STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR	VIEKIRA PAK, VIEKIRA XR	41644		GPI-10 (1235990460)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a contraindication to therapy with Epclusa AND Harvoni
   - The patient has previously failed a short trial with Epclusa or Harvoni (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa or Harvoni that did not achieve SVR will not be approved]

   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 have one or more of the following conditions?
   - Decompensated liver disease
   - Moderate liver impairment (Child-Pugh B) or severe liver impairment (Child-Pugh C)
   - A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - Patient is on hemodialysis
   - Concurrent use with any of these (contraindicated or not recommended by the manufacturer) medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, salmeterol
   - Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
   - Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
   - Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)

   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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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

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

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of hepatitis C, genotype 1 and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin; (**NOTE:** Ribavirin combination therapy with Viekira is approved for genotype 1a without cirrhosis, genotype 1a with cirrhosis, and for use in liver transplant patients.)?

   If yes, continue to #6.
   If no, continue to #12.

6. Is the patient a liver transplant recipient?

   If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients who are liver transplant recipients to complete a total of 24 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #7.

7. Does the patient have genotype 1a without cirrhosis?

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a without cirrhosis to complete a total maximum of 12 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #8.

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GUIDELINES FOR USE (CONTINUED)

8. Does the patient have genotype 1a with cirrhosis **AND** is treatment naïve?

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows treatment naïve patients with genotype 1a with cirrhosis to complete a total maximum of 12 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #9.

9. Does the patient have genotype 1a with cirrhosis and has received prior treatment (e.g., treatment-experienced patient) for hepatitis C with peginterferon and ribavirin; (**NOTE:** Approval not granted for patients with history of prior use of **OR** concurrent use of HCV protease inhibitors or HCV polymerase inhibitors: Olysio (simeprevir), Victrelis (boceprevir), Incivek (telaprevir), Sovaldi (sofosbuvir), or Harvoni (ledipasvir/sofosbuvir)?

   If yes, continue to #10.
   If no, continue to #12.

10. Is the patient a previous prior relapser or a prior partial responder?

    If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous prior relapsers or prior partial responders to complete a total of 12 weeks of therapy):**
    - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
    - **Viekira Pak: #112 tablets (1 pack) per 28 days**

    If no, continue to #11.

11. Is the patient a treatment-experienced patient and is a previous null responder?

    If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous null responders to complete a total of 24 weeks of therapy):**
    - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
    - **Viekira Pak: #112 tablets (1 pack) per 28 days**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

12. Does the patient have genotype 1b?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1b to complete a total of 12 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

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 **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak, Viekira XR)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 1 (a type of liver infection)
B. You are 18 years of age or older
C. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
D. You will be using ribavirin with the requested medication, unless you have genotype 1b
E. You have previously failed a short trial with Epclusa or Harvoni unless you have a medical reason why you cannot use (contraindication) BOTH drugs. Reasons for failure include adverse effect early in therapy, intolerance to therapy (**NOTE:** If you completed a full course of therapy with Epclusa or Harvoni and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
F. You have an HCV RNA level (amount of virus in the blood) within the past 6 months

(Denial text continued on the next page)

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following patients:

A. You are using any of the following medications at the same time while on Viekira: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have decompensated cirrhosis (symptoms related to liver damage)
C. You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
D. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
E. You have a limited life expectancy (less than 12 months) due to other conditions not related to the liver
F. You have previously used/failed a full course of therapy, or currently using any of the following regimens:
    1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
    2. A combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
    3. A hepatitis C virus protease inhibitor (type of hepatitis drug) including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved except 24 weeks of therapy for 1) genotype 1a with cirrhosis if patient is treatment experienced, previous null responder or 2) a liver transplant recipient.

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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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

RATIONALE

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

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 November 3, 2022.
- Viekira Pak [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.
- Viekira XR [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 01/15
Client Approval: 11/22
P&T Approval: 01/20