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Coverage Policy Number **IP0189**

Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (**Viekira Pak™**).

Coverage for ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (Viekira Pak) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (Viekira Pak) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) genotype 1a when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. Does NOT have cirrhosis or has compensated cirrhosis (Child-Pugh A)
3. Viekira Pak is prescribed in combination with ribavirin
4. Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
5. Preferred products are required:
   Employer Group Plans
   Documentation of failure, contraindication, or intolerance to **ONE** of the following:
   a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
   b. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
   c. Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir) [may require prior authorization]

   Individual and Family Plans
   Documentation of failure, contraindication, or intolerance to **ONE** of the following:
   a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
   b. sofosbuvir/velpatasvir [may require prior authorization]
   c. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
   d. ledipasvir/sofosbuvir [may require prior authorization]

Ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (Viekira Pak) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) genotype 1b when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. Does NOT have cirrhosis or has compensated cirrhosis (Child-Pugh A)
3. Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Preferred products are required:
   Employer Group Plans
   Documentation of failure, contraindication, or intolerance to **ONE** of the following:
   a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
   b. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
   c. Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir) [may require prior authorization]

   Individual and Family Plans
   Documentation of failure, contraindication, or intolerance to **ONE** of the following:
   a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
   b. sofosbuvir/velpatasvir [may require prior authorization]
   c. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
   d. ledipasvir/sofosbuvir [may require prior authorization]

Ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (Viekira Pak) is considered medically necessary for the treatment of recurrent hepatitis C virus (HCV) genotype 1 post-liver transplantation when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. Viekira Pak is prescribed in combination with ribavirin
3. Medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
4. Preferred products are required:
   Employer Group Plans

Documentation of failure, contraindication, or intolerance to **ONE** of the following:

a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
b. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
c. Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir) [may require prior authorization]

Individual and Family Plans

Documentation of failure, contraindication, or intolerance to **ONE** of the following:

a. Epclusa® (sofosbuvir/velpatasvir) [may require prior authorization]
b. sofosbuvir/velpatasvir [may require prior authorization]
c. Harvoni® (ledipasvir/sofosbuvir) [may require prior authorization]
d. ledipasvir/sofosbuvir [may require prior authorization]

Ombitasvir/paritaprevir/ritonavir and dasabuvir [co-packaged] (Viekira Pak) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) or recurrent hepatitis C virus (HCV) genotype 1 post-liver transplantation when the individual has already been started on Viekira Pak and will be completing a course of therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration:

1. **Chronic Hepatitis C Virus (HCV) Genotype 1a without Cirrhosis**: up to 12 weeks in combination with ribavirin
2. **Chronic Hepatitis C Virus (HCV) Genotype 1a with Compensated Cirrhosis (Child-Pugh A):** up to 24 weeks in combination with ribavirin
3. **Chronic Hepatitis C Virus (HCV) Genotype 1b without Cirrhosis or with Compensated Cirrhosis (Child-Pugh A)**: up to 12 weeks
4. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1**: up to 24 weeks in combination with ribavirin

Reauthorization approval duration: not applicable

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Hepatitis C Virus (HCV), Child-Pugh Class B or Child-Pugh Class C Liver Disease (Moderate or Severe Hepatic Impairment).** Viekira Pak is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh Class B or C).[1] The AASLD recommend *against* the use of Viekira Pak in patients with chronic HCV with decompensated cirrhosis (Child-Pugh Class B or C).

2. **Hepatitis C Virus (HCV) [Any Genotype], Combination with Any Other Direct-Acting Antivirals (DAAs) Not Including Ribavirin.** Viekira Pak provides a complete antiviral regimen for patients with genotype 1 HCV.

Viekira Pak is indicated with ribavirin for some patients. In the opinion of a specialist physician reviewing the data we have adopted this criterion.

3. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment.[2] According to AASLD guidance, the panel continues to recommend treatment for all patients with chronic HCV infection, *except* those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

4. **Pediatric Patients (Age less than 18 Years).** The safety and efficacy of Viekira Pak have not been established in pediatric patients less than 18 years of age.[1]

5. **Retreatment with Viekira Pak in Patients Who Have Previously Received Viekira Pak, Viekira XR, or Technivie** (e.g., retreatment in prior null responders, prior partial responders, prior relapse patients, patients who have not completed a course of therapy due to an adverse reaction or for other reasons). Technivie, Viekira Pak, and Viekira XR contain the same active ingredients; Viekira Pak and Viekira XR additionally contain dasabuvir.

Background

OVERVIEW
Viekira Pak contains ombitasvir, a hepatitis C virus (HCV) NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, ritonavir, a cytochrome P450 (CYP)3A inhibitor and dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor.[1]

Viekira Pak is indicated for the treatment of patients with **genotype 1 chronic HCV**.[1] Viekira Pak is indicated in patients with:

- Genotype 1b without cirrhosis or with compensated cirrhosis; or
- Genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

The recommended dose of Viekira Pak is two co-formulated ombitasvir/paritaprevir/ritonavir tablets once daily (in the morning) and one dasabuvir tablet twice daily (morning and evening). When administered with Viekira Pak, the recommended dose of ribavirin is weight-based. For patients with HCV/human immunodeficiency virus (HIV)-1 co-infection the recommendations are the same as for those without co-infection. Of note, product labeling notes that some patients with genotype 1a with cirrhosis may be treated for 12 weeks with Viekira Pak + weight-based ribavirin based on data from the TURQUOISE-II trial. In liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤ 2) the recommended duration of therapy with Viekira Pak is 24 weeks, irrespective of HCV genotype 1 subtype.

Table 1. FDA-Approved Regimens and Treatment Duration for Viekira Pak.[1]

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira Pak + WBR	12 weeks
Genotype 1a, with cirrhosis	Viekira Pak + WBR	24 weeks**
Genotype 1b, with or without cirrhosis	Viekira Pak	12 weeks

* Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection; WBR – Weight-based ribavirin; ** A 12 week treatment duration may be considered for some patients based on prior treatment history.

Guidelines
Viekira Pak is not addressed in the American Association for the Study of Liver Diseases (AASLD) Guidelines recommended (or alternative) regimens.[2] It has been supplanted by other direct-acting antivirals.

References

1. Viekira Pak™ tablets [prescribing information]. North Chicago, IL: AbbVie; December 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Updated October 24, 2023. Available at: http://www.hcvguidelines.org. Accessed on November 2, 2022.