

## 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 for the treatment of chronic hepatitis C virus genotype 1 or 4 infection in adults. Zepatier is indicated for use with ribavirin in certain patient populations.

All other indications are considered experimental/investigational and are 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 APPROVAL

##### A. 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 resistance-associated substitutions (RASs)/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 resistance-associated substitutions (RASs)/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.

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| Reference number(s) |
| 2145-A, 2684-A      |

## **B. 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 resistance-associated substitutions (RASs)/polymorphisms who are either of the following:

- Treatment-naïve
- 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:

- Treatment-naïve
- 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 treatment-naïve.

### **4. Kidney transplant recipients**

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Section V) who have HCV genotype 1 or 4 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

### **5. Organ recipient from HCV-viremic donor**

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Section V) who have HCV genotype 1 or 4 infection and have received an organ transplanted from an HCV-viremic donor.

## **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 SUBSTITUTIONS (POLYMORPHISMS)**

NS5A resistance-associated substitutions (polymorphisms) at amino acid positions M28, Q30, L31 or Y93. Examples include M28A/T, Q30H/R, L31M/V, and Y93C/H/N.

## **VI. REFERENCES**

- Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2019.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last changes made January 21, 2021. Accessed January 21, 2021.