STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		GPI-10 (1235990235)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?
   - The patient is 3 years of age or older

   If yes, continue to #2.
   If no, continue to #12.

2. Does the patient have an HCV RNA level within the past 6 months?

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

3. 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), medications containing ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
   - 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 [ombitasvir/paritaprevir/ritonavir/dasabuvir], Viekira XR [ombitasvir/paritaprevir/ritonavir/dasabuvir extended release], Technivie [ombitasvir/paritaprevir/ritonavir], Vosevi [sofosbuvir/velpatasvir/voxilaprevir], Zepatier [elbasvir/grazoprevir], or previous concurrent treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
   - The 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 #4.

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GUIDELINES FOR USE (CONTINUED)

4. Has the patient previously received a full treatment of a regimen that contains a NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir], or Daklinza [daclatasvir]/Sovaldi [sofosbuvir] combination)?

   If yes, continue to #11.
   If no, continue to #5.

5. Has the patient failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agent(s) as specified below?
   - For genotype 1, 4, 5, or 6 HCV infection: a short trial of Epclusa (sofosbuvir/velpatasvir) or Harvoni (ledipasvir/sofosbuvir) (e.g., adverse effect early in therapy to Harvoni [ledipasvir/sofosbuvir] or Epclusa [sofosbuvir/velpatasvir]) or contraindication to BOTH agents
   - For genotype 2 or 3 HCV infection: a short trial of Epclusa (sofosbuvir/velpatasvir) (e.g., adverse effect early in therapy to Epclusa [sofosbuvir/velpatasvir]) or contraindication to this agent

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. 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 for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #7.

7. Is the patient post kidney transplant or post-liver transplant and meet **ALL** of the following criteria?
   - Treatment experienced or treatment naïve
   - Without cirrhosis or with compensated cirrhosis

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #8.

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GUIDELINES FOR USE (CONTINUED)

8. Does the patient meet **ONE** of the following criteria?
   - 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 for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #9.

9. Does the patient meet **ONE** of the following criteria?
   - 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., Victrelis (boceprevir), Incivek (telaprevir), Olysio (simeprevir)]) AND is NS5A inhibitor naïve)

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #10.

10. 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 for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #11.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

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

    If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #12.

12. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:
    A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
    B. You have chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6
    C. You are 3 years of age or older
    D. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
    E. You have compensated cirrhosis (type of liver condition) or no cirrhosis (no liver damage) and meet ONE of the following:
        1. You are treatment naïve (never been treated) (genotype 1-6)
        2. You are treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6)
        3. You are treatment experienced with NS5A (nonstructural protein 5A) inhibitor or NS3/4A protease inhibitor (genotype 1)
        4. You had a kidney transplant or liver transplant and are treatment naive or treatment experienced (genotype 1-6)

    (Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

F. You had a short trial of a preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (harmful for) to therapy with the preferred formulary agent(s) as specified below unless you had prior NS5A (nonstructural protein 5A) inhibitor treatment:
   1. If you have genotype 1, 4, 5, or 6 infection, you had a short trial of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir), or you have a contraindication (harmful for) to BOTH agents
   2. If you have genotype 2 or 3 infection, you had a short trial of Epclusa (velpatasvir/sofosbuvir) or you have a contraindication (harmful for) to this agent

Mavyret will not be approved if you meet any of the following:

A. You are 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), medications containing ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir) or Zepatier (elbasvir/grazoprevir)
B. You have moderate or severe liver impairment (Child-Pugh B or C)
C. You have prior failure of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor AND NS3/4A protease inhibitor (such as Technivie [ombitasvir/paritaprevir/ritonavir], Viekira [ombitasvir/paritaprevir/ritonavir/dasabuvir], Viekira XR [ombitasvir/paritaprevir/ritonavir/dasabuvir extended release], Vosevi [sofosbuvir/velpatasvir/voxilaprevir], Zepatier [elbasvir/grazoprevir]) or you had previous concurrent (used at the same time) treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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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; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 09/17
Client Approval: 08/23
P&T Approval: 07/23