GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** the following criteria?
   - The patient is at least 12 years old or weighing at least 45 kg
   - The medication prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Documentation of chronic HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE of** the following criteria?
   - The patient has moderate or severe liver impairment (Child-Pugh B or C)
   - The patient is concurrently taking any of the following medications (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
   - The patient has prior failure of a direct-acting antiviral (DAA) regimen that contains a NS5A inhibitor **AND** a NS3/4A protease inhibitor (e.g., Viekira Pak, Viekira XR, Technivie, Vosevi, Zepatier), or previous concurrent treatments containing a NS5A inhibitor **AND** NS3/4A protease inhibitor
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

3. Is the patient post kidney transplant or post-liver transplant and meet **ONE** of the following criteria?
   - Genotype 1 infection, treatment experienced (previous treatment with NS5A inhibitor) **AND** NS3/4A protease inhibitor naïve
   - Genotype 3 infection, treatment experienced (previous treatment with a regimen that contains interferon or peginterferon with ribavirin, and/or sofosbuvir)

   If yes, **approve for 16 weeks by HICL for #3 tablets per day.**
   If no, continue to #4.

4. Is the patient post kidney transplant or post-liver transplant and meet **ALL** of the following criteria?
   - Genotype 1, 2, 3, 4, 5 or 6 infection
   - Treatment experienced or treatment naïve
   - Without cirrhosis or with compensated cirrhosis

   If yes, **approve for 12 weeks by HICL for #3 tablets per day.**
   If no, continue to #5.

5. Has the patient previously received a full treatment of a regimen that contains a NS5A inhibitor (e.g., Harvoni, Epclusa, or Daklinza/Sovaldi combination)?

   If yes, continue to #8.
   If no, continue to #6.

6. Is the patient **ONE** of the following?
   - Genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis and treatment naïve
   - Genotype 1, 2, 4, 5 or 6 infection without cirrhosis and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)

   If yes, **approve for 8 weeks by HICL for #3 tablets per day.**
   If no, continue to #7.

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GUIDELINES FOR USE (CONTINUED)

7. Is the patient **ONE** of the following?
   - Genotype 1, 2, 4, 5 or 6 infection with compensated cirrhosis and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)
   - Genotype 1 infection and treatment experienced (previous treatment with NS3/4A inhibitor (e.g., boceprevir, telaprevir, simeprevir) **AND** is NS5A inhibitor naïve)

   If yes, **approve for 12 weeks by HICL for #3 tablets per day.**
   If no, continue to #8.

8. Does the patient have genotype 1, 2, 3, 4, 5 or 6 infection with compensated cirrhosis and treatment naïve?

   If yes, **approve for 8 weeks by HICL for #3 tablets per day.**
   If no, continue to #9.

9. Is the patient **ONE** of the following?
   - Genotype 1 infection and treatment experienced (previous treatment with NS5A inhibitor **AND** is NS3/4A protease inhibitor naïve)
   - Genotype 3 infection and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)

   If yes, **approve for 16 weeks by HICL for #3 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C. The following criteria must also be met:
   - The patient is at least 12 years old or weighing at least 45 kilograms
   - The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Documentation of HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)
   - Patient has compensated cirrhosis or no cirrhosis and meets one of the following: 1) treatment naïve (genotype 1-6), or 2) treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6), or 3) treatment experienced with NS5A inhibitor or NS3/4A protease inhibitor (genotype 1), or 4) post kidney transplant or post liver transplant and is treatment naïve or treatment experienced (genotype 1-6)

   (Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following:

- Patient is concurrently taking (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
- Patient has moderate or severe liver impairment (Child-Pugh B or C)
- Patients with prior failure of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor AND NS3/4A protease inhibitor (e.g., Technivie, Viekira, Vosevi, Zepatier) or previous concurrent treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 7, 2017.
- Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 09/17
Client Approval: 11/19
P&T Approval: 10/19