

# Specialty Guideline Management

## Viekira Pak

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Viekira Pak	ombitasvir-paritaprevir-ritonavir-dasabuvir

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication<sup>1</sup>

Viekira Pak is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):

- Genotype 1b without cirrhosis or with compensated cirrhosis
- Genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin (RBV)

All other indications are considered experimental/investigational and not medically necessary.

### Exclusions

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

Reference number(s)
Policy: 2143-A
Qsets: 5920-A, 6284-A

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

## Prescriber Specialties

This medication must be prescribed by or in consultation with provider experienced in the management of hepatitis C virus infection.

## Coverage Criteria

### Hepatitis C Virus Infection, Without Ribavirin<sup>1</sup>

#### Genotype 1b Infection

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1b infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV).

### Hepatitis C Virus Infection, in Combination with Ribavirin<sup>1</sup>

#### Genotype 1a/Mixed Genotype 1/Unknown Genotype 1 infection

- Authorization of up to 12 weeks total may be granted for members without cirrhosis who are treatment-naïve or who failed prior treatment with peginterferon alfa (PEG-IFN) and RBV.
- Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV.

#### Recurrent HCV Infection Post Liver Transplantation

Authorization of up to 24 weeks total may be granted for members with recurrent HCV genotype 1 infection (irrespective of subtype) post liver transplantation who have a Metavir fibrosis score of 2 or lower.

### Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection<sup>1</sup>

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

## Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

## Other

- This medication will be approved for use in adult members only.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
  - Treatment status (i.e., treatment-naïve or retreatment)
  - For initial treatment: confirmation of member readiness
  - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
  - Hepatitis B virus screening results
  - Metavir/Fibrosis score

## References

1. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.