CareFirst Family of health care plans

CVS caremark™

SPECIALTY GUIDELINE MANAGEMENT

ZEPATIER (elbasvir and grazoprevir)

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
Zepatier is indicated with or without ribavirin for the treatment of chronic hepatitis C virus genotypes 1 or 4 infection in adults.

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. Liver transplant recipient or awaiting liver transplantation

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 (RBV)**

1. Genotype 1a infection

a. Authorization of up to 16 weeks total may be granted for members with baseline NS5A polymorphisms (see Section V) who are either of the following:
   i. Treatment-naïve
   ii. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)
b. Authorization of up to 12 weeks total may be granted for members without baseline NS5A polymorphisms (see Section V) who have failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

2. Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

3. Genotype 4 infection

Authorization of up to 16 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV.

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

1. Genotype 1a infection

Authorization of up to 12 weeks total may be granted for members without baseline NS5A polymorphisms (see Section V) who are either of the following:
a. Treatment-naïve
b. Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

2. Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who are either of the following:

a. Treatment-naïve
b. Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

3. Genotype 4 infection

Authorization of up to 12 weeks total may be granted for members who are either of the following:

a. Treatment-naïve
b. 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. APPENDIX: NS5A RESISTANCE-ASSOCIATED POLYMORPHISMS

NS5A resistance-associated polymorphisms at amino acid positions M28, Q30, L31 or Y93. Examples include M28V, Q30H, L31M, and Y93H.

VI. REFERENCES

1. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2016.
2. 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.