Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

Daklinza (daclatasvir)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Based on Genotype, Treatment status, Cirrhosis status, Transplant status, Polymorphism, 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 of Daklinza
Genotype 1 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis or without cirrhosis)	Daklinza + Sovaldi	12 weeks
Genotype 3 (treatment-naïve or -dual P/R[2b] treatment-experienced, without cirrhosis, no Y93H polymorphism)	Daklinza + Sovaldi	12 weeks
Genotype 3 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis, no Y93H)	Daklinza + Sovaldi + RBV	12 weeks
Genotypes 1or 3 (treatment-naïve or -experienced without sofosbuvir or NS5A[2a] with decompensated cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks
Genotypes 1or 3 (treatment-naïve or –experienced without NS5A[2a], post-liver allograft transplant, with compensated cirrhosis, without cirrhosis, or decompensated cirrhosis)	Daklinza + Sovaldi + RBV	12 weeks

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

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[a], which includes genotype and a positive HCV RNA result (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 has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to authorized generic Epclusa (sofosbuvir/velpatasvir) OR Mavyret, unless one of the following conditions apply:

A. Individual is using with **one** of the following antiviral treatment regimens (Label) :
   1. Individual is using in combination with Sovaldi (sofosbuvir) for **one** of the following:

      a. Individual is treatment-naïve or dual P/R[2b] treatment-experienced without cirrhosis, Genotype 1; **AND**
      b. Individual meets one of the following criteria:
         i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) AND Mavyret with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
         ii. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
         iii. 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. Individual is treatment-naïve, or dual P/R[2b] treatment-experienced, without cirrhosis, no polymorphism present at Y93H amino acid position, and Genotype 3; **AND**
      d. Individual meets one of the following criteria:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) AND Mavyret with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
ii. Individual is currently on and completing a course of therapy with requested regimen; **OR**
iii. 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

e. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen with decompensated[1] cirrhosis and Genotypes 1 or 3; **AND**
f. Individual meets one of the following criteria:
   i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
   ii. Individual is currently on and completing a course of therapy with requested regimen; **OR**
   iii. 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

2. In combination with Sovaldi (sofosbuvir) and ribavirin for **one** of the following:

a. Individual is treatment-naïve or dual P/R[2b] treatment-experienced with compensated cirrhosis, no polymorphism present at Y93H amino acid position, and Genotype 3; **AND**
b. Individual meets one of the following criteria:
   i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) AND Mavyret with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
   ii. Individual is currently on and completing a course of therapy with requested regimen; **OR**
   iii. 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

c. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

NS5A[2a]-containing regimen, with decompensated[1] cirrhosis, Genotypes 1 or 3; **AND**

d. Individual meets one of the following criteria:
    i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Sovaldi or Daklinza; **OR**
    ii. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    iii. 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

e. Individual is a post-liver allograft transplant recipient, treatment-naïve or treatment experienced without a NS5A[2a] containing regimen, with compensated[1] cirrhosis or without cirrhosis and Genotypes 1 or 3; **AND**
f. Individual meets one of the following criteria:
    i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) AND Mavyret with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
    ii. Individual is currently on and completing a course of therapy with requested regimen; **OR**
    iii. 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

k. Individual is a post-liver allograft transplant recipient, treatment-naïve or treatment experienced without a NS5A[2a] containing regimen, with decompensated cirrhosis, and Genotypes 1 or 3; **AND**
l. Individual meets one of the following criteria:
    i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in Daklinza or Sovaldi; **OR**
    ii. Individual is currently on and completing a course of therapy with requested regimen; **OR**
    iii. 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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

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, including but not limited to the following: amiodarone (when used in combination with sofosbuvir) or strong cytochrome (CYP) 3A inducers (including 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**
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 and AASLD/IDSA treatment guidance 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:
   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)

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	NA	X	NA	X	X	NA

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
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

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Applicable	NA	NA	X	NA	X	X	NA

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.

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