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

Mavyret (glecaprevir/pibrentasvir)

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

Medication	Quantity Limit
Mavyret (glecaprevir/pibrentasvir)	3 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 Mavyret
Genotypes 1, 2, 3, 4, 5, or 6 (treatment-naïve, without cirrhosis)	Mavyret	8 weeks
Genotypes 1, 2, 3, 4, 5, or 6 (treatment-naïve, with compensated cirrhosis)	Mavyret	12 weeks
Genotype 1 (treatment-experienced with an NS5A[2a] inhibitor and without prior treatment with an NS3/4A[2c] protease inhibitor, with compensated cirrhosis or without cirrhosis)	Mavyret	16 weeks
Genotype 1 (treatment-experienced with an NS3/4A[2c] protease inhibitor or sofosbuvir and without prior treatment with an NS5A[2a] inhibitor, with compensated cirrhosis or without cirrhosis)	Mavyret	12 weeks
Genotype 2 (treatment-experienced with sofosbuvir + ribavirin, with compensated cirrhosis or without cirrhosis)	Mavyret	12 weeks
Genotype 3 (dual P/R[2b] treatment-experienced with compensated cirrhosis or without cirrhosis)	Mavyret	16 weeks

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

Genotypes 1, 2, 4, 5, or 6 (dual P/R[2b] treatment-experienced without cirrhosis)	Mavyret	8 weeks
Genotypes 1, 2, 4, 5, and 6 (dual P/R[2b] treatment-experienced, with compensated cirrhosis)	Mavyret	12 weeks
Genotypes 1, 2, 3, 4, 5, or 6 (treatment-naïve or treatment-experienced, post-liver allograft transplant recipient, with compensated cirrhosis or without cirrhosis)	Mavyret	12 weeks
Genotypes 1, 2, 3, 4, 5, or 6 (treatment-naïve or treatment-experienced, post-kidney transplant recipient, with compensated cirrhosis or without cirrhosis)	Mavyret	12 weeks

APPROVAL CRITERIA

Requests for Mavyret (glecaprevir/pibrentasvir) may be approved if the following criteria are met:

I. Individual is 12 years of age or older **or** weighing at least 45 kg; **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 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. Individuals who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program; **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 2018):
    A. As monotherapy for **one** of the following:
        1. Individual is treatment-naïve, with compensated[1] cirrhosis or without cirrhosis, and Genotypes 1, 2, 3, 4, 5, or 6;

        OR

        2. Individual is treatment-experienced with a prior HCV NS5A[2a] inhibitor regimen without prior HCV treatment with an NS3/4A[2c] protease inhibitor with compensated[1] cirrhosis or without cirrhosis, and Genotype 1;

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

OR

3. Individual is treatment-experienced with a prior HCV NS3/4A[2c] protease inhibitor regimen without prior HCV treatment with an NS5A[2a] inhibitor, with compensated[1] cirrhosis or without cirrhosis, and Genotype 1;

OR

4. Individual is dual P/R[2b] treatment-experienced without prior HCV treatment with an HCV NS3/4A[2c] protease inhibitor, sofosbuvir-based regimen or NS5A[2a] inhibitor, with compensated[1] cirrhosis or without cirrhosis, and Genotypes 1, 2, 3, 4, 5, or 6;

OR

5. Individual is treatment-experienced with a sofosbuvir-containing regimen without an NS5A[2b] inhibitor, with compensated[1] cirrhosis or without cirrhosis, and Genotypes 1 or 2;

OR

6. Individual is a post-liver allograft transplant recipient with or without compensated[1] cirrhosis, and Genotypes 1, 2, 3, 4, 5, or 6;

OR

7. Individual is a post-kidney transplant recipient, with or without compensated[1] cirrhosis, and Genotypes 1, 2, 3, 4, 5, or 6.

Mavyret (glecaprevir/pibrentasvir) may **not** be approved for the following:

I. Individual has decompensated[1] cirrhosis; **OR**
II. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to ritonavir-containing antiretroviral regimens, efavirenz, etravirine, nevirapine, darunavir/cobicistat, atazanavir, carbamazepine, St John's wort, ethinyl estradiol-containing medications, atorvastatin, lovastatin, simvastatin, and rifampin; **OR**
III. Individual is using in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir) or nucleotide NS5B polymerase inhibitor (such as sofosbuvir); **OR**
IV. Individual is using in combination with a regimen containing another NS5A[2a] inhibitor; **OR**
V. Individual is using in combination with a regimen containing another NS3/4A[2c] protease inhibitor; **OR**
VI. Individual is requesting the regimen for re-treatment 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

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

prior successfully completed treatment regimen consisting of elbasvir/grazoprevir, ombitasvir/paritaprevir/ritonavir and dasabuvir, ombitasvir/paritaprevir/ritonavir, or sofosbuvir/velpatasvir/voxilaprevir.

Notes:

[a]Per label and AASLD/IDSA treatment guidance, Mavyret (glecaprevir/pibrentasvir) may be used in individuals who are co-infected with HIV-1.

1. **Compensated Liver Disease:**
   According to the American Association for the Study of Liver Diseases (AASLD/IDSA2017), 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)

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

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. 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.

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

Washington D.C.	2/1/2018	Washington D. C. has state criteria; please see Washington D. C. State Specific Criteria

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