Reference number(s)
2143-A, 2682-A

SPECIALTY GUIDELINE MANAGEMENT

VIEKIRA PAK
(ombitasvir/paritaprevir/ritonavir/dasabuvir)

POLICY

I. 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 Indications
Viekira Pak is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):
A. genotype 1b without cirrhosis or with compensated cirrhosis
B. 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.

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

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.

1. Genotype 1a infection
i. Authorization of up to 12 weeks total may be granted for members without cirrhosis who are either of the following:
   a. Treatment-naïve
   b. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV
ii. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are either of the following:
   a. Treatment-naïve
   b. Failed prior treatment with PEG-IFN and RBV

2. Recurrent HCV infection post liver transplantation
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
Genotype 1b infection
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are either of the following:
1. Treatment-naïve
2. Failed prior treatment with PEG-IFN and RBV

C. HCV and HIV coinfection
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in section A or B above are met.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

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