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

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Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Based on Genotype, Treatment status, Cirrhosis status or Polymorphism status.

Medication	Quantity Limit
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	1 tablet per day

APPROVAL DURATION

Genotype and Status (HCV mono-infected)	Associated Treatment Regimens	Total Approval Duration for Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Genotype 1 (NS5A[2a] treatment-experienced, with compensated cirrhosis or without cirrhosis)	Vosevi	12 weeks
Genotype 1a (previous sofosbuvir-containing regimen without an NS5A[2a], with compensated cirrhosis or without cirrhosis)	Vosevi	12 weeks
Genotype 3 (DAA[2e] treatment-experienced, without cirrhosis)	Vosevi	12 weeks
Genotype 3 (non-NS5A[2a] treatment-experienced, with compensated cirrhosis)	Vosevi	12 weeks
Genotype 3 (NS5A[2a] treatment-experienced, with compensated cirrhosis)	Vosevi + RBV	12 weeks
Genotype 3 (dual P/R[2b] treatment-experienced, with compensated cirrhosis)	Vosevi	12 weeks
Genotype 3 (treatment naïve with compensated cirrhosis or	Vosevi	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

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dual P/R[2b] treatment-experienced without cirrhosis, with Y93H polymorphism)		
Genotypes 4, 5, or 6 (DAA[2e] treatment experienced with compensated cirrhosis or without cirrhosis)	Vosevi	12 weeks

APPROVAL CRITERIA

Requests for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 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);

AND

VI. Individual is using in **one** of the following antiviral treatment regimens (AASLD/IDSA 2017):
  A. As monotherapy for **one** of the following:
    1. Individual is NS5A[2a] treatment-experienced with compensated[1] cirrhosis or without cirrhosis, and Genotype 1;

    OR

    2. Individual is treatment experienced with a sofosbuvir-containing regimen without an NS5A[2b] inhibitor, with compensated[1] cirrhosis or without cirrhosis, and Genotype 1a; **AND**
    3. 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 Vosevi; **OR**

Market Applicability														
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Applicable	NA	X	NA	NA	NA	NA	X	NA	X	X	X	NA	NA	NA

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b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Vosevi; **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**
d. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A[2a] inhibitor;

OR

4. Individual is direct acting antiviral (DAA)[2e] treatment-experienced without cirrhosis, and Genotype 3;

OR

5. Individual is non-NS5A[2a] treatment-experienced with compensated[1] cirrhosis, and Genotype 3;

OR

6. Individual is dual P/R[2b] treatment-experienced, with compensated[1] cirrhosis, and Genotype 3;

OR

7. Individual is treatment-naïve, with compensated[1] cirrhosis or dual P/R[2b] treatment-experienced without cirrhosis, polymorphism present at the Y93H amino acid position, and Genotype 3;

OR

8. Individual is DAA[2e] treatment-experienced with compensated[1] cirrhosis or without cirrhosis, and Genotype 4, 5 or 6;

OR

B. In combination with ribavirin for the following:
1. Individual is NS5A[2a] treatment-experienced, with compensated[1] cirrhosis and Genotype 3.

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

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Vosevi (sofosbuvir/velpatasvir/voxilaprevir) may **not** be approved for the following:

I. Individual has severe or end-stage CKD[3] or requires dialysis; **OR**
II. Individual has decompensated[1] cirrhosis; **OR**
III. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to the following: amiodarone, atazanavir- or lopinavir containing regimens, tipranavir/ritonavir, efavirenz, etravirine, nevirapine, rosuvastatin, and pitavastatin, cyclosporine, poly glycoprotein (P-gp) inducers and moderate or strong cytochrome (CYP) 3A4 inducers (such as but not limited to, phenytoin, St. John's Wort, phenobarbital, rifampin, rifabutin, rifapentine, carbamazepine, oxcarbazepine), or Breast Cancer Resistance Protein (BCRP) substrates (such as but not limited to, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan); **OR**
IV. Individual is using in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir) or another nucleotide NS5B polymerase inhibitor; **OR**
V. Individual is using in combination with a regimen containing another NS5A[2a] inhibitor; **OR**
VI. Individual is using in combination with a regimen containing another NS3/4A[2c] protease inhibitor.

Notes:

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

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

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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/IDSA2017)

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

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

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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
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:

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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

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

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.

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