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

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[1]

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).

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[1]

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[1]

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[1]

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.