ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: February 2016

Prior Authorization: Hepatitis C medications

Products Affected: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir), Zepatier (elbasvir/grazoprevir)

Medication Indications:

EPCLUSA is indicated for adults and pediatric patients ≥3 years of age with chronic hepatitis C virus (HCV) infection genotypes 1, 2, 3, 4, 5, and 6 without cirrhosis or with compensated cirrhosis or in combination with ribavirin in patients with decompensated cirrhosis.

HARVONI is indicated for the treatment of chronic hepatitis C (CHC) genotype 1,4, 5 or 6 infection in adults and pediatric patients ≥3 years of age without cirrhosis or with compensated cirrhosis; genotype 1 infection in adult and pediatric patients ≥3 years of age with decompensated cirrhosis, in combination with ribavirin; and genotype 1 or 4 infection in adult and pediatric patients ≥3 years of age who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

MAVYRET is indicated for the treatment of chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection in adult and pediatric patients 3 years without cirrhosis or with compensated cirrhosis (Child-Pugh A). HCV genotype 1 infection in adults and pediatric patients ≥3 years of age, previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

SOVALDI is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection. Treatment of genotype 1, 2, 3, or 4 chronic hepatitis C virus (HCV) infection in adults and genotype 2 or 3 chronic HCV infection in pediatric patients ≥3 years of age without cirrhosis or with compensated cirrhosis, as a component of a combination antiviral treatment regimen.

VIEKIRA PAK Treatment of adults with chronic hepatitis C virus (HCV) infection genotype 1a, in combination with ribavirin, in patients without cirrhosis or with compensated cirrhosis (Child-Pugh class A), and genotype 1b patients without cirrhosis or with compensated cirrhosis (Child-Pugh class A).

VOSEVI is indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh class A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or who have genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

ZEPATIER is indicated for the treatment of chronic hepatitis C, genotypes 1 or 4 infection in adults and pediatric patients ≥12 years of age or ≥30 kg (with or without ribavirin).

Criteria:

ConnectiCare considers **Epclusa, Harvoni, Mavyret, Sovaldi, Viekira, Vosevi, and Zepatier** to be medically necessary when all of the following criteria are met:

1. Treatment is being prescribed by a gastroenterologist, hepatologist or ID specialist

2. Patient must have a genotype as follows:

Bolded Agents are Preferred:

Genotype 1	**Zepatier**
	Epclusa
	Vosevi
	Sovaldi
	Harvoni
	Mavyret
	Viekira
Genotype 2	**Epclusa**
	Vosevi
	Sovaldi
	Mavyret
Genotype 3	**Epclusa**
	Vosevi
	Sovaldi
	Mavyret
Genotype 4	**Zepatier**
	Epclusa
	Vosevi
	Harvoni
	Mavyret
Genotype 5	**Epclusa**
	Vosevi
	Harvoni
	Mavyret
Genotype 6	**Epclusa**
	Vosevi
	Harvoni
	Mavyret

3. HCV genotype and quantitative baseline viral load must be provided with a collection date within 3 months before the initiation of therapy

4. Patient must demonstrate treatment readiness and ability to adhere to drug regimen; documented through a provider-patient agreement or chart notes

5. Female patients of child-bearing age must have a negative pregnancy test collected within 30 days prior to initiation of therapy if starting a regimen containing ribavirin

In addition to the above criteria:

For **Harvoni** coverage:

- For Genotype 1 and 4, member has a contraindication to the use of Zepatier and Epclusa
- If member has a contraindication to Zepatier and Epclusa, member must also have a contraindication to Viekira Pak
- For Genotypes 5 and 6, member has a contraindication to Epclusa

For **Mavyret** coverage:

- Member does not have cirrhosis or has compensated cirrhosis (Child Pugh A)

OR

- Member has genotype 1 and has been previously treated with a regimen containing and NS5A inhibitor or an NS3/4A protease inhibitor, but not both

For **Sovaldi** coverage:

- Member has not been previously treated with Sovaldi
- For Genotype 1, member has a contraindication to the use of Epclusa and Zepatier
- For Genotypes 2 and 3, member has a contraindication to Epclusa

For **Viekira** coverage:

- Member has not been previously treated with a protease inhibitor (Incivek, Olysio, Victrelis)
- Member has not been previously treated with Sovaldi
- Member has a contraindication to the use of Zepatier and Epclusa

For **Vosevi** coverage:

- Member does not have cirrhosis OR member has compensated cirrhosis (Child Pugh A)
- Member has been previously treated with an NS5A inhibitor

OR

- Member has Genotype 1a or 3
- Member has been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

For **Zepatier** coverage:

- If member is Genotype 1A, member has been tested for the presence of virus with NS5A resistance-associated polymorphisms in genotype 1a

Coverage duration:

EPCLUSA AND VOSEVI - The recommended treatment duration is 12 weeks.

HARVONI –

Ledipasvir/Sofosbuvir Treatment Duration in Patients with Genotype 1, 4, 5, or 6 HCV[1]		
Genotype	**Patient population**	**Recommended treatment duration**
Genotype 1	Treatment-naive with or without cirrhosis	12 weeks[a]
	Treatment-experienced[b] without cirrhosis	12 weeks
	Treatment-experienced[b] with cirrhosis	24 weeks[c]
Genotype 4, 5, or 6	Treatment-naive and treatment-experienced,[b] with or without cirrhosis	12 weeks

[a]Ledipasvir/sofosbuvir for 8 weeks can be considered in treatment-naive genotype 1 patients without cirrhosis who have pretreatment HCV RNA less than 6 million units/mL.
[b]Treatment-experienced patients included those who have failed a peginterferon alfa plus ribavirin based regimen with or without an HCV protease inhibitor.
[c] Ledipasvir/sofosbuvir plus ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin.

MAVYRET –

PATIENT POPULATION	DURATION
Treatment Naïve, Without cirrhosis	8 weeks
Treatment Naïve, With compensated cirrhosis	8 weeks
Genotype 1, Prior treatment with an NS5A inhibitor	16 weeks
Genotype 1, Prior treatment with an NS3/4A protease inhibitor	12 weeks
Genotype 1, 2, 4, 5 or 6, Prior treatment with interferons, ribavirin and/or sofosbuvir, without cirrhosis	8 weeks
Genotype 1, 2, 4, 5 or 6, Prior treatment with interferons, ribavirin and/or sofosbuvir, with compensated cirrhosis	12 weeks
Genotype 3, Prior treatment with interferons, ribavirin and/or sofosbuvir, with compensated	16 weeks

cirrhosis	

SOVALDI –

Sofosbuvir Combination Therapy Regimens and Treatment Duration[1,a]		
Patient population	**Treatment**	**Duration**
Genotype 1 chronic hepatitis C	*Patients who can receive interferon:* 400 mg once daily + peginterferon alfa[b] + ribavirin[b]	12 wk
	Patients who cannot receive interferon: 400 mg once daily + ribavirin[b]	24 wk
Genotype 2 chronic hepatitis C	400 mg once daily + ribavirin[b]	12 wk
Genotype 3 chronic hepatitis C	400 mg once daily + ribavirin[b]	24 wk
Genotype 4 chronic hepatitis C	400 mg once daily + peginterferon alfa[b] + ribavirin[b]	12 wk
Hepatocellular carcinoma patients awaiting liver transplantation	400 mg once daily + ribavirin[b]	48 wk or until the time of liver transplantation, whichever occurs first
[a]See Off-Label Dosing for AASLD/IDSA recommendations. [b]See ribavirin and peginterferon alfa prescribing information for dosing recommendation.		

VIEKIRA –

PATIENT POPULATION	TREATMENT*	DURATION
Genotype 1a, without cirrhosis	Viekira + Ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis	Viekira + Ribavirin	24 weeks**
Genotype 1b, with or without compensated cirrhosis	Veikira	12 weeks

*Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection. **VIEKIRA PAK administered with ribavirin for 12 weeks may be considered for some patients based on prior treatment history

Genotype 1, unknown subtype or mixed infection: 12 weeks (without cirrhosis); 24 weeks (with cirrhosis).

Liver transplant recipients (Metavir fibrosis score 2 or less), regardless of genotype 1 subtype: 24 weeks

ZEPATIER –

PATIENT POPULATION	TREATMENT	DURATION
Genotype 1a: Treatment naïve or PegIFN/RBV-experienced without baseline NS5A polymorphisms	Zepatier	12 weeks
Genotype 1a: Treatment naïve or PegIFN/RBV-experienced with baseline NS5A polymorphisms	Zepatier + Ribavirin	16 weeks
Genotype 1b: Treatment naïve or PegIFN/RBV-experienced	Zepatier	12 weeks
Genotype 4: Treatment naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced	Zepatier + Ribavirin	16 weeks

Limitations:

The quantity is limited to a maximum of a 30 day supply per fill.
Additional benefit of Vosevi over Epclusa was not shown with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

References:

1. Facts & Comparisons Online
2. Daklinza package insert, Bristol Myers Squibb, Princeton, NJ
3. Harvoni package insert, Foster City, CA, Gilead Pharmaceuticals
4. Olysio Package Insert, J&J, Titusville, NJ
5. COSMOS trial results, announced April 12, 2014
6. Recommendations for Testing, Managing, and Treating Hepatitis C, http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting- treatment
7. Sovaldi package insert, Gilead Sciences, Foster City, CA
8. Technivie package insert, Abbvie Inc, North Chicago, IL
9. Viekira Pak package insert, Abbvie Inc, Chicago, IL
10. Zepatier package insert, Merck Sharp & Dohme Corp, Whitehouse Station, NJ

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
5	Revision	Removal of limited life expectancy and previously cured patients	Other criteria	12/9/2022
4	Revision	Removal of urine toxicology screen and alcohol/drug abstinence	Other criteria	9/22/2022
3	Revision			7/2022
2	Update			2/2016, 5/2016, 7/2016, 8/2016, 11/2016, 11/2017, 5/2019, 10/2019
1	P&T Review History			2/2016, 5/2016, 11/2016, 2/2017, 11/2017, 01/2018