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 3 or Stage 4 hepatic fibrosis, including one of the following confirmatory tests:

  Liver biopsy confirming a METAVIR fibrosis score of 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

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

- Patient must be at least 18 years of age.

- Initial PA will be authorized for 6 weeks, pending viral load at 4 weeks. If HCV RNA < 25 IU/mL at TW 4, then continue approval. Prescriber agrees to obtain and submit HCV RNA viral load levels 4 weeks after initiation of treatment and 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.

- Futility Rules: Consider discontinuation of therapy in patients who do not achieve <2 log reduction in HCV RNA from baseline at 4 weeks or detectable levels of HCV RNA at treatment week 12 or 24.

Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira Pak™)

HCV Genotype and Comorbidities	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira Pak™ + ribavirin	12 weeks
Genotype 1a, with cirrhosis	Viekira Pak™ + ribavirin	24 weeks
Genotype 1b, without cirrhosis	Viekira Pak™	12 weeks
Genotype 1b, with cirrhosis	Viekira Pak™ + ribavirin	12 weeks

*Follow genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.
*The recommended duration of treatment for Viekira Pak with ribavirin is 24 weeks in patients who have received a liver transplant.
*Patients with HCV/HIV-1 co-infection, follow the above treatment regimen.

Exclusion Criteria:

- Previously failed treatment with a hepatitis C protease inhibitor (non-responder or relapsed)
- Pregnant patients (only if ribavirin is required)
- Decompensated cirrhosis
- Concomitant use of
    - Medications that are highly dependent on CYP3A for clearance - alfuzosin, phenobarbital, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol, lovastatin, simvastatin, pimozide, sildenafil, triazolam, midazolam
    - Moderate or Strong CYP3A Inducers – avasimibe, carbamazepine, phenytoin, rifampin, St. John's Wort, bosentan, efavirenz, etravirine, modafinil, nafcillin
    - Strong CYP2C8 Inhibitors – gemfibrozil
    - Moderate or Strong CYP2C8 Inducers – rifampin

Ledipasvir/Sofosbuvir (Harvoni®)

HCV Genotype and Comorbidities	Treatment	Duration
Treatment naïve, genotype 1, without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	sofosbuvir + ledipasvir	8 weeks
Treatment naïve, genotype 1, with or without cirrhosis	sofosbuvir + ledipasvir	12 weeks
Treatment experienced, genotype 1, without cirrhosis	sofosbuvir + ledipasvir	12 weeks
Treatment experienced, genotype 1, with cirrhosis	sofosbuvir + ledipasvir	24 weeks
Treatment experienced , genotype 1 with cirrhosis	sofosbuvir + ledipasvir + ribavirin	12 weeks
Treatment-naïve and treatment experienced, genotype 4,5 or 6, with or without cirrhosis	sofosbuvir + ledipasvir	12 weeks

For patients with HCV/HIV-1 co-infection, follow the dosage recommendations in the table above.

Exclusion Criteria:

- Concomitant use of

    - P-gp inducers: rifampin, St. John's Wort
    - Amiodarone
    - Rosuvastatin
    - Tipranivir/ritonavir
    - Elvitegravir/cobicistat/emtricitabin with tenofivir disoproxil fumarate
- End-stage renal disease or severe renal impairment (eGFR<30)

Simeprevir (Olysio™)

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 1 with or without cirrhosis*	Simeprevir + peg-interferon alpha + ribavirin	12 weeks (Treatment naïve and prior relapsers should be treated with an additional 12 weeks of peg-interferon alpha and ribavirin, for a total of 24 weeks of therapy) Prior non-responders (including partial and null-responders) should be treated for an additional 36 weeks of peg-interferon alpha and ribavirin for a total of 48 weeks of therapy. *Treatment futility If HCV RNA is greater than or equal to 25 IU/mL at Week 4, Week 12 or Week 24, discontinue simeprevir, peginterferon alpha and ribavirin.*
Genotype 1Treatment-naïve and treatment-experienced* patients without cirrhosis	Simeprevir + sofosbuvir	12 weeks
Genotype 1 Treatment-naïve and treatment-experienced* patients with cirrhosis	Simeprevir + sofosbuvir	24 weeks

Peg-interferon and Ribavirin

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.

Sofosbuvir (Sovaldi®) must be used with ribavirin

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

**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)

Exclusion Criteria:

- Pregnant patients
- End-stage renal disease or severe renal impairment (eGFR<30)
- Concomitant use of
    - Amiodarone
    - P-gp inducers: rifampin, St. John's Wort
    - Anticonvulsants: carbamazepine, phenytoin, phenobarbital, oxcarbazepine

Daclatasvir (Daklinza™)

HCV Genotype and Comorbidities	Treatment	Duration
Genotype 3, without cirrhosis	daclatasvir + sofosbuvir	12 weeks

Dose Adjustments:

- Concomitant use of strong CYP3A inhibitors – Reduce dose to 30 mg once daily
- Concomitant use of moderate CYP3A inducers – Increase dose to 90 mg once daily

Exclusion Criteria:

- Concomitant use of
    - Strong CYP3A Inducers – rifampin, phenytoin, carbamazepine, St. John's Wort
    - Amiodarone

Ombitasvir/Paritaprevir/Ritonavir (Technivie ™)

HCV Genotype and Comorbidities	Treatment*	Duration
Genotype 4, without cirrhosis	Technivie™ + ribavirin	12 weeks

***** Treatment naïve patients unable to tolerate ribavirin may use Technivie ™ without ribavirin for 12 weeks.

Exclusion Criteria:

- Severe hepatic impairment (Child-Pugh Class C)
- Hypersensitivity to ritonavir
- Pregnant patients
- Concomitant use of
    - Medications that are highly dependent on CYP3A for clearance - alfuzosin, phenobarbital, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol, lovastatin, simvastatin, pimozide, sildenafil, triazolam, midazolam
    - Moderate or Strong CYP3A Inducers – avasimibe, carbamazepine, phenytoin, rifampin, St. John's Wort, bosentan, efavirenz, etravirine, modafinil, nafcillin
    - Moderate or Strong CYP2C8 Inducers – rifampin
    - Ethinyl estradiol