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

Sovaldi (sofosbuvir)

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

Medication	Quantity Limit
Sovaldi (sofosbuvir) 200 mg, 400 mg tablets	1 tablet per day
Sovaldi (sofosbuvir) 200 mg pellets	2 packets of pellets per day
Sovaldi (sofosbuvir) 150 mg pellets	1 packet of pellets per day

APPROVAL DURATION

Genotype and Status (HCV mono-infected or HCV/HIV-1 co-infected[a])	Associated Treatment Regimens	Total Approval Duration of Sovaldi
3 years of age or older, Genotype 2 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis or without cirrhosis)	Sovaldi + RBV	12 weeks
3 years of age or older, Genotype 3 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis or without cirrhosis)	Sovaldi + RBV	24 weeks
12 years of age or older, Genotypes 1, 2, 3, 4, 5, or 6 (treatment failure with Mavyret monotherapy, with compensated cirrhosis or without cirrhosis)	Sovaldi + Mavyret + RBV	16 weeks
Genotype 1 or 4 (treatment-naïve with compensated cirrhosis or without cirrhosis)	Sovaldi + PEG + RBV	12 weeks
Genotype 1 (treatment-naïve with compensated cirrhosis or without cirrhosis)	Sovaldi + RBV[b]	24 weeks
Genotype 1 (treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis or without cirrhosis)	Sovaldi + Daklinza	12 weeks

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

Genotype 3 (treatment-naive or dual P/R[2b] treatment-experienced, without cirrhosis, no Y93H polymorphism)	Sovaldi + Daklinza	12 weeks
Genotype 3 (treatment-naïve, or dual P/R[2b] treatment-experienced, no Y93H polymorphism, with compensated cirrhosis)	Sovaldi + Daklinza + RBV	12 weeks
Genotypes 1or 3 (treatment-naïve or -experienced without sofosbuvir or NS5A[2a], with decompensated cirrhosis)	Sovaldi + Daklinza + RBV	12 weeks
Genotypes 1 or 3 (treatment-naïve or –experienced without NS5A[2a], post-liver allograft transplant, with-compensated cirrhosis, without cirrhosis, or decompensated cirrhosis)	Sovaldi + Daklinza + RBV	12 weeks
Genotype 3 (dual P/R[2b] treatment-experienced with compensated cirrhosis)	Sovaldi + Zepatier	12 weeks

APPROVAL CRITERIA

Requests for Sovaldi (sofosbuvir) may be approved if the following criteria are met:

I. 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**
II. Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy; **AND**
III. 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**
IV. Individual has compensated[1] liver disease (with or without cirrhosis) or decompensated[1] liver disease;

AND

V. 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/AASLD/IDSA 2019):
   1. In combination with ribavirin for the following:
      a. Individual is 3 years of age or older, treatment-naïve or dual P/R[2b] treatment-experienced, with compensated cirrhosis or without cirrhosis, and Genotype 2 or 3; **AND**
      b. Individual meets one of the following criteria:
         i. Prior trial of authorized generic Epclusa (sofosbuvir/velpatasvir) AND

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

Mavyret with documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient which is not also in 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 regimens; **OR**

iv. Individual is 3 to 5 years of age;

OR

c. Individual is 18 years of age or older, treatment-naïve, with compensated cirrhosis or without cirrhosis, and Genotype 1; **AND**

d. 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 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 regimens;

OR

2. In combination with ribavirin and peginterferon alfa for the following:

a. Individual is 18 years of age or older, treatment-naïve, with compensated cirrhosis or without cirrhosis, and Genotype 1 or 4; **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 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 regimens;

OR

3. In combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin for the following:

a. Individual is 12 years of age of older with compensated cirrhosis or without cirrhosis, and Genotype 1, 2, 3, 4, 5, or 6; **AND**

b. Individual had treatment failure with Mavyret (glecaprevir/pibrentasvir) monotherapy;

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

OR

4. Individual is 18 years of age or older; **AND**
5. In combination with Daklinza (daclatasvir) for **one** of the following:
    a. Individual is treatment-naïve, dual P/R[2b] treatment-experienced without cirrhosis and 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 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 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:
        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 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 treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen with decompensated[1] cirrhosis and Genotypes 1or 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 Sovaldi or Daklinza ; **OR**
        ii. Individual is currently on and completing a course of therapy with the requested regimen; **OR**

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

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

6. Individual is 18 years of age or older; **AND**
7. In combination with Daklinza (daclatasvir) 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 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

   c. Individual is treatment-naïve or treatment-experienced without a sofosbuvir or NS5A[2a]-containing regimen, with decompensated[1] cirrhosis and Genotype 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:

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 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 regimens;

OR

g. Individual is a post-liver allograft transplant recipient, treatment-naïve or treatment experienced without a NS5A[2a] containing regimen, with decompensated cirrhosis Genotypes 1or 3; **AND**
h. 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

8. Individual is 18 years of age or older; **AND**
9. In combination with Zepatier for the following:
   a. Individual is dual P/R[2b] treatment-experienced, with compensated[1] cirrhosis 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 Sovaldi or Zepatier; **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**
      iv. Individual has had a prior trial of Mavyret with documented hypersensivity, as manifested by a severe allergic reaction to any ingredient which is not also in Sovaldi or Zepatier, AND is not a candidate

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

for the Epclusa regimen when it contains ribavirin, due to being ribavirin ineligible (examples include individuals with hemoglobinopathies, significant cardiac disease, creatinine clearance less than 50 mL/min, documented severe allergic reaction, or pregnancy);

AND

VI. If requesting Sovaldi 200 mg oral pellets, individual is unable to swallow the oral tablet dose form due to a clinical condition, including, but not limited to the following:
   A. Dysphagia; **OR**
   B. Individual's age.

Sovaldi (sofosbuvir) may **not** be approved for the following:

I. Individual has severe or end-stage CKD3 or requires dialysis; **OR**
II. Individual is using in combination with daclatasvir 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, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St John's Wort, tipranavir/ritonavir; **OR**
IV. Individual is using in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir); **OR**
V. Individual is using in combination with a regimen containing a NS3/4A[2c] protease inhibitor other than simeprevir, elbasvir/grazoprevir, or glecaprevir/pibrentasvir; **OR**
VI. Individual is using in combination with a regimen containing a NS5A[2a] inhibitor other than daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir; **OR**
VII. Individual is requesting for re-treatment in combination with simeprevir 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 a NS3/4A[2c] protease inhibitor NS5B polymerase inhibitor (such as sofosbuvir or dasabuvir), or NS5A[2a] inhibitor; **OR**
VIII. Individual is requesting for re-treatment in combination with simeprevir 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 triple[2d] therapy treatment regimen, unless requested following a liver allograft transplant; **OR**
IX. Individual is requesting for re-treatment in combination with daclatasvir 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 a NS5A[2a] inhibitor;

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

Notes:

[a]Per label and AASLD/IDSA treatment guidance, Sovaldi (sofosbuvir) may be used in individuals co-infected with HIV-1

[b]Per label, Sovaldi + ribavirin for 24 weeks can be considered in adult patients with genotype 1 who are ineligible for interferon-based regimen.

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)

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

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

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 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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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.

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

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