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

Treatment will only be considered in patients who are at greatest risk of progressing to cirrhosis or serious hepatic complications from HCV:

- Fibrosis- Submit evidence of Stage 2, Stage 3 or Stage 4 hepatic fibrosis, including one of the following confirmatory tests:
- Liver biopsy confirming a METAVIR fibrosis score of F2, F3 or F4

Metavir Classification for Staging of Hepatitis C Liver Disease	Description
F0	No scarring.
F1	Minimal scarring.
F2	Scarring has occurred and extends outside the areas in the liver that contains blood vessels.
F3	Bridging fibrosis is spreading and connecting to other areas that contain fibrosis.
F4	Cirrhosis or advanced scarring of the liver.

OR

- Other diagnostic evaluation supporting hepatic fibrosis
  - Ultrasound-based transient elastography (Fibroscan) score ≥ 8.0 kPa, or
  - Evidence of any two of the following:
    - Fibrotest (Fibrosure) score ≥ 0.48
    - Fibrosis-4 Index (FIB-4) > 1.2
    - Aspartate aminotransferase/platelet ration index (APRI) score > .49

OR

- Patients with hepatocellular carcinoma awaiting transplant
- Co-morbid conditions (HIV/AIDS, Hepatitis B, Insulin-resistant diabetes type 2)
- Severe extrahepatic complications such as cryoglobulinemia
- Other documentation of immediate need to treat

- Patient must be evaluated for past or current history of substance use disorder (SUD) or alcohol abuse, using a standardized model of assessment, such as ASAM criteria. If present, prescriber must attest that patient has been abstinent of alcohol and IV drug use for at least the last 6 months and/or evidence of participation in recovery treatment program. All patients must have a negative standard drug urine screen report completed within 15 days before date of prior authorization request. Pharmacologic treatment of SUD does not affect definition of abstinence.

- Documentation of treatment plan which includes instruction on the prevention of reinfection, methods of decreasing the risks of re-infection, and abstinence from engaging in such activities.

- Patient has demonstrated readiness per the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) free interactive online tool, completed by the prescriber or the following are documented in the patient's chart. (Submit documentation with request.)

  Motivation: Reasons client wants to begin HCV treatment, concerns about treatment, and importance of treatment.

  Information: Knowledge about HCV treatment and one's own HCV disease status.

Medication Adherence: Current prescribed medications and adherence to them in prior month.

Self-Efficacy: Self-confidence about adhering to HCV treatment.

Social Support and Stability: Stability of financial, housing, and social support resources

Alcohol and Substance Use: Alcohol and substance use behaviors and current treatment. Patient must be evaluated for current history of alcohol and substance abuse with a validated screening instrument, such as AUDIT C, CAGE alcohol screen or NIDA's drug screening tool. Patient must be abstinent for past 6 months or more. Lab results demonstrating abstinence must be submitted for coverage periodically throughout treatment.

Psychiatric Stability: Current psychiatric status, previous and current treatment.

Energy Level: Attains adequate sleep and currently lacks signs of fatigue.

Cognitive Functioning: Perceived difficulty with communication in health care setting, problem-solving ability, and memory

- Prescriber agrees to obtain and submit HCV RNA viral load levels 12 weeks after completion of treatment.
- 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, such as a documented house fire.

Documentation for all direct acting antiviral medication requests will include testing for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

NOTE:

- Interferons will only be authorized for doses up to FDA approved maximum doses.

An educational pamphlet titled “Living with Chronic Hepatitis C,” is available from the Centers for Disease Control at no charge. The following is a direct link to the pamphlet: http://www.cdc.gov/hepatitis/HCV/PDFs/HepCLivingWithChronic.pdf

Daklinza® (daclatasvir) Patient must be at least 18 years of age.

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 1 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	daclatasvir + sofosbuvir	12 weeks
Genotype 1 with decompensated cirrhosis (Child-Pugh B or C) or post transplant	daclatasvir + sofosbuvir + ribavirin	12 weeks
Genotype 3 without cirrhosis	daclatasvir + sofosbuvir	12 weeks
Genotype 3 with compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis or post transplant	daclatasvir + sofosbuvir + ribavirin	12 weeks

Exclusion Criteria:

- If used in combination with RBV, all contraindications to RBV also apply.
- Concomitant use of
    - Strong CYP3A Inducers – rifampin, phenytoin, carbamazepine, St. John's Wort

Epclusa® (sofosbuvir/velpatasvir) Patient must be at least 18 years of age.

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

May be used in patients co-infected with HIV.

Exclusion Criteria:

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

Harvoni® (ledipasvir/sofosbuvir) Patient must be at least 12 years of age or weighing at least 35 kg.

HCV Genotype and Comorbidities	Treatment	Duration
Treatment naïve, Genotype 1, without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	ledipasvir/sofosbuvir	8 weeks
Treatment naïve, Genotype 1, with or without cirrhosis	ledipasvir/sofosbuvir	12 weeks
Treatment experienced, Genotype 1, without cirrhosis	ledipasvir/sofosbuvir	12 weeks
Treatment-naïve and treatment experienced with decompensated cirrhosis (Child-Pugh B or C)	ledipasvir/sofosbuvir + ribavirin	12 weeks
Treatment experienced, Genotype 1, with cirrhosis	ledipasvir/sofosbuvir	24 weeks
	ledipasvir/sofosbuvir + ribavirin	12 weeks
Treatment-naïve and treatment experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A) Genotype 1 or 4	ledipasvir/sofosbuvir + ribavirin	12 weeks
Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) Genotype 4, 5, or 6	ledipasvir/sofosbuvir	12 weeks
Pediatric patients (ages 12 to 17 years) who are treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) or treatment experienced without cirrhosis Genotype 1	ledipasvir/sofosbuvir	12 weeks
Pediatric patients (ages 12 to 17 years) who are treatment-experienced with compensated cirrhosis Genotype 1	ledipasvir/sofosbuvir	24 weeks
Pediatric patients (ages 12 to 17 years) who are treatment-naiive without cirrhosis or with compensated cirrhosis or treatment-experienced without cirrhosis or with compensated cirrhosis Genotype 4, 5 or 6	ledipasvir/sofosbuvir	12 weeks

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 18 years of age.

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)	12 weeks

HCV Genotype and Comorbidities for Treatment-Experienced Patients	**Patients Previously Treated With a Regimen Containing:**	**Duration**	
		No Cirrhosis	**Compensated Cirrhosis – Child-Pugh A**
1	NS5A inhibitor without an NS3/4A protease inhibitor*	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

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.

*NS5A inhibitors include ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

**NS3/4APIs include simeprevir and sofosbuvir, or simeprevir, boceprevir or telaprevir with pegylated interferon and ribavirin.

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

Exclusion criteria: patients with severe hepatic impairment (Child-Pugh C) or patients taking atazanavir or rifampin.

Sovaldi® (sofosbuvir) must be used with ribavirin Patient must be at least 12 years of age or weighing at least 35 kg.

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 1 or 4 (Interferon Eligible)	sofosbuvir 400 mg daily ribavirin 1000 mg - 1200 mg daily peg-interferon weekly	12 weeks
Genotype 1 (Only if Interferon Ineligible)*	sofosbuvir 400 mg daily ribavirin 1000 mg - 1200 mg daily	24 weeks
Genotype 2	sofosbuvir 400 mg daily ribavirin 1000 mg - 1200 mg daily	12 weeks
Genotype 3	sofosbuvir 400 mg daily ribavirin 1000 mg - 1200 mg daily	24 weeks
Treatment of CHC in patient with hepatocellular carcinoma awaiting liver transplant	sofosbuvir 400 mg daily ribavirin 1000 mg - 1200 mg daily	Up to 48 weeks or until liver transplantation, whichever comes first
Pediatric patients (ages 12 to 17 years of age) with chronic HCV infection without cirrhosis or with compensated cirrhosis Genotype 2	sofosbuvir 400 mg daily ribavirin based on weight	12 weeks
Pediatric patients (ages 12 to 17 years of age) with chronic HCV infection without cirrhosis or with compensated cirrhosis Genotype 3	sofosbuvir 400 mg daily ribavirin based on weight	24 weeks

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)

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 #N5SA 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: peginterfereon alfa/ribavirin, ribavirin, boceprevir, simeprevir or telaprevir.

Exclusion criteria: Patients taking rifampin

Zepatier™ (elbasvir/grazoprevir) Patient must be at least 18 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 18 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.