Drug Quantity Management – Per Days
Hepatitis C – Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets [co-packaged]

Table of Contents

Product Identifier(s)

Effective 1/1/23 to 2/27/23: 108895

Effective 2/28/23: 49729

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.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to prevent stockpiling and waste and address potential order entry error of Viekira Pak. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 365 days*	Home Delivery Maximum Quantity per 365 Days*
Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets)	One monthly carton containing 112 tablets.	336 tablets	336 tablets

*112 tablets per dispensing (28-days). This is a quantity sufficient to treat for 12 weeks. For additional quantities coverage review is required.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

1. **Chronic Hepatitis C Virus (HCV) Genotype 1a.** If the individual has cirrhosis, approve 672 tablets per 365 days at retail or home delivery.
   Note: This is a quantity sufficient to treat for 24 weeks.

2. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1.** Approve 672 tablets per 365 days at retail or home delivery.
   Note: This is a quantity sufficient to treat for 24 weeks.

3. For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 672 tablets per 365 days at retail or home delivery to complete a course of therapy (e.g., if the individual has received 28 days of therapy [112 tablets], approve 560 tablets to complete 24 weeks of treatment).

Conditions Not Covered

Any other exception is considered not medically necessary.

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.

Dosing
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).[1] 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

* 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.

Availability
Viekira Pak is available in a monthly carton for a total of 28 days of therapy.[2] Each monthly carton contains four weekly cartons. Each weekly carton contains seven daily dose packs. Each daily dose pack contains four tablets: two 12.5/75/50 mg ombitasvir/paritaprevir/ritonavir co-formulated tablets and two 250 mg dasabuvir tablets, and indicates which tablets need to be taken in the morning and evening.

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. Available at: http://www.hcvguidelines.org. Updated October 5, 2021. Accessed on September 13, 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes. Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	09/13/2022