CareFirst Family of health care plans

CVS caremark™

SPECIALTY GUIDELINE MANAGEMENT

VIEKIRA PAK
VIEKIRA XR
(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/Viekira XR is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):
A. genotype 1b infection without cirrhosis or with compensated cirrhosis
B. genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin (RBV)

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

A. Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).
B. Prior treatment failure with an HCV protease inhibitor (eg, telaprevir, boceprevir, simeprevir, paritaprevir) despite adequate dosing and duration of therapy

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

III. CRITERIA FOR 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
   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

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:
   a. Genotype 1 infection (irrespective of subtype)
   b. 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 who meet all of the following criteria:
a. Member meets the criteria for approval for the requested regimen in section A or B above
b. Member is currently receiving antiretroviral therapy

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.; June 2016.
2. Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; July 2016.
3. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made July 8, 2016. Accessed September 6, 2016.