blue of california

HARVONI (ledipasvir/sofosbuvir)
ledipasvir/sofosbuvir (HARVONI)

All coverage requests are reviewed by a Blue Shield clinician.

Coverage is provided when patients meet the following requirements:

1. Age 3 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 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. For all Hep C anti-viral regimens (except Harvoni when used in patients previously treated with a sofosbuvir-containing regimen): Patient has not been treated with a NS5A inhibitor (daclatasvir, ledipasvir, ombitasvir, elbasvir, velpatasvir) containing therapy in the past, and
6. Harvoni 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. specific coverage requirements by subpopulations below:

For Genotype-1 (<u>not post-liver transplant</u>):

a) Patient does not have decompensated cirrhosis

Coverage:

- ***Treatment naïve: 12 weeks*** *(claims limited to 30-day supply per prescription)*
- ***Treatment experienced (except sofosbuvir):***

Evidence of Cirrhosis	Combination with Ribavirin	Treatment (weeks)
no	no	12

yes	yes	12
yes	no	24

- ***Treatment experienced with sofosbuvir:***

Evidence of Cirrhosis	Treatment (weeks)
no	12
yes	24

For Genotype-1 (post-liver transplant):

a) One of the following:

I. Used in combination with ribavirin unless contraindicated, **OR**

II. If ineligible for ribavirin therapy, patient must be treatment naïve (not previously treated for HCV infection) post-liver transplant.

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

- ***Treatment combination with ribavirin: 12 weeks***
- ***Treatment without ribavirin: 24 weeks***

For Genotype-1 (WITH decompensated liver disease):

a) Used in combination with ribavirin.

Coverage: 12 weeks *(claims limited to 30-day supply per prescription)*

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

a) Patient does not have decompensated cirrhosis

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

- ***Treatment naïve: 12 weeks*** *(claims limited to 30-day supply per prescription)*
- ***Treatment experienced:***

Evidence of	Combination with	Treatment (weeks)

Cirrhosis	Ribavirin	
no	yes	12
Yes	Yes	12
yes	no	24

For Genotype-4 (post-liver transplant):

a) Used in combination with ribavirin unless contraindicated, **OR**

b) If ineligible for ribavirin therapy, patient must be treatment naïve (not previously treated for HCV infection) post-liver transplant

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

- ***Treatment combination with ribavirin: 12 weeks***
- ***Treatment without ribavirin: 24 weeks***

For Genotype-4 (WITH decompensated liver disease):

a) Used in combination with ribavirin.

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

- ***Treatment combination with ribavirin: 12 weeks***
- ***Treatment without ribavirin: 24 weeks***

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

a) Patient does not have decompensated cirrhosis, and

b) *For PEG/RBV treatment experienced patients*: Patient has a specific contraindication to Epclusa that is not also expected with Harvoni therapy.

Coverage: 12weeks *(claims limited to 30-day supply per prescription)*

Harvoni Treatment Duration table:

Patient population			Treatment Duration
No Liver Transplant			
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	24 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
Post Liver Transplant			
1 & 4	With ribavirin	n/a	12 weeks
1 & 4	Ribavirin ineligible	w/o decompensated disease	24 weeks
Decompensated Liver Disease			
1 & 4	With ribavirin	n/a	12 weeks

*Harvoni for 8 weeks can be considered in treatment-naïve genotype-1 patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL

Effective Date: 11/30/2022