

**EPCLUSA (velpatasvir/sofosbuvir)
velpatasvir/sofosbuvir (EPCLUSA)**

All coverage requests are reviewed by a Blue Shield clinician.

Coverage is provided when patients meet the following requirements:

1. Patient is 6 years and older or weighing at least 17 kilograms, 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 anti-viral drug to treat HCV infection unless recommended in nationally recognized treatment guidelines and supported by high quality evidence (e.g. AASLD/IDSA Category Level A or B), and
5. Patient has not been treated with a NS5A inhibitor (daclatasvir, ledipasvir, ombitasvir, elbasvir, velpatasvir) containing therapy in the past, and
6. Dose does not exceed the FDA label recommended maximum daily dose, and
7. Prescribed Hepatitis C regimen is aligned to nationally recognized treatment guidelines, and
8. For generic sofosbuvir/velpatasvir (Epclusa) request: Intolerance or contraindication to brand Epclusa not expected with generic sofosbuvir/velpatasvir, **and**
9. **AND** specific coverage requirements by subpopulations below:

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

- a) Patient does not have decompensated cirrhosis.

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-1 (WITH decompensated liver disease):

- a) Used in combination with ribavirin unless contraindicated.

Coverage:

- **Combination with ribavirin: 12 weeks** (claims limited to 28-day supply per prescription)
- **Combination without ribavirin: 24 weeks** (claims limited to 28-day supply per prescription)

For Genotype-2 (not post-liver transplant)

- a) Patient does not have decompensated cirrhosis

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-2 (WITH decompensated liver disease):

- a) Used in combination with ribavirin.

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-3 (not post-liver transplant)

- a) Patient does not have decompensated cirrhosis

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-3 (WITH decompensated liver disease):

- a) Used in combination with ribavirin.

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

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

- a) Patient does not have decompensated cirrhosis.

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-4 (WITH decompensated liver disease):

- a) Used in combination with ribavirin unless contraindicated.

Coverage:

- **Combination with ribavirin: 12 weeks** (claims limited to 28-day supply per prescription)
- **Combination without ribavirin: 24 weeks** (claims limited to 28-day supply per prescription)

For Genotype-5 or 6 (not post-liver transplant):

- a) Patient does not have decompensated cirrhosis.

Coverage: 12 weeks (claims limited to 28-day supply per prescription)

For Genotype-5 or 6 (WITH decompensated liver disease):

- a) Not being used in post liver-transplantation patient, **and**
b) Patient has not previously received a sofosbuvir-containing HCV therapy, **and**
c) Being used in combination with ribavirin unless contraindicated.

Coverage:

- **Combination with ribavirin: 12 weeks** (claims limited to 28-day supply per prescription)
- **Combination without ribavirin: 24 weeks** (claims limited to 28-day supply per prescription)

Epclusa Treatment Duration table:

Patient population			Treatment Duration
Compensated Liver Disease			
Genotype	Treatment Characteristics	Cirrhosis?	
1	Treatment naïve	No	12 weeks
1	Treatment naïve	Yes	12 weeks
1	Treatment experienced (failed prior therapy)	No	12 weeks
1	Treatment experienced (failed prior therapy)	Yes	12 weeks
4	Treatment experienced (failed prior therapy)	No	12 weeks
4	Treatment naïve	No	12 weeks
5 & 6	Treatment naïve	n/a	12 weeks
5 & 6	Treatment experienced (failed prior therapy)	n/a	12 weeks
Decompensated Liver Disease			
1 & 4	With ribavirin	n/a	12 weeks

1 & 4	Without ribavirin	n/a	24 weeks
2 & 3	With ribavirin	n/a	12 weeks
5 & 6	With ribavirin	n/a	12 weeks
5 & 6	Without ribavirin	n/a	24 weeks

Effective Date: 03/02/2022