Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Daklinza (daclatasvir)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Based on Genotype, Treatment status, Cirrhosis status, Transplant status, or Ribavirin Eligibility

Medication	Quantity Limit
Daklinza (daclatasvir)	1 tablets per day

APPROVAL DURATION

Genotype and Status (HCV mono-infected or HCV/HIV-1 co-infected[a])	Associated Treatment Regimens	Total Approval Duration for Daklinza
Genotype 1 (treatment-naïve or dual P/R[2b] treatment-experienced, without cirrhosis)	Daklinza + Sovaldi	12 weeks
Genotype 2 (treatment-naïve or dual P/R[2b] treatment-experienced, without cirrhosis	Daklinza + Sovaldi	12 weeks
Genotype 2 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis)	Daklinza + Sovaldi	16 or 24 weeks
Genotype 3 (treatment-naïve or -dual P/R[2b] treatment-experienced, without cirrhosis)	Daklinza + Sovaldi	12 weeks
Genotype 3 (treatment-naïve, with compensated cirrhosis)	Daklinza + Sovaldi ± RBV	24 weeks
Genotypes 1, 2, 3, 4, 5 or 6 (treatment-naïve or -experienced, post-liver allograft transplant, with compensated cirrhosis or without cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks
Genotypes 2 or 3 (treatment-naïve or -experienced, post-liver allograft transplant, with decompensated cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Genotypes 1, 2, 3, or 4 (treatment-naïve or -experienced without sofosbuvir or NS5A[2a] with decompensated cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks
Genotypes 1, 2, 3, or 4 (treatment-naïve or -experienced without sofosbuvir or NS5A[2a], ribavirin ineligible, with decompensated cirrhosis)	Daklinza + Sovaldi	24 weeks
Genotypes 2, 3, 5 or 6 (treatment-naïve or -experienced, post-kidney transplant, with compensated cirrhosis or without cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks

APPROVAL CRITERIA

Requests for Daklinza (daclatasvir) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013);

AND

III. Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy; **AND**
IV. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017); **AND**
V. Individual has compensated[1] liver disease (with or without cirrhosis) or decompensated[1] liver disease;

AND

VI. Individual is using with **one** of the following antiviral treatment regimens (AASLD/IDSA 2017) :
    A. Individual is using in combination with Sovaldi (sofosbuvir) for **one** of the following:
        1. Individual is treatment-naïve or dual P/R[2b] treatment-experienced without cirrhosis, Genotype 1; **AND**
        2. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
            a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

3. Individual is treatment-naïve or dual P/R[2b] treatment-experienced with compensated[1] cirrhosis or without cirrhosis, and Genotype 2;
   OR
4. Individual is treatment-naïve, without cirrhosis and Genotype 3;

AND

5. Individual has had a prior trial and inadequate response to Mavyret; **OR**
   a. Individual is currently on and completing a course of therapy with requested regimen; **OR**
   b. Documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
   c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen; **OR**
   d. Individual is a post-allograft transplant recipient;

OR

6. Individual is dual P/R[2b] treatment-experienced, without cirrhosis and Genotype 3;

OR

7. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen, ribavirin ineligible, with decompensated[1] cirrhosis and Genotypes 1, 2, or 3

OR

8. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen, ribavirin ineligible, with decompensated[1] cirrhosis and Genotype 4;
   AND
9. Individual has had a prior trial and inadequate response to Epclusa; **OR**
   a. Individual is currently on and completing a course of therapy with requested regimen; **OR**
   b. Documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Epclusa which is not also in Daklinza or Sovaldi; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen;

OR

B. In combination with Sovaldi (sofosbuvir) with or without ribavirin for the following:
1. Individual is treatment-naïve, with compensated[1] cirrhosis, and Genotype 3; **AND**
2. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
   a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
   b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
   c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

C. In combination with Sovaldi (sofosbuvir) and ribavirin for **one** of the following:
10. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen, with decompensated[1] cirrhosis, Genotypes 1, 2, or 3 ;

OR

11. Individual is treatment-naïve, or dual treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen, with decompensated[1] cirrhosis, Genotype 4; **AND**
12. Individual has had a prior trial and inadequate response to Epclusa; **OR**

a. Individual is currently on and completing a course of therapy with requested regimen; **OR**
b. Documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Epclusa which is not also in Daklinza or Sovaldi; **OR**
c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen;

OR

13. Individual is a post-liver allograft transplant recipient with compensated[1] cirrhosis and Genotypes 1, 4, 5 or 6;

OR

14. Individual is a post-liver allograft transplant recipient without cirrhosis and Genotypes 1, 4, 5 or 6; **AND**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

15. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
    a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
    c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

16. Individual is a post-liver allograft transplant recipient without cirrhosis, and Genotypes 2 or 3; **AND**
17. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**

a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

18. Individual is a post-liver allograft transplant recipient with compensated[1] cirrhosis, and Genotypes 2 or 3; **OR**
19. Individual is a post-liver allograft transplant recipient with decompensated[1] cirrhosis, and Genotypes 2 or 3;

OR

20. Individual is a post-kidney transplant recipient, with compensated[1] cirrhosis or without cirrhosis, and Genotypes 2, 3, 5, or 6; **AND**
21. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**

a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; **OR**
c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Daklinza (daclatasvir) may **not** be approved for the following:

I. Individual is using with sofosbuvir and has severe or end-stage CKD[3] or requires dialysis; **OR**
II. Individual is using sofosbuvir and a known NS5A polymorphism is present; **OR**
III. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to the following: amiodarone (when used in combination with sofosbuvir) or strong cytochrome (CYP) 3A inducers (such as but not limited to, carbamazepine, phenytoin, rifampin, or St John's Wort); **OR**
IV. Individual is using with sofosbuvir and requesting in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such dasabuvir) or another nucleotide NS5B polymerase inhibitor (such as sofosbuvir); **OR**
V. Individual is using with sofosbuvir and requesting in combination with a regimen containing another NS5A[2a]; **OR**
VI. Individual is using with sofosbuvir and requesting in combination with a regimen containing a NS3/4A[2c] protease inhibitor; **OR**
VII. Individual is requesting the regimen for re-treatment in combination with sofosbuvir and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of an NS5A[2a] inhibitor.

Notes:

[a]Per label, use in combination with Sovaldi (sofosbuvir) for individuals co-infected with HIV-1 is included with dosing to follow same recommendations as mono-infected individuals. The Daklinza label provides dose adjustment recommendations when concomitantly used with select HIV antiviral agents.

1. **Compensated Liver Disease**: According to the American Association for the Study of Liver Diseases (AASLD/IDSA 2017), the specific criteria for compensated liver disease include all of the following: a total bilirubin; serum albumin; prothrombin time/INR; presence of ascites; and presence of hepatic encephalopathy. However, these criteria do not establish a comprehensive definition of compensated liver disease. The AASLD guidance refers to compensated liver disease as Class A based on the Child Pugh-Turcotte (CPT) classification scoring system.

   Moderate to Severe (Decompensated) Liver Disease:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

The AASLD guidance refers to decompensated (moderate to severe) liver disease as Class B or C based on the Child-Pugh Turcotte (CPT) classification scoring system.

Child Pugh Classification (AASLD/IDSA 2017)

Parameters			
Points Assigned	1 point	2 points	3 points
Total Bilirubin (µmol/L)	<34	34-50	>50
Serum Albumin (g/L)	>35	28-35	<28
Prothrombin time/INR	<1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)

Child Pugh Score Interpretation (AASLD/IDSA 2017)

Class A	5-6 points	Well compensated liver disease
Class B	7-9 points	Significant functional compromise (moderate hepatic impairment)
Class C	10-15 points	Uncompensated liver disease (severe hepatic impairment)

2. Past Treatment Exposure Definitions (AASLD/IDSA 2017):
   a. NS5A Inhibitor: includes daclatasvir, ledipasvir, elbasvir, ombitasvir, pibrentasvir, or velpatasvir-containing regimens
   b. P/R: includes peginterferon (or non-pegylated interferon) ± ribavirin
   c. NS3/4A Protease Inhibitor: includes simeprevir, grazoprevir, paritaprevir, glecaprevir, and voxilaprevir-containing regimens
   d. Triple therapy: includes NS3 protease inhibitor (simeprevir, boceprevir or telaprevir) plus peginterferon and ribavirin
   e. Direct Acting Antiviral (DAA): includes NS5A inhibitors, NS3/4A protease inhibitors, and NS5B polymerase inhibitors (sofosbuvir, dasabuvir)

3. Chronic Kidney Disease (CKD) Definitions (AASLD/IDSA 2017):
   Severe CKD (Stage 4): eGFR 15-29 mL/min
   End-Stage CKD (Stage 5): eGFR < 15 mL/min

4. Metavir Scoring Systems for Fibrosis Staging (AASLD 2009):

Stage (F)	
0	No fibrosis

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

1	Periportal fibrotic expansion
2	Periportal septae 1 (septum)
3	Porto-central septae
4	Cirrhosis

5. Hepatitis C virus (HCV) direct acting antiviral (DAA) agents have a black box warning for risk of hepatitis B virus (HBV) reactivation in individuals with HCV-HBV co-infection. Individuals should be tested for evidence of current or prior HBV infection prior to initiation of DAA therapy. HBV reactivation has been reported in HCV/HBV co-infected individuals currently taking or previously completed DAA therapy and not concomitantly receiving HBV antiviral therapy. Some cases of HBV reactivation have led to fulminant hepatitis, hepatic failure, and death. Individuals should be monitored for hepatitis flare or HBV reactivation during and following HCV DAA therapy. Individuals should be appropriately managed for HBV infection as indicated.

State Specific Mandates		
State/Market	**Date**	**Description**
Georgia Medicaid	10/2016	Georgia has state mandated criteria; please see Georgia State Specific Criteria.
Louisiana Medicaid	2/1/2018	Louisiana has state criteria; please see Louisiana State Specific Criteria
Maryland Medicaid		Maryland has state mandated criteria; please see Maryland State Specific Criteria
New Jersey Medicaid	7/1/2016	New Jersey Medicaid has state mandated criteria for all Direct Acting Antiviral (DAA) agents for treatment of Hepatitis C. Please see New Jersey State Criteria
Virginia Medicaid	7/1/2016	Virginia has state mandated criteria; please see Virginia State Specific Criteria.
Washington D.C.	2/1/2018	Washington D. C. has state criteria; please see Washington D. C. State Specific Criteria

Key References:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0295-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

American Association for the Study of Liver Diseases and the Infectious Disease Society of America, in collaboration with the International Antiviral Society-USA. Recommendations for testing, managing and treating hepatitis C. Available at http://www.hcvguidelines.org/. Published on: January 29, 2014. Updated on: September 21, 2017. Accessed on: January 25, 2018.

Centers for Disease Control and Prevention. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. *MMWR*. 2013; 62(18):362-365. Available from: https://www.cdc.gov/mmwr/pdf/wk/mm6218.pdf. Accessed on: December 27, 2017.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed on: January 25, 2018.

European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2016. *J Hepatol*. 2017; 66(1):153-194. Available from: http://www.journal-of-hepatology.eu/article/S0168-8278(16)30489-5/pdf. Accessed on: December 27, 2017.

U.S. Food & Drug Administration. Drugs@FDA: FDA Approved Drug Products (Package inserts). Available from: http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed on: January 25, 2018.

U.S. Department of Health and Human Services AIDSinfo treatment guidelines. Concomitant use of selected antiretroviral drugs and hepatitis C virus direct-acting antiviral drugs for treatment of HCV in adults with HIV. Available at https://aidsinfo.nih.gov/guidelines/htmltables/1/5536. Accessed on: December 27, 2017.

DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

PL Detail-Document, Cytochrome P450 Drug Interactions. Pharmacist's Letter/Prescriber's Letter. May 2016.

PL Detail-Document, OATP Drug Interactions. Pharmacist's Letter/Prescriber's Letter. March 2014.

PL Detail-Document, P-glycoprotein Drug Interactions. Pharmacist's Letter/Prescriber's Letter. April 2016