PHARMACY PRE-AUTHORIZATION CRITERIA

ConnectiCare

DRUG (S)	**Hepatitis C medications** **Daklinza (daclatasvir)** **Epclusa (sofosbuvir/velpatasvir)** **Harvoni (sofosbuvir/ledipasivir)** **Mavyret (glecaprevir/pibrentasvir)** **Olysio (simprevir)** **Sovaldi (sofosbuvir)** **Technivie (ombitasvir/paritaprevir/ritonavir)** **Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir)** **Vosevi (sofosbuvir/velpatasvir/voxilaprevir)** **Zepatier (elbasvsir/grazoprevir)**
POLICY #	**21101**
INDICATIONS	**DAKLINZA** is a hepatitis C virus NS5A inhibitor indicated for use with sofosbuvir (Sovaldi) for the treatment of chronic HCV Genotype 3 infection. **EPCLUSA** is indicated for adults with chronic hepatitis C virus (HCV) infection genotypes 1, 2, 3, 4, 5, and 6. **HARVONI** is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults. **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 12 years and older or weighing at least 45 kg adults without cirrhosis or with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult and pediatric patients 12 years and older weighing at least 45 kg with HCV genotype 1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. **OLYSIO** is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Its efficacy has been established in combination with peginterferon alfa and ribavirin in HCV genotype 1 infected subjects with compensated liver disease (including cirrhosis). OLYSIO must not be used as monotherapy. **SOVALDI** is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. **TECHNIVIE** is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. **VIEKIRA PAK**, with or without ribavirin, is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. VIEKIRA PAK is not

	recommended for use in patients with decompensated liver disease.
DRUG (S)	**Hepatitis C medications** **#21101**
INDICATIONS	**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 (with or without ribavirin).
CRITERIA	ConnectiCare considers **Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, 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
	Daklinza with Sovaldi
	Harvoni
	Mavyret
	Sovaldi with Olysio
	Viekira
Genotype 2	**Epclusa**
	Vosevi
	Daklinza with Sovaldi
	Mavyret
Genotype 3	**Epclusa**
	Vosevi

	Daklinza and Sovaldi
	Mavyret
Genotype 4	**Zepatier**
	Epclusa
	Vosevi
	Harvoni
	Mavyret
	Technivie and weight-based ribavirin
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) Urine toxicology screen for all patients (regardless of past history of drug use) demonstrating abstinence from substance abuse drugs, with a collection date within 30 days of start of treatment

6) Documented abstinence from alcohol and all substance abuse drugs for previous 6 months prior to initiation of treatment; with continued abstinence documented in the provider-patient agreement in item 4 above

7) 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

8) Patients with limited life expectancy (< 12 months due to non-liver related comorbidities) are not covered. Per American Association for the Study of Liver Diseases (AASLD) guidelines, HCV therapy would not improve symptoms or prognosis in this patient population and do not require treatment.

9) Patients previously cured will not be eligible for any treatment upon reinfection

In addition to the above criteria:

For **Daklinza** coverage:

- Must be prescribed 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 **Epclusa** coverage:

- For Genotype 1 , 2, 3, 4, 5, and 6, for members who are Child-Pugh A.

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 **Olysio** coverage:

- Olysio is being used with both peginterferon and ribavirin
- Olysio is not being used as monotherapy
- Member does not have the presence of virus with the NS3 Q80K polymorphism at baseline
- Member has not been previously treated with any protease inhibitors
- Member has a contraindication to the use of Epclusa and Zepatier

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 **Technivie** coverage:

- Technivie is being used with Ribavirin
- Patient does not have cirrhosis of the liver
- Member has a contraindication to the use of Zepatier and 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 does not have 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

DURATION OF THERAPY

DAKLINZA, EPCLUSA, VOSEVI and TECHNIVIE—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.

OLYSIO—

Simeprevir, Peginterferon Alfa, and Ribavirin Duration of Therapy for Chronic Hepatitis C Infection in HCV Genotype 1 or 4 Monoinfected and HCV/HIV-1 Coinfected Patients[1]			
	Treatment with simeprevir, peginterferon alfa, and ribavirin[a]	**Treatment with peginterferon alfa and ribavirin[a]**	**Total treatment duration[a]**
Treatment-naive and	First 12 weeks	Additional	24 weeks

prior relapser patients,[b] including those with or without cirrhosis who are not coinfected with HIV or patients without cirrhosis who are coinfected with HIV		12 weeks	
Treatment-naive patients and prior relapser patients[b] with cirrhosis, who are coinfected with HIV	First 12 weeks	Additional 36 weeks	48 weeks
Prior nonresponder patients[c] (including partial and null responders), with or without cirrhosis, with or without HIV coinfection	First 12 weeks	Additional 36 weeks	48 weeks

[a]Recommended duration of treatment if patient does not meet stopping rule (see Discontinuation of Therapy).
[b]Prior relapser: undetectable HCV RNA at the end of prior interferon-based therapy and detectable HCV RNA during follow-up. Also refer to Off-Label Dosing for American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) recommendations.
[c]Prior partial responder: prior on-treatment at least 2 $\log_{10}$ units/mL reduction in HCV RNA from baseline at week 12 and detectable HCV RNA at end of prior interferon-based therapy. Prior null responder: prior on-treatment less than 2 $\log_{10}$ reduction in HCV RNA from baseline at week 12 during prior interferon-based therapy.

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	16 weeks

with interferons, ribavirin and/or sofosbuvir, with compensated 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

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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

PHARMACY PRE-AUTHORIZATION CRITERIA

P&T REVIEW HISTORY	2/16, 5/16, 11/16, 2/17, 11/17, 1/18
REVISION RECORD	2/16, 5/16, 7/16, 8/16, 11/16, 11/17, 5/19, 10/19