NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Nebraska Department of Health and Human Services
Nebraska Medicaid Fee-For-Service Pharmacy Benefit

Prior Authorization Criteria
For treatment of Chronic Hepatitis C (CHC)

Non-preferred products require trial of preferred agents within the same group and/or will only be considered with documentation of why the preferred product is not appropriate.

All of the following documentation is required for prior authorization review:

1. Hepatits C genotype (Submit completed lab results) Genotype 1a, 1b, 2, 3, 4, 5, 6, **AND**
2. Baseline quantitative HCV RNA viral load (Submit completed lab results within the past year), **AND**
3. HCV RNA viral load levels 12 weeks after completion of treatment (Submit completed lab results), **AND**
4. Documentation of patient's treatment status (treatment naive, treatment experienced, or previous treatment failure), **AND**
5. Documentation of patient's status of cirrhosis (none, compensated, decompensated), **AND**
6. Documentation of:
    - Counselling provided to the member on the harms of alcohol and/or substance use behaviors on treatment.
    - Counselling encouraging the member to abstain from alcohol before initiation of and during antiviral treatment
    - Continued support to the member for alcohol and/or substance use counseling services during antiviral treatment.
7. Documentation for all direct acting antiviral medication requests must include testing for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment.

Note:

- Interferons will only be authorized for doses up to FDA approved maximum doses.
- Lost or misplaced medications will not be replaced, and further treatment will not be approved. Exceptions will be made only in cases of extreme hardship, as determined by the State.
- Prescribers are strongly encouraged to use best practice resources for managing and treating Hepatitis C:
    - https://prepc.org/
    - https://www.hcvguidelines.org/
    - https://www.cdc.gov/hepatitis/hcv/index.htm

Effective Date January 2024
Previous Revised Date July 2021

Epclusa® (sofosbuvir/velpatasvir)

Recommended Treatment Regimen and Duration in Patients 3 Years of Age and Older with Genotype 1, 2, 3, 4, 5, or 6 HCV

HCV Genotype and Comorbidities	Treatment	Duration
Treatment naïve and treatment experienced patients without cirrhosis and with compensated cirrhosis (Child-Pugh A) Genotype 1, 2, 3, 4, 5, 6	sofosbuvir/velpatasvir	12 weeks
Treatment naïve and treatment experienced patients with decompensated cirrhosis (Child-Pugh B or C) Genotype 1, 2, 3, 4, 5, 6	sofosbuvir/velpatasvir + ribavirin	12 weeks

Dosing for Pediatric Patients 3 Years and Older with Genotype 1, 2, 3, 4, 5, or 6 HCV using EPCLUSA Oral Pellets or Tablets

Body Weight (kg)	EPCLUSA Daily Dose	Dosing of EPCLUSA Oral Pellets	Dosing of EPCLUSA Tablet
Less than 17	150 mg/37.5 mg per day	one 150 mg/37.5 mg packet of pellets once daily	N/A
17 to less than 30	200 mg/50 mg per day	one 200 mg/50 mg packet of pellets once daily	one 200 mg/50 mg tablet once daily
at least 30	400 mg/100 mg per day	two 200 mg/50 mg packets of pellets once daily	one 400 mg/100 mg tablet once daily

Epclusa® (sofosbuvir/velpatasvir)
Recommended Dosing for Ribavirin in Combination Therapy with EPCLUSA for Pediatric Patients
3 Years and Older

Body Weight (kg)	Oral Ribavirin Daily Dosage
less than 47	15 mg per kg per day (divided dose AM and PM)
47–49	600 mg per day (1 × 200 mg AM, 2 × 200 mg PM)
50–65	800 mg per day (2 × 200 mg AM, 2 × 200 mg PM)
66–80	1,000 mg per day (2 × 200 mg AM, 3 × 200 mg PM)
greater than 80	1,200 mg per day (3 × 200 mg AM, 3 × 200 mg PM)

May be used in patients co-infected with HIV.

Exclusion Criteria:

- If used in combination with RBV, all contraindications to RBV also apply.

Effective Date January 2024
Previous Revised Date July 2021

Recommended Treatment Regimen and Duration for HARVONI in Patients 3 Years of Age and Older with Genotype 1, 4, 5, or 6 HCV

HCV Genotype	Patient Population	Treatment and Duration
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	ledipasvir/sofosbuvir 12 weeks*
	Treatment-experienced without cirrhosis	ledipasvir/sofosbuvir 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	ledipasvir/sofosbuvir 24 weeks
	Treatment-naïve and treatment experienced with decompensated cirrhosis (Child-Pugh B or C)	ledipasvir/sofosbuvir + ribavirin 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	ledipasvir/sofosbuvir + ribavirin 12 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	ledipasvir/sofosbuvir 12 weeks

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

Harvoni® (ledipasvir/sofosbuvir) continued

Dosing for Pediatric Patients 3 Years and Older Using HARVONI Tablets or Oral Pellets

Body Weight (kg)	Dosing of HARVONI Tablets or Oral Pellets	HARVONI Daily Dose
at least 35	one 90 mg/400 mg tablet once daily or two 45 mg/200 mg tablets once daily or two 45 mg/200 mg packets of pellets once daily	90 mg/400 mg per day
17 to less than 35	one 45 mg/200 mg tablet once daily or one 45 mg/200 mg packet of pellets once daily	45 mg/200 mg per day
less than 17	one 33.75 mg/150 mg packet of pellets once daily	33.75 mg/150 mg per day

Recommended Dosing for Ribavirin in Combination Therapy with HARVONI for Pediatric Patients 3 Years and Older

Body Weight (kg)	Oral Ribavirin Daily Dosage
Less than 47	15 mg per kg per day (divided dose AM and PM)
47-49	600 mg per day (1 x 200 mg AM, 2 x 200 mg PM)
50-65	800 mg per day (2 x 200 mg AM, 2 x 200 mg PM)
66-80	1000 mg per day (2 x 200 mg AM, 3 x 200 mg PM)
Greater than 80	1200 mg per day (3 x 200 mg AM, 3 x 200 mg PM)

May be used in patients co-infected with HIV.

Exclusion Criteria: If used in combination with RBV, all contraindications to RBV also apply.

Mavyret (glecaprevir and pibrentasvir)

Patient must be at least 3 years of age and older

Treatment-Naïve Patients

HCV Genotype and Comorbidities for Treatment-Naïve Patients	Duration
1, 2, 3, 4, 5, or 6 (No cirrhosis)	8 weeks
1, 2, 3, 4, 5, or 6 (Compensated cirrhosis – Child-Pugh A)	8 weeks

Treatment-Experienced Patients

HCV Genotype and Comorbidities for Treatment-Experienced Patients	Patients Previously Treated With a Regimen Containing:	Duration	
		No Cirrhosis	Compensated Cirrhosis – Child-Pugh A
1	An NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor (PI)	16 weeks	16 weeks
	NS3/4A PI without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5 or 6	PRS*	8 weeks	12 weeks
3	PRS*	16 weeks	16 weeks

*PRS includes interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no NS3/4A PI or NS5A inhibitor.

Mavyret (glecaprevir and pibrentasvir) continued

Recommended Dosage in Pediatric Patients 3 Years of Age and Older

Body Weight (kg) or Age (yrs)	Daily Dose of glecaprevir/pibrentasvir	Dosing of MAVYRET
Less than 20 kg	150 mg/60 mg per day	Three 50 mg/20 mg packets of oral pellets once daily
20 kg to less than 30 kg	200 mg/80 mg per day	Four 50 mg/20 mg packets of oral pellets once daily
30 kg to less than 45 kg	250 mg/100 mg per day	Five 50 mg/20 mg packets of oral pellets once daily
45 kg and greater OR 12 years of age and older	300 mg/120 mg per day	Three 100 mg/40 mg tablets once daily

May be used in patients co-infected with HIV. HCV/HIV-1 co-infection and patients with any degree of renal impairment: Follow the dosage recommendations in the tables above.

Requests for retreatment must include documentation of previous failure to reach SVR.

Exclusion criteria: (a) patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation (b) patients taking atazanavir or rifampin.

Sovaldi® (sofosbuvir)

Treatment Regimen and Duration (must be used with ribavirin)

HCV Genotype and Comorbidities	Patient Population	Treatment Regimen and Duration
Adult patients Genotype 1 or 4 (Interferon Eligible)	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	12 weeks sofosbuvir 400 mg daily ribavirin 1000 mg – 1200 mg daily peg-interferon weekly
Adult patients Genotype 1 (Only if Interferon Ineligible)*	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	24 weeks sofosbuvir 400 mg daily ribavirin 1000 mg – 1200 mg daily
Adult patients Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	12 weeks sofosbuvir 400 mg daily ribavirin 1000 mg – 1200 mg daily
Adult patients Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	24 weeks sofosbuvir 400 mg daily ribavirin 1000 mg – 1200 mg daily
Pediatric patients (ages 3 years and older) Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	12 weeks sofosbuvir + ribavirin (See dosing chart below)
Pediatric patients (ages 3 years and older) Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	24 weeks sofosbuvir + ribavirin (See dosing chart below)

Dosing for Pediatric Patients 3 Years and Older Using SOVALDI Tablets or Oral Pellets

Body Weight (kg)	Dosing of SOVALDI Tablets or Oral Pellets	SOVALDI Daily Dose
At least 35	one 400 mg tablet once daily or two 200 mg tablets once daily or two 200 mg packets of pellets once daily	400 mg per day
17 to less than 35	one 200 mg tablet once daily or one 200 mg packet of pellets once daily	200 mg per day
Less than 17	one 150 mg packet of pellets once daily	150 mg per day

Sovaldi® (sofosbuvir) continued

Recommended Dosing for Ribavirin in Combination Therapy with SOVALDI for Pediatric Patients 3 Years and Older

Body Weight (kg)	Oral Ribavirin Daily Dosage
less than 47	15 mg per kg per day (divided dose AM and PM)
47–49	600 mg per day (1 x 200 mg AM, 2 x 200 mg PM)
50–65	800 mg per day (2 x 200 mg AM, 2 x 200 mg PM)
66–80	1000 mg per day (2 x 200 mg AM, 3 x 200 mg PM)
greater than 80	1200 mg per day (3 x 200 mg AM, 3 x 200 mg PM)

Exclusion Criteria:

- If used in combination with RBV, all contraindications to RBV also apply.

**Interferon Ineligible* defined as one or more of the following:

- Previous intolerance to interferon
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to Peg-interferon or any of its components
- Major uncontrolled psychiatric illness
- A baseline neutrophil count below 1500/µL
- A baseline platelet count below 90,000/µL
- A baseline hemoglobin below 10 g/dL
- A history of preexisting cardiac disease (the patient must be on therapy and compliant with therapy)

Viekira Pak® (ombitasvir/paritaprevir/ritonavir/dasabuvir)

Patient must be at least 18 years of age

[Treatment-naïve, or interferon-experienced]

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 1a, without cirrhosis	Viekira Pak + ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis (Child-Pugh A)	Viekira Pak + ribavirin	24 weeks**
Genotype 1b, with or without compensated cirrhosis (Child-Pugh A)	Viekira Pak	12 weeks

May be used in patients co-infected with HIV. Any HCV/HIV-1 co-infected patients treated with Viekira Pak should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

*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 *[see Clinical Studies in product labeling].*

Exclusion Criteria:

- If used in combination with RBV, all contraindications to RBV also apply.
- Patients with moderate to severe hepatic impairment.

Co-administration with drugs that are: highly dependent on CYP3A for clearance; moderate or strong inducers of CYP3A or and strong inducers of CYP2C8; and strong inhibitors of CYP2C8.

Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) Patient must be at least 18 years of age.

For patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have previously been treated with a NS5A inhibitor or sofosbuvir

HCV Genotype	Previous Regimen Contained	Duration
1, 2, 3, 4, 5, or 6	NS5A inhibitor*	12 weeks
1a or 3	Sofosbuvir without #NS5A inhibitor**	12 weeks

Requests for retreatment must include documentation of previous failure to reach SVR.

*NS5A inhibitors include daclasasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.

**Prior treatment includes sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, boceprevir, simeprevir or telaprevir.

Exclusion criteria: Patients taking rifampin

Zepatier (elbasvir/grazoprevir) Patient must be at least 12 years of age.

NS5A Resistance Testing in HCV Genotype 1a-Infected Patients Testing patients with HCV Genotype 1a infection for the presence of virus with NS5A resistance associated polymorphisms is recommended prior to initiation of treatment with ZEPATIER to determine dosage regimen and duration.

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBVexperienced* without baseline NS5A polymorphisms†	**elbasvir/grazoprevir**	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBVexperienced* with baseline NS5A polymorphisms†	**elbasvir/grazoprevir** + ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBVexperienced*	**elbasvir/grazoprevir**	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced‡	**elbasvir/grazoprevir** + ribavirin	12 weeks
Genotype 4: Treatment-naïve	**elbasvir/grazoprevir**	12 weeks
Genotype 4: PegIFN/RBV-experienced*	**elbasvir/grazoprevir** + ribavirin	16 weeks

*Peginterferon alfa + ribavirin.
†Polymorphisms at amino acid positions 28, 30, 31, or 93.
‡Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor

May be used in patients co-infected with HIV. HCV/HIV-1 co-infection and patients with any degree of renal impairment: Follow the dosage recommendations in the tables above.

Exclusion Criteria:

- If used in combination with RBV, all contraindications to RBV also apply.
- Patients with moderate or severe hepatic impairment (Child-Pugh B or C)
- OATP1B1/3 inhibitors, strong CYP3A inducers and efavirenz

DUAL THERAPY – PEGINTERFERON, RIBAVIRIN
Peg-Interferon and Ribavirin
Treatment is available for patients regardless of fibrosis score. Patient must be at least 3 years of age.

Upon completing 12 weeks of therapy, a second test of viral load and Genotype is required to be submitted to Magellan Medicaid Administration. The assay must be the same as the assay used to determine the patient's baseline (prior to treatment) viral load.

At week 12, a 2 log decrease in viral titer is required to continue treatment. If such a reduction is observed, authorization will be extended for 12 weeks (24 weeks total) for Genotypes 2 or 3 or for 36 weeks (48 weeks total) for Genotypes 1 or 4. If at week 12 the 2 log decrease reported is a detectible viral titer and Genotype is 1 or 4 a 24 week lab will be required. Continued therapy will not be authorized if the 24 week lab results in a detectible viral titer.

All contraindications to RBV also apply.