. **Changed** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **to** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir), or Zepatier™ (elbasvir/grazoprevir)" **under Exclusion Criteria.**
4. **Added** "Zepatier™" **to** "Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection" **line on table underneath Exclusion Criteria.**
5. **Changed table following Authorization under Approval Length from:**

Patient Characteristics		Daklinza™ Authorization Information	
Genotype, Other Features	Hepatitis C Treatment History	Treatment	Authorization Duration
1a or 1b, without cirrhosis	Treatment-naïve or Treatment-experienced (failed 1, 2, or 3: 1. peginterferon alfa + ribavirin; 2. Sovaldi® + Olysio®; 3. Protease inhibitor + peginterferon alfa + ribavirin)	Daklinza™ + Sovaldi®	12 weeks
1a or 1b, with cirrhosis	Treatment-naïve or Treatment-experienced (failed 1, 2, or 3: 1. peginterferon alfa + ribavirin; 2. Sovaldi® + Olysio®; 3. Protease inhibitor + peginterferon alfa + ribavirin)	Daklinza™ + Sovaldi®	24 weeks
2	Treatment-naïve	Daklinza™ + Sovaldi®	12 weeks

2	Treatment-experienced (failed Sovaldi® + ribavirin)	Daklinza™ + Sovaldi®	24 weeks
3, without cirrhosis	Treatment-naïve or Treatment-experienced (failed peginterferon alfa + ribavirin)	Daklinza™ + Sovaldi®	12 weeks
3, without cirrhosis	Treatment-experienced (failed Sovaldi® + ribavirin)	Daklinza™ + Sovaldi® + ribavirin	24 weeks
3, with cirrhosis	Treatment-naïve	Daklinza™ + Sovaldi®	24 weeks
3, with cirrhosis	Treatment-experienced (failed 1 or 2: 1. peginterferon alfa + ribavirin; 2. Sovaldi® + ribavirin)	Daklinza™ + Sovaldi® + ribavirin	24 weeks

to:

Drug Therapy	Cirrhosis	Authorization Duration									
		G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Daklinza™ + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w ¹		
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Comp	24w	24w ⁵	24w	24w ⁵	16-24w	16-24w ¹ , 24w ²	24w			
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Decomp	24w		24w							24w
Daklinza™ + Sovaldi® + RBV	No								24w ²		
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ^{1,2}		
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w		12w		12w	

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.