# Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the use of the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

When a referral is received for a non-preferred agent, the requested agent is paid at the client's standard specialty copay if the patient has a paid claim for the requested agent in the past 30 days. If the patient does not have a claim for the requested agent in the previous 30 days, the Post Step Therapy Criteria for Approval will be applied. If the patient meets the criteria for approval, then the requested agent is paid at the standard specialty copay.

## POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review:

- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Genotype and subtype (if applicable)
- Baseline or current viral load


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- Laboratory testing for resistance-associated variants (if applicable)
- METAVIR fibrosis score (if applicable)
- Liver transplantation status
- Treatment plan including treatment regimen and duration
- Prior treatment regimen(s) and response
- Prescriber specialty

Exclusions

- Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C)

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

Criteria for Approval

***** The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

**A. Chronic hepatitis C virus infection, in combination with ribavirin**

Note: Members with mixed genotype 1 infection or unknown genotype 1 subtype should follow the criteria for approval for genotype 1a infection.

**A.1 Genotype 1a infection**

a) Authorization of up to 12 weeks total may be granted for members without cirrhosis who are either of the following:
   i. Treatment-naïve
   ii. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV.

b) Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are either of the following:
   i. Treatment-naïve
   ii. Failed prior treatment with PEG-IFN and RBV.

**A.2 Recurrent HCV infection post liver transplantation**

a) Authorization of up to 24 weeks total may be granted for members with recurrent HCV infection post liver transplantation who meet all of the following criteria:
   i. Genotype 1 infection (irrespective of subtype)
   ii. Metavir fibrosis score of 2 or lower.

**B. Chronic hepatitis C virus infection, without ribavirin**

**B.1 Genotype 1b infection**

a) Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are either of the following:
   i. Treatment-naïve
   ii. Failed prior treatment with PEG-IFN and RBV

**C. HCV and HIV coinfection**

a) Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in section 1 or 2 above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.


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Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- Viekira Pak - 112 tablets per 28 days

Dispensing Limits

- A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

## PROCEDURES AND BILLING CODES

***To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

## REFERENCES


- Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.
- Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; March 2017.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made on August 27, 2020. Accessed September 18, 2020.


*Some content reprinted from CVSHealth

## POLICY HISTORY

**Policy #:** 05.01.100
**Policy Creation:** January 2016
**Reviewed:** October 2020
**Revised:** October 2019
**Current Effective Date:** January 31, 2020


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