

ZEPATIER (elbasvir/grazoprevir)

All coverage requests are reviewed by a Blue Shield clinician.

Coverage is provided when patients meet the following requirements:

1. Age 18 years and older, and
2. Currently has detectable serum Hepatitis C virus (HCV) RNA, and
3. Hepatitis C regimen is prescribed by an appropriate specialist in the care of patients with Hepatitis C (hepatologist, gastroenterologist, infectious disease), and
4. Will not be used together with another direct-acting anti-viral drug to treat HCV infection (*Daklinza, Harvoni, Olysio, Sovaldi, Technivie, Viekira, etc.*), and
5. Patient has not been treated with a NS5A inhibitor (daclatasvir, elbasvir, ledipasvir, ombitasvir, elbasvir) containing therapy in the past, and
6. Patient has not been treated with a sofosbuvir-containing regimen in the past, and
7. Zepatier dose does not exceed the FDA label recommended maximum daily dose, and
8. Prescribed Hepatitis C regimen is aligned to nationally recognized treatment guidelines, and
9. Specific coverage requirements by subpopulations below:

For Genotype-1 (not post-liver transplant):

- a) Patient has a specific contraindication to Harvoni therapy that is not also expected with a Zepatier containing regimen, and
- b) Patient does not have decompensated cirrhosis, and
- c) *For patients with genotype-1a with NS5A polymorphism, OR patients with genotype-1 and prior treatment with a peginterferon + ribavirin + protease inhibitor regimen:* Used in combination with ribavirin.

Coverage: (claims limited to 30-day supply per prescription)

- **Treatment naïve:**

Genotype	NS5A resistance	Evidence of Cirrhosis	Treatment (weeks)
1a	no	no	12
1a	no	yes	12

1a	yes	no	12
1a	yes	yes	16
1b	n/a	n/a	12

- Treatment experienced:***

Genotype	Prior Treatment	NS5A resistance	Treatment (weeks)
1a	PEG/RBV	no	12
1a	PEG/RBV	yes	16
1a	PI+PEG/RBV	no	12
1a	PI+PEG+RBV	yes	16
1b	PEG/RBV	n/a	12
1b	PI+PEG/RBV	n/a	12

PI- protease inhibitor; PEG- peginterferon; RBV- ribavirin

For Genotype-4 (not post-liver transplant):

- Patient does not have decompensated cirrhosis, and
- Patient has a specific contraindication to Harvoni therapy that is not also expected with a Zepatier containing regimen, and
- For patients with prior peginterferon + ribavirin treatment:* Used in combination with ribavirin

Coverage: (*claims limited to 30-day supply per prescription*)

- Treatment naïve: 12 weeks***
- Treatment experienced:***

Prior PEG/RBV	Treatment (weeks)
relapse	12
failure	16

PEG- peginterferon; RBV- ribavirin

Zepatier Treatment Duration table:

Patient population			Treatment Duration
Genotype	Treatment Characteristics	Combo with Ribavirin	

		(RBV)	
1a	<i>For patients without NS5A polymorphism:</i> Treatment naïve or failed prior peginterferon + ribavirin therapy	No	12 weeks
1a	<i>For patients with NS5A polymorphism:</i> Treatment naïve or failed prior peginterferon + ribavirin +/- protease inhibitor therapy	Yes	16 weeks
1b	Treatment naïve or failed prior peginterferon + ribavirin therapy	No	12 weeks
1b	Treatment experienced failed prior peginterferon + ribavirin + protease inhibitor therapy	Yes	12 weeks
4	Treatment naïve	No	12 weeks
4	Treatment experienced – e.g. failed prior therapy with peginterferon + ribavirin	Yes	16 weeks

Effective Date: 3/02/2022