MEDICATION POLICY

Generic Name: Daclatasvir

Therapeutic Class or Brand Name: Daklinza®

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

Date of Origin: 9/22/15 **Date Last Reviewed/Revised:** 8/11/16

GPI Code: 1235302510

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, or 4 infection.

II. Documentation that patient meets ONE of the following criteria A, B, or C:

- A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis).
- B. Is post-liver transplant.
- C. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2:
  1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).
  2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

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™ and Epclusa®.
  2. 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.
  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.
- 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.

C. Patient has genotype 3 AND meets ONE of criteria 1 through 3:
1. Patient has a documented contraindication to Epclusa® and Zepatier™.
2. Patient has decompensated cirrhosis (Child-Pugh B) and criterion a is met:
   a. Patient has a documented contraindication to Epclusa®.
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.

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

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.

VI. Minimum age requirement: 18 years old.

VII. 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), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), or Zepatier™ (elbasvir/grazoprevir).
- Child-Pugh C.
- 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 (*Hypericum perforatum*)
Other NS5A inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection	Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Olysio® (simeprevir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), 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:** See table directly below.

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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.

[1]For patients who have failed pegIFN/RBV.

[2]For patients who have failed sofosbuvir + RBV.

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

- **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.

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Historical Tracking Of Changes Made To Policy	
8/11/2016	1. **Changed** "Daklinza™" **to** "Daklinza®" **throughout policy**. 2. **Changed** "III. A. 1. Patient has a documented contraindication to Zepatier™" **to** "III. A. 1. Patient has a documented contraindication to Zepatier™ and Epclusa®" **under Prior Authorization Criteria**. 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) 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**. 4. **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™

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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

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.

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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**

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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.

[1]For patients who have failed pegIFN/RBV.

[2]For patients who have failed sofosbuvir + RBV.

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

6.