# Oral Hepatitis C First and Second Gen Antivirals Prior Authorization Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid, for the New to Market section only.

## POLICY REVIEW CYCLE

| Effective Date | Date of Origin |
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| 11/1/2023 | 1/6/2017 |

## FDA APPROVED INDICATIONS AND DOSAGE

| Agent(s) | FDA Indication(s) | Notes | Ref# |
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| Epclusa®<br><br>(sofosbuvir/velpatasvir)<br><br>Oral tablet | • Treatment of adult and pediatric patients 3 years of age and older with chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection:<br>○ Without cirrhosis or with compensated cirrhosis<br>○ With decompensated cirrhosis in combination with ribavirin | | 1 |
| Harvoni®<br><br>(ledipasvir/sofosbuvir)<br><br>Oral tablet/Oral pellets | • Treatment of chronic hepatitis C in adults and pediatric patients 3 years of age and older:<br>○ For patients with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis<br>○ For patients with genotype 1 infection with decompensated cirrhosis in combination with ribavirin<br>○ For patients with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis in combination with ribavirin | | 2 |
| Mavyret®<br><br>(glecaprevir/pibrentasvir)<br><br>Oral tablet | • Treatment of adult and pediatric patients 3 years and older with chronic hepatitis C who have:<br>○ Genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)<br>○ 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 | | 3 |
| Sovaldi®<br><br>(sofosbuvir)<br><br>Oral tablet/Oral pellets | • Treatment of adult patients with chronic HCV genotype 1, 2, 3, or 4 infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen<br>• Treatment of pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or in combination with ribavirin for patients with compensated cirrhosis | | 4 |
| Viekira Pak®<br><br>(ombitasvir/paritaprevir/rit | • Treatment of adult patients with chronic hepatitis C virus who have: | | 5 |



 

| Agent(s) | FDA Indication(s) | Notes | Ref# |
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| onavir co-packaged with dasavuvir)<br><br>Oral tablet | ○ Genotype 1b without cirrhosis or with compensated cirrhosis<br>○ Genotype 1a without cirrhosis or with compensated cirrhosis used in combination with ribavirin | | |
| Vosevi®<br><br>(sofosbuvir/velpatasvir/voxilaprevir)<br><br>Oral tablet | • Treatment of adult patients with HCV infection without cirrhosis or compensated cirrhosis (Child-Turcotte-Pugh A) who have:<br>○ Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor<br>○ Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor | | 6 |
| Zepatier®<br><br>(elbasvir/grazoprevir)<br><br>Oral tablet | • Treatment of chronic hepatitis C genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Zepatier is indicated for use with ribavirin in certain patient populations | | 7 |

*See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm*

## CLINICAL RATIONALE

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| Hepatitis C | Hepatitis C is an infection of the liver caused by the Hepatitis C virus (HCV), a blood-borne virus. Today, most people become infected with HCV by sharing needles or other equipment to inject drugs. Hepatitis C infection can either be acute or chronic. Acute HCV infection is defined as presenting within 6 months following exposure to the virus. In 2018, the reported acute hepatitis C case count in the United States corresponded to a rate of 1.2 cases per 100,000 population, an over 71% increase from the reported incidence rate in 2014. The infection is defined as chronic if the virus is present beyond 6 months following exposure. More than 50% of people who become infected with HCV develop chronic infection. Chronic hepatitis C is a serious disease that can result in cirrhosis, liver cancer, and death.(9)<br><br>The American Association for the Study of Liver diseases (AASLD) along with the Infectious Diseases society of America (IDSA) recommend the following:(8)<br><br>• One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years and older<br>• One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection<br>• Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy<br>• Periodic repeat HCV testing should be offered to all persons with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure<br>• Annual HCV testing is recommended for all persons who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking pre-exposure prophylaxis (PrEP)<br><br>Risk activities:<br><br>• Injection drug use (current or ever, including those who injected only once) |



 

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| | • Intranasal illicit drug use<br>• Use of glass crack pipes<br>• Male engagement in sex with men<br>• Engagement in chem sex (defined as the intentional combining of sex with the use of particular nonprescription [illicit] drugs in order to facilitate or enhance the sexual encounter)<br><br>Risk exposures:<br><br>• Persons on long-term hemodialysis (ever)<br>• Persons with percutaneous/parenteral exposures in an unregulated setting<br>• Healthcare, emergency medical, and public safety workers after needlestick, sharps, or mucosal exposure to HCV-infected blood<br>• Children born to HCV-infected women<br>• Recipients of a prior transfusion or organ transplant, including persons who:<br>  ○ Were notified that they received blood from a donor who later tested positive for HCV<br>  ○ Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992<br>  ○ Received clotting factor concentrates produced before 1987<br>• Persons who were ever incarcerated<br><br>Other conditions and circumstances:<br><br>• HIV infection or HBV infection<br>• Sexually active persons about to start pre-exposure prophylaxis (PrEP) for HIV<br>• Chronic liver disease and/or chronic hepatitis, including unexplained elevated alanine aminotransferase (ALT) levels<br>• Solid organ donors (living and deceased) and solid organ transplant recipients |
| AASLD/IDSA guidelines on when and in whom to initiate HCV therapy | The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response (SVR) (defined as the continued absence of detectable HCV RNA for at least 12 weeks after completion of therapy). According to the AASLD/IDSA guidelines, treatment is recommended for all patients with acute or chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Treatment should be initiated early because delaying therapy may decrease the benefits of SVR and increase the rates of liver-related mortality.(8)<br><br>Although the prevalence of chronic HCV is lower in children than adults, an estimated 3.5-5 million children worldwide have chronic HCV infection. Data from the National Health and Nutrition Examination Survey (NHANES) collected between 2003 and 2010 indicates that 0.2% of 6 to 11 year olds (31,000 children) and 0.4% of 12 to 19 year olds (101,000 adolescents) in the US are HCV antibody positive.(11)<br><br>Birth to an HCV-infected mother is a known risk for infection and these children should be evaluated and tested for HCV. The rate of mother-to-child transmission (MTCT) of HCV infection is approximately 5%, although rates are higher among women with inadequately controlled HIV co-infection, and women with higher HCV-RNA levels, or viral loads (greater than 6 log IU/mL). Identifying, following, and treating exposed children is recommended. The basis for evaluation early in life is HCV-RNA testing, as maternal antibodies and consequently anti-HCV assay positivity may persist for 18 months. About 25% to 50% of infected infants spontaneously resolve HCV infection (loss of previously detectable HCV RNA) by 3 years of age. HCV RNA is more expensive than an antibody-based test; and there is no intervention or treatment that will occur prior to age 3 because of lack of approved drugs for this age group and to allow for possible spontaneous clearance.(11) |



 

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| Simplified Treatment(12) | Direct-acting antiviral agents (DAAs) offer the potential for highly effective, interferon-free (and in many cases, ribavirin-free) regimens for the majority of hepatitis C virus infected patients. Regimen selection varies by genotype and other patient factors, such as the presence of cirrhosis and treatment history. Patients who are co-infected with HCV and either hepatitis B or HIV should be treated as those mono-infected with HCV.<br><br>The National Academies of Science, Engineering, and Medicine have proposed a strategy to reduce cases of chronic HCV infection by 90% by 2030. Data shows that HCV treatment can be effectively provided by a broad range of health care professionals with differing expertise – including specialists, primary care physicians, nurse practitioners, clinical pharmacy specialists, physician assistants, and registered nurses- without compromising treatment efficacy or safety. AASLD/IDSA has created simplified regimens to treat HCV in adults without cirrhosis or compensated cirrhosis who have not been previously treated for their infection to allow for the expansion of healthcare professionals who prescribe antiviral therapy and increase the number of persons treated. These simplified treatment algorithms are designed to be used by any health care provider knowledgeable about HCV disease and treatment, including those without extensive experience, who have timely access to a specialist. Any patients not included in the simplified treatment regimens should be seen by a specialist.<br><br>For patients without cirrhosis, the pretreatment evaluation should include:<br><br>• Calculate FIB-4 score<br>• Cirrhosis assessment (liver biopsy is not required – a patient is presumed to have cirrhosis if they have a FIB-4 score greater than 3.25 or any of the following findings from a previously performed test<br>  ○ Transient elastography indicating cirrhosis (e.g., FibroScan stiffness greater than 12.5 kPa)<br>  ○ Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (e.g., FibroSure, Enhanced Liver Fibrosis Test)<br>  ○ Clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count less than 150,000/mm3)<br>  ○ Prior liver biopsy showing cirrhosis<br>• Medication reconciliation<br>• Potential drug-drug interactions assessment<br>• Patient education about proper administration of medications, adherence, and prevention of reinfection<br><br>Patients without cirrhosis who have any of the following are NOT eligible for simplified treatment:<br><br>• Prior hepatitis C treatment<br>• Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)<br>• Hepatitis B surface antigen (HBsAg) positive<br>• Current pregnancy<br>• Known or suspected hepatocellular carcinoma<br>• Prior liver transplantation<br><br>The recommended treatment regimens are glecaprevir (300 mg)/pibrentasvir (120 mg) taken with food for 8 weeks or sofosbuvir (400 mg)/velpatasvir (100 mg) for a duration of 12 weeks.<br><br>For patients with compensated cirrhosis (Child-Turcotte-Pugh class A), the pretreatment evaluation should include:<br><br>• Calculate FIB-4 score (liver biopsy not required)<br>• Calculate Child-Turcotte-Pugh (CTP) score |



 

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| | • Ultra-sound imaging of the liver within the prior 6 months to evaluate for hepatocellular carcinoma (HCC) and sub clinical ascites<br>• Medication reconciliation<br>• Potential drug-drug interaction assessment<br>• Patient education about proper administration of medications, adherence, and prevention of reinfection<br>• Pretreatment laboratory testing:<br>  ○ Within 3 months of initiating treatment:<br>  ▪ Complete blood count (CBC)<br>  ▪ International normalized ratio (INR)<br>  ▪ Hepatic function panel (i.e., albumin, total and direct bilirubin, ALT, AST)<br>  ▪ Calculated glomerular filtration rate (eGFR)<br>  ○ Any time prior to starting antiviral therapy:<br>• Quantitative HCV RNA (HCV viral load)<br>  ○ HIV antigen/antibody test<br>  ○ Hepatitis B surface antigen<br>  ○ HCV genotype (if treating with sofosbuvir/velpatasvir)<br>• Before initiating antiviral therapy<br>  ○ Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age<br><br>Patients with compensated cirrhosis who have any of the following are NOT eligible for simplified treatment:<br><br>• Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 7)<br>• Prior hepatitis C treatment<br>• End-stage renal disease (i.e., eGFR less than 30 mL/min/m^2)<br>• HBsAg positive<br>• Current pregnancy<br>• Known or suspected hepatocellular carcinoma<br>• Prior liver transplantation<br><br>The recommended regimens for genotype 1-6 are glecaprevir (300 mg)/pibrentasvir (120 mg) taken with food for 8 weeks or for genotypes 1, 2, 4, 5, or 6, sofosbuvir (400 mg)/velpatasvir (100 mg) for a duration of 12 weeks (note for sofosbuvir/velpatasvir: patients with genotype 3 require baseline NS5A resistance-associated substitution (RAS) testing. Those without Y93H can be treated with sofosbuvir/velpatasvir for a duration of 12 weeks). |
| Efficacy | **Epclusa(1)**<br><br>Epclusa (sofosbuvir/velpatasvir) contains a hepatitis C nucleotide analog NS5B polymerase inhibitor (sofosbuvir) and a hepatitis C virus NS5A inhibitor (velpatasvir). Efficacy of this combination agent was evaluated in five phase 3 trials (ASTRAL-1, ASTRAL-2, ASTRAL-3, ASTRAL-4, and ASTRAL-5). All these trials included patients who were either treatment naïve or had previously been treated with an interferon based regimen (peginterferon plus ribavirin with or without a protease inhibitor). The primary endpoint for these trials was sustained virologic response at 12 weeks (SVR12) following completion of therapy.<br><br>ASTRAL-1 was a placebo controlled trial that enrolled patients with HCV infection genotype 1, 2, 4, 5, or 6. Overall, the SVR 12 rate was 99% in patients who received Epclusa and 0% in those receiving placebo (95% confidence interval, p less than 0.001). |



 

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| | ASTRAL-2 and ASRTAL-3 were randomized, open label trials evaluating efficacy in patients with HCV genotype 2 or 3 respectively. Those with HCV genotype 2 received either Epclusa for 12 weeks or sofosbuvir plus ribavirin for 12 weeks. The SVR12 rates for the two treatment arms were 99% and 94% respectively. Subjects with HCV genotype 3 were randomized to receive either Epclusa for 12 weeks or sofosbuvir plus ribavirin for 24 weeks. The SVR12 rates were 95% and 80% respectively.<br><br>ASTRAL-4 was an open label trial that evaluated efficacy of Epclusa in patients with decompensated cirrhosis. Patients were randomized to receive one of three treatment regimens: Epclusa for 12 weeks, Epclusa for 24 weeks, or Epclusa plus ribavirin for 12 weeks. SVR12 rates were 83%, 86%, and 94% respectively.<br><br>ASTRAL-5 was an open-label trial that evaluated 12 weeks of Epclusa in patients with genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection who were coinfected with HIV-1. The patients were all on antiretroviral therapy of various regimens. The primary endpoint was SVR12. The SVR12 ranged from 92-100% depending on genotype and in genotype 1 the subtype. No patient had HIV-1 rebound during treatment and CD4+ counts were stable during treatment.<br><br>Trial 4062 was on open-label clinical trial that evaluated 12 weeks of treatment with Epclusa in 59 HCV-infected adults with end stage renal disease (ESRD) requiring dialysis. The overall SVR rate was 95%. Of the subjects completing 12 weeks of Epclusa, 1 subject experienced virologic relapse.<br><br>The efficacy of Epclusa once daily for 12 weeks was evaluated in an open-label trial (Study 1143) in 173 genotype 1, 2, 3, 4, or 6 HCV treatment-naïve or treatment-experienced pediatric subjects 3 years of age and older without cirrhosis or with compensated cirrhosis.<br><br>In patients 12 years to less than 18 years of age (genotypes 1, 2, 3, 4 and 6), the SVR rates were:<br><br>• 93% for genotype 1<br>• 100% for genotypes 2, 3, 4, and 6<br><br>In patients 6 years to less than 12 years of age (genotypes 1, 2, 3, and 4) the SVR rates were:<br><br>• 93% for genotype 1<br>• 91% for genotype 3<br>• 100% for genotypes 2 and 4<br><br>In patients 3 years to less than 6 years of age the SVR rates were:<br><br>• 83% among all subjects<br>• 88% for genotype 1<br>• 50% for genotype 2<br>• 100% for genotype 3 and 4<br><br>Trial 2104 was an open-label clinical trial that evaluated 12 weeks of treatment with Epclusa in 79 HCV-infected treatment-naïve and previously treated adult subjects who had undergone liver transplantation. The overall SVR12 rate was 96%.<br><br>Trial 4062 was an open-label clinical trial that evaluated 12 weeks of treatment with Epclusa in 59 HCV-infected adults with end stage renal disease (ESRD) requiring dialysis. The overall SVR rate was 95%. |



 

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| | **Harvoni(2)**<br><br>Harvoni (ledipasvir/sofosbuvir) is a combination of an NS5A inhibitor (ledipasvir) and nucleotide analog NS5B polymerase inhibitor (sofosbuvir). Its efficacy was evaluated in several phase 2 and 3 clinical trials. These trials enrolled a broad range of patient populations including treatment naïve and treatment experienced patients, those without cirrhosis and with cirrhosis (compensated and decompensated), post-liver transplant patients, pediatric patients who were at least 3 years old or weighed more than 35 kg, as well as those with HIV/HCV co-infection. All the trials had a primary end point of sustained virologic response at 12 weeks (SVR12) following completion of treatment. Overall SVR12 was greater than 90% for the various patient populations. The treatment duration of this agent varies from 8 weeks to 24 weeks. Per the FDA labeling, treatment naïve patients with HCV genotype 1 with RNA of less than 6 million can be successfully treated with 8 weeks of Harvoni. This duration of treatment is not recommended in patients with cirrhosis, HIV, are post-liver transplantation, and/or black or African-American. Treatment experienced patients with cirrhosis may be treated with Harvoni alone for 24 weeks or in combination with ribavirin for 12 weeks. These two regimens are equally efficacious with SVR12 of 96% and 97% respectively.<br><br>**Mavyret(3)**<br><br>Mavyret (glecaprevir/pibrentasvir) is a combination of an NS3/4A protease inhibitor (glecaprevir) and an NS5A inhibitor (pibrentasvir). Its safety and efficacy have been demonstrated in treatment naïve patients or patients previously treated with regimens containing peginterferon, ribavirin, and/or sofosbuvir (PRS) with HCV genotype 1, 2, 3, 4, 5 or 6 without cirrhosis or with compensated cirrhosis. Its safety and efficacy has also been demonstrated in patients who have previously been treated with a regimen containing an NS5A inhibitor or an NS3/4A protease inhibitor but not both. Patients with prior treatment with both an NS5A inhibitor and NS3/4A inhibitor were at an increased risk of virologic failure when retreated with Mavyret.<br><br>The efficacy of Mavyret in treatment naïve or PRS treatment experienced adults with HCV genotype 1, 2, 4, 5, or 6 infection without cirrhosis was evaluated in the ENDURANCE-1, ENDURANCE-4, SURVEYOR-1 (part 2), and SURVEYOR-2 (part 2 and part 4) trials. The SVR12 ranged from 93% to 100% depending on genotype. The EDURANCE-1 trial demonstrated numerically similar efficacy in genotype 1 treatment naïve patients without cirrhosis treated for 8 weeks vs 12 weeks. The SURVEYOR-2 trial also demonstrated very high SVR12 for genotypes 2, 4, 5, or 6 after 8 weeks of treatment. Therefore, the recommended length of therapy for treatment naïve patients without cirrhosis is 8 weeks.<br><br>The efficacy of Mavyret in treatment naïve or PRS treatment experienced adults with HCV genotypes 1, 2, 4, 5, or 6 infection with compensated cirrhosis was evaluated in the EXPEDITION-1 trial. Patients received Mavyret for 12 weeks. The SVR12 was 99-100% depending on genotype.<br><br>The efficacy of Mavyret in treatment naïve or PRS treatment experienced adults with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis was evaluated in the ENDURANCE-3 and SURVEYOR-2 (part 3) trial. For patients without cirrhosis the SVR12 was numerically similar for patients without cirrhosis and the recommendation for these patients is to treat for 8 weeks. The overall SVR12 for all patients in these trials ranged from 94.9-98% depending on cirrhosis status and previous treatment.<br><br>The efficacy of Mavyret in treatment naïve and PRS treatment experienced adults with genotype 2, 4, 5, or 6 without cirrhosis was evaluated in the SURVEYOR-2 (part 2 and part 4), ENDURANCE-4, and SURVEYOR-1 (part 2) trials. SVR12 ranged from 93-100% depending on genotype. |



 

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| | The efficacy of Mavyret in treatment naïve or PRS treatment experienced adults with HCV genotype 1, 2, 4, 5, or 6 infection with compensated cirrhosis was evaluated in the EXPEDITION-1 trial. The SVR12 ranged from 99-100% depending on genotype.<br><br>The EXPEDITION-4 trial evaluated treatment naïve and PRS treatment experienced adults with chronic kidney disease stage 4 and 5 and chronic HCV infection without cirrhosis or with compensated cirrhosis. The overall SVR12 was 98%.<br><br>The MAGELLAN-1 trial evaluated adults who were NS5A inhibitor or NS3/4A protease inhibitor experienced patients without cirrhosis or with compensated cirrhosis. The SVR12 ranged from 92-94% depending on previous treatment.<br><br>The MAGELLAN-2 trial evaluated patients who were treatment-naïve or PRS treatment-experienced who have had a liver or kidney transplant. The overall SVR12 rate was 98%.<br><br>The efficacy of Mavyret was evaluated in an open-label study (DORA Part 1) that evaluated adolescent subjects 12 years to less than 18 years without cirrhosis who received Mavyret for 8 or 16 weeks. Treatment duration was chosen to match approved adult durations based on HCV genotype and prior treatment experience. The overall SVR12 rate was 100%.<br><br>DORA part 2 enrolled patients aged 3 years to less than 12 years and used weight-based dosing of Mavyret. The overall SVR12 rate for the subjects who received the recommended dosage was 98.4%.<br><br>**Sovaldi (sofosbuvir)(4)**<br><br>Sovaldi is a nucleotide analog NS5B polymerase inhibitor. It is indicated for use in combination with other DAAs including daclatasvir and simeprevir. It may also be used in combination with peg-interferon and ribavirin. To date, sofosbuvir is the only oral DAA indicated for treatment of patients with hepatocellular carcinoma secondary to chronic HCV infection.<br><br>The safety and efficacy of Sovaldi was evaluated in five Phase 3 trials in a total of 1724 HCV mono-infected subjects with genotypes 1 to 6 chronic hepatitis C virus, one Phase 3 trial in 223 HSC/HIV-1 coinfected subjects with genotype 1, 2, or 3 HCV, and one trial in 106 pediatric subjects 3 years of age and older with genotype 2 or 3 HCV. The efficacy of Sovaldi (SVR12) is dependent on the combination regimen in which it is used, the patient's genotype, and patient's treatment history (range 82% - 100%).<br><br>The most common adverse events of sofosbuvir when used with ribavirin include fatigue headache and insomnia. Nausea, insomnia, and anemia were the most common adverse events when sofosbuvir was used in combination with ribavirin and peg-interferon.<br><br>**Viekira Pak(5)**<br><br>Viekira Pak (ombitasvir/paritaprevir/ritonavir co-packaged with dasabuvir) is a combination therapy containing a hepatitis C virus NS3/4A protease inhibitor (paritaprevir), a CYP3A inhibitor (ritonavir), a hepatitis C virus NS5A inhibitor (ombitasvir), and a hepatitis C NS5B palm polymerase inhibitor (dasabuvir). Safety and efficacy of this combination was evaluated in trials including treatment naïve, previous failures, cirrhotic and non-cirrhotic genotype 1 patients. The studies (SAPPHIRE-1, SAPPHIRE-II, PEARL-II, PEARL-III, PEARL-IV, TURQUOISE-II, AND TURQUIOISE-III) all had a primary efficacy endpoint of SVR12. |



 

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| | Patients with genotype 1a infection without cirrhosis were evaluated in the SAPPHIRE-I, SAPPHIRE-II, and PEARL-IV trials. The SVR12 ranged from 95-97% depending on previous treatment.<br><br>Patients with genotype 1b infection without cirrhosis were evaluated in the PEARL-II and PEARL-III trials. SVR12 for both of these studies was 100%.<br><br>Patients with genotype 1a and genotype 1b infection with compensated cirrhosis were evaluated in the TURQUOISE-II and TURQUOISE-IV trials. The SVR12 ranged from 89-100% depending on genotype subtype and length of treatment.<br><br>Treatment guidelines recommend that patients that have failed a previous protease inhibitor containing regimen receive ledipasvir/sofosbuvir. Ombitasvir/paritaprevir/ritonavir + dasabuvir is not a recommended regimen in previous protease inhibitor failures due to risk of resistance.<br><br>**Vosevi(6)**<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is a fixed-dose combination of a hepatitis C virus nucleotide analog NS5B polymerase inhibitor (sofosbuvir), an HCV NS5A inhibitor (velpatasvir), and an HCV NS3/4A protease inhibitor (voxilaprevir). Efficacy of this combination agent was evaluated in two phase 3 trials. The primary endpoint in both trials was SVR12.<br><br>The efficacy of Vosevi in patients with hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who were treatment experienced with a NS5A inhibitor (POLARIS-1 trial). The SVR12 ranged from 91-100% depending on genotype.<br><br>The efficacy of Vosevi in patients with hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who previously failed a hepatitis C direct acting antiviral (POLARIS-4 trial). The SVR12 ranged from 94-100% depending on genotype and in genotype 1, the subtype. Additional benefit of this combination agent over sofosbuvir/velpatasvir has not been shown in patients with genotype 1b, 2, 4, 5, or 6 infection who were previously treated with sofosbuvir without an NS5A inhibitor.<br><br>**Zepatier(7)**<br><br>Zepatier (elbasvir/grazoprevir) is a combination regimen of an NS5A replication inhibitor (elbasvir) and an NS3/4A protease inhibitor (grazoprevir). Its efficacy was evaluated in several phase 2 and 3 clinical trials. All the trials had a primary end point of sustained virologic response at 12 weeks (SVR12) following completion of treatment.<br><br>Efficacy of Zepatier in treatment naïve patients with HCV genotype 1 with or without cirrhosis was evaluated in the C-EDGE TN and C-EDGE COINFECTION trials. Subjects in both trials received Zepatier for 12 weeks. SVR12 was 95% in both trials. There were no significant differences in SVR12 between cirrhotic and non-cirrhotic patients. The C-EDGE TE trial evaluated efficacy of this combination in treatment experienced HCV genotype 1 patients with or without cirrhosis who had previously failed peginterferon plus ribavirin. Subjects received Zepatier monotherapy for 12 weeks or Zepatier with ribavirin for 16 weeks. SVR12 rates in the two treatment groups were 94% and 97% respectively.<br><br>Efficacy in HCV genotype 1 patients with or without cirrhosis who had previously failed peginterferon, ribavirin, plus a protease inhibitor was evaluated in the C-SALVAGE |



 

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| | trial. This was an open label, single arm trial. All subjects received Zepatier plus ribavirin for 12 weeks. Overall SVR12 was 96%.<br><br>Efficacy of Zepatier in patients with HCV genotype 1 with or without cirrhosis and who had Chronic Kidney Disease (CKD) stage 4 (eGFR 15-29 mL/min/1.73 m^2) or CKD Stage 5 (eGFR less than 15 mL/min/1.73 m^2), including patients on hemodialysis was evaluated in the C-SURFER trial. Patients were randomized to receive either Zepatier for 12 weeks or placebo for 12 weeks followed by 12 weeks of Zepatier (deferred treatment group). Overall SVR12 was 99%. There were no significant differences with regard to safety in the Zepatier group versus placebo group.<br><br>These trials found that presence of NS5A amino acid polymorphisms in patients with HCV genotype 1a was associated with reduced efficacy of Zepatier regardless of treatment history or cirrhosis status. It is recommended to test for NS5A polymorphisms in HCV genotype 1a patients prior to starting treatment with this combination. If the polymorphism is present, addition of ribavirin to the treatment regimen and extension of the duration of treatment to 16 weeks is recommended.<br><br>Efficacy of Zepatier in HCV genotype 4 patients was evaluated in the C-SCAPE, C-EDGE TE, C-EDGE TN, and C-EDGE COINFECTION trials. Treatment naïve patients in these trials received Zepatier for 12 weeks while those who were treatment experienced received Zepatier plus ribavirin for 12 to 16 weeks. SVR12 in the treatment naïve and treatment experienced patients was 97% and 100% respectively. |
| Safety(1-7) | • **Epclusa** (sofosbuvir/velpatasvir) has the following contraindication(s):<br>o Epclusa and ribavirin combination regimen is contraindicated in patients for whom ribavirin is contraindicated<br>• **Harvoni** (ledipasvir/sofosbuvir) has the following contraindication(s):<br>o If used in combination with ribavirin, all contraindications to ribavirin also apply to Harvoni combination therapy<br>• **Mavyret** (glecaprevir/pibrentasvir) has the following contraindication(s):<br>o Patients with severe hepatic impairment (Child-Turcotte-Pugh B or C) or those with any history of prior hepatic decompensation<br>o Coadministration with atazanavir or rifampin<br>• **Sovaldi** (sofosbuvir) has the following contraindication(s):<br>o When used in combination with peginterferon alfa/ribavirin or ribavirin alone, all contraindications to peginterferon alfa and/or ribavirin also apply to Sovaldi combination therapy<br>o Because ribavirin may cause birth defects and fetal death, Sovaldi in combination with peginterferon alfa and/or ribavirin is contraindicated in pregnant women and men whose female partners are pregnant<br>• **Viekira PAK** (paritaprevir/ritonavir/ombitasvir + dasabuvir) has the following contraindication(s):<br>o Patients with moderate to severe hepatic impairment [decompensated cirrhosis (Child-Turcotte-Pugh B or C)]<br>o Known hypersensitivity to ritonavir (e.g., toxic epidermal necrolysis, Steven-Johnson syndrome)<br>o Co-administration with drugs that are: highly dependent on CYP3A for clearance; moderate or strong inducers of CYP3A and strong inducers of CYP2C8; and strong inhibitors of CYP2C8<br>o If Viekira is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen<br>• **Zepatier** (elbasvir/grazoprevir) has the following contraindication(s):<br>o Patients with moderate or severe hepatic impairment [decompensated cirrhosis (Child-Turcotte-Pugh B or C)]<br>o Organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors, strong CYP3A inducers, and efavirenz<br>o If Zepatier is administered with ribavirin, the contraindications to ribavirin also apply |



 

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| Risk of Hepatitis B infection reactivation with HCV Direct Acting Antivirals(10) | In October of 2016, the FDA issued a safety alert concerning risk of reactivation of hepatitis B viral (HBV) infection in patients treated with HCV direct acting antivirals (DAA). At the time of the alert, the FDA had identified 24 cases of HBV infection reactivation in patients who had been treated with an HCV DAA. In a few of these cases, the HBV reactivation resulted in serious liver problems or death. As a result, the FDA has required labeling for all HCV DAAs to include a boxed warning for HBV infection reactivation. In addition, the FDA has recommended that all patients be screened for evidence of current or prior HBV infection before starting treatment with HCV DAAs and be monitored for HBV reactivation during and after treatment with an HCV DAA. |

## REFERENCES


| Number | Reference |
|---|---|
| 1 | Epclusa prescribing information. Gilead. April 2022. |
| 2 | Harvoni prescribing information. Gilead. March 2020. |
| 3 | Mavyret prescribing information. AbbVie. September 2021. |
| 4 | Sovaldi prescribing information. Gilead. March 2020. |
| 5 | Viekira Pak prescribing information. Abbvie Inc. December 2019. |
| 6 | Vosevi prescribing information. Gilead. November 2019. |
| 7 | Zepatier prescribing information. Merck. May 2022. |
| 8 | AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Testing Hepatitis C. Available at www.hcvguidelines.org. |
| 9 | The center for Disease Control and Prevention. Viral Hepatitis Statistics and Surveillance. Available at http://www.cdc.gov/hepatitis/statistics. |
| 10 | Direct-Acting Antivirals for Hepatitis C: FDA Drug Safety Communication-Risk of Hepatitis B Reactivation. Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523690.htm |
| 11 | AASLD/IDSA HCV Guidance: Unique and Key populations – HCV in children. https://www.hcvguidelines.org/unique-populations/children. |
| 12 | AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology, Vol. 71, No.2, 2020. |


## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|---|---|---|---|---|---|---|
| | | | | | | |
| Zepatier | elbasvir-grazoprevir tab | 50-100 MG | M ; N ; O ; Y | N | | See Preferred Agents Detail |
| Mavyret | glecaprevir-pibrentasvir pellet pack ; glecaprevir-pibrentasvir tab | 100-40 MG ; 50-20 MG | M ; N ; O ; Y | N | | See Preferred Agents Detail |
| Harvoni | ledipasvir-sofosbuvir pellet pack ; ledipasvir-sofosbuvir tab | 33.75-150 MG ; 45-200 MG ; 90-400 MG | M ; N ; O ; Y | M ; N | | See Preferred Agents Detail |
| Viekira pak | ombitas-paritapre-riton & dasab tab pak | 12.5-75-50 &250 MG | M ; N ; O ; Y | N | | See Preferred Agents Detail |
| Sovaldi | sofosbuvir pellet pack ; sofosbuvir tab | 150 MG ; 200 MG ; 400 MG | M ; N ; O ; Y | N | | See Preferred Agents Detail |



 

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|---|---|---|---|---|---|---|
| Epclusa | sofosbuvir-velpatasvir pellet pack ; sofosbuvir-velpatasvir tab | 150-37.5 MG ; 200-50 MG ; 400-100 MG | M ; N ; O ; Y | M ; N | | See Preferred Agents Detail |
| Vosevi | sofosbuvir-velpatasvir-voxilaprevir tab | 400-100-100 MG | M ; N ; O ; Y | N | | See Preferred Agents Detail |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Epclusa | sofosbuvir-velpatasvir pellet pack ; sofosbuvir-velpatasvir tab | 150-37.5 MG ; 200-50 MG ; 400-100 MG | |
| Harvoni | ledipasvir-sofosbuvir pellet pack ; ledipasvir-sofosbuvir tab | 33.75-150 MG ; 45-200 MG ; 90-400 MG | |
| Mavyret | glecaprevir-pibrentasvir pellet pack ; glecaprevir-pibrentasvir tab | 100-40 MG ; 50-20 MG | |
| Sovaldi | sofosbuvir pellet pack ; sofosbuvir tab | 150 MG ; 200 MG ; 400 MG | |
| Viekira pak | ombitas-paritapre-riton & dasab tab pak | 12.5-75-50 &250 MG | |
| Vosevi | sofosbuvir-velpatasvir-voxilaprevir tab | 400-100-100 MG | |
| Zepatier | elbasvir-grazoprevir tab | 50-100 MG | |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Oral Hepatitis C First and Second Gen Antivirals – Through Preferred Agent(s) Prior Authorization – Medicaid** |

- All drugs used to treat Hepatitis C infections require prior authorization.
- Hepatitis C drug authorization criteria will vary by patient's genotype.
- Preferred drugs require patients to meet preferred drug authorization criteria before payment.
- Nonpreferred drugs require patients to meet nonpreferred drug authorization criteria before payment.
- Certain requested regimen with no FDA-approved treatment duration will be evaluated on a case-by-case basis. All other requested regimens must meet treatment duration described in the FDA-approved label.
- Prior authorization requests for patients with mixed genotypes will be evaluated on a case-by-case basis.

**Preferred Agents:**

| **Genotype 1 Treatment-Naïve Patients** | |
|---|---|
| **Preferred** | **Non-preferred** |
| **Mavyret** | **Zepatier** |
| | Sofosbuvir/Velpatasvir |
| | **Epclusa** |
| | Ledipasvir/Sofosbuvir |
| | **Harvoni tablet** |
| | **Harvoni pellet** |
| | **Sovaldi tablet** |
| | **Sovaldi pellet** |
| | **Viekira Pak** |



 

| Module | Clinical Criteria for Approval | |
|---|---|---|
| | **Genotype 1 Treatment-Experienced Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret**<br><br>**Vosevi** | **None** |
| | **Genotype 2 Treatment-Naïve Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret** | Sofosbuvir/Velpatasvir |
| | | **Epclusa** |
| | | **Sovaldi tablet** |
| | | **Sovaldi pellet** |
| | **Genotype 2 Treatment-Experienced Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret**<br><br>**Vosevi** | **None** |
| | **Genotype 3 Treatment-Naïve Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret** | Sofosbuvir/Velpatasvir |
| | | **Epclusa** |
| | | **Sovaldi tablet** |
| | | **Sovaldi pellet** |
| | **Genotype 3 Treatment-Experienced Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret**<br><br>**Vosevi** | **None** |
| | **Genotype 4 Treatment-Naïve Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret** | **Zepatier** |
| | | Sofosbuvir/Velpatasvir |
| | | **Epclusa** |
| | | Ledipasvir/Sofosbuvir |
| | | **Harvoni tablet** |
| | | **Harvoni pellet** |
| | | **Sovaldi tablet** |
| | | **Sovaldi pellet** |
| | **Genotype 4 Treatment-Experienced Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret**<br><br>**Vosevi** | **None** |
| | **Genotype 5 or 6 Treatment-Naïve Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret** | Sofosbuvir/Velpatasvir |
| | | **Epclusa** |
| | | Ledipasvir/Sofosbuvir |
| | | **Harvoni tablet** |
| | | **Harvoni pellet** |
| | **Genotype 5 or 6 Treatment-Experienced Patients** | |
| | **Preferred** | **Non-preferred** |
| | **Mavyret**<br><br>**Vosevi** | **None** |
| 1. Hepatitis | **TARGET DRUGS - Hepatitis C Genotype 1 - Treatment Naive** | |



 

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>C Genotype 1 - Treatment Naive</td><td>
<table>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)</td><td>Zepatier (elbasvir/grazoprevir)<br><br>Sofosbuvir/Velpatasvir<br><br>Epclusa (sofosbuvir/velpatasvir)<br><br>Ledipasvir/Sofosbuvir<br><br>Harvoni (ledipasvir/sofosbuvir) tablet, pellet<br><br>Sovaldi (sofosbuvir) tablet, pellet<br><br>Viekira PAK (ombitasvir/paritaprevir/ritonavir + dasabuvir)</td></tr>
</table>
<br>Mavyret (glecaprevir/pibrentasvir) will be approved when ALL of the following criteria are met:<br><br>
1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen AND<br>
2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>
A. Patient is treatment-experienced OR<br>
B. Patient has Hepatitis B, or HIV co-infection, or both OR<br>
C. Patient has undergone liver transplantation OR<br>
D. Patient has liver cancer OR<br>
E. Patient has severe liver disease defined as:<br>
1. APRI greater than 1.5 OR<br>
2. FibroSURE greater than 0.49 OR<br>
3. Fibroscan greater than 9.5 kPa OR<br>
4. FIB-4 greater than 3.25 OR<br>
5. MR Elastography greater than 6 kPa OR<br>
6. Fibrospect greater than 42 OR<br>
7. Liver Biopsy greater than F3 AND<br>
3. If the patient has a substance use disorder or IV drug use, the patient must:<br>
A. Be enrolled in a substance use disorder treatment program and provider’s attestation of enrollment is provided at time of request OR<br>
B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND ONE of the following:<br>
1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>
A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>
B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>
C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
|---|---|
| | D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines<br><br>**Epclusa** (sofosbuvir/velpatasvir) |



 

| Module | Clinical Criteria for Approval |
|---|---|
| | **Sofosbuvir/Velpatasvir**<br><br>**Harvoni** (ledipasvir/sofosbuvir) tablet<br><br>**Harvoni** (ledipasvir/sofosbuvir) pellet<br><br>**Ledipasvir/Sofosbuvir**<br><br>**Sovaldi** (sofosbuvir) tablet<br><br>**Sovaldi** (sofosbuvir) pellet<br><br>**Viekira PAK** (ombitasvir/paritaprevir/ritonavir + dasabuvir)<br><br>**Zepatier** (elbasvir/grazoprevir) will be approved when ALL of the following criteria are met:<br><br>1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting |



 

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up AND<br>
5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death AND<br>
6. Clinical documentation of patient’s liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration AND<br>
7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request AND<br>
8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request AND<br>
9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) AND<br>
10. Patient does NOT have ANY of the following exclusion criteria:<br>
A. Clinically significant drug interactions with patient’s existing medications that cannot be mitigated<br>
B. Pregnancy<br>
C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>
D. Clinically-significant illness or any other major medical disorder that may interfere with patients’ ability to complete a course of treatment<br>
E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>
F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>
G. MELD less than or equal to 20 and ONE of the following:<br>
1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>
2. Malignancy outside the liver not meeting oncologic criteria for cure<br>
3. Hepatocellular carcinoma<br>
4. Intrahepatic cholangiocarcinoma<br>
5. Hemangiosarcoma<br>
H. Contraindication to requested drug or drug combination<br>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. If the request for the nonpreferred drug is due to a non-mitigatable drug interaction with the preferred drug, the prescriber must conduct and submit a comprehensive review of the patient’s entire drug therapy regimen (such as, all drugs prescribed by all prescribers and dispensed to the patient) clearly identifying the interacting drug(s) at the time of request (comprehensive review submission required) AND<br>
12. The prescriber provides clinical rationale why the preferred agent Mavyret cannot be used AND<br>
13. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>2. Hepatitis C Genotype 1 - Treatment</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 1 - Treatment Experienced</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
</table>
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
|---|---|
| Experienced | <table><tr><td>Mavyret (glecaprevir/pibrentasvir)<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>None</td></tr></table><br><br>**Mavyret** (glecaprevir/pibrentasvir)<br><br>**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) will be approved when ALL of the following criteria are met:<br><br>1. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>2. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above **AND**<br>3. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>4. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND** |



 

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
5. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration AND<br>
6. Clinical documentation of patient's prior treatment including drug name and date(s) of therapy AND<br>
7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request AND<br>
8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request AND<br>
9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) AND<br>
10. Patient does NOT have ANY of the following exclusion criteria:<br>
A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>
B. Pregnancy<br>
C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>
D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>
E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>
F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>
G. MELD less than or equal to 20 and ONE of the following:<br>
1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>
2. Malignancy outside the liver not meeting oncologic criteria for cure<br>
3. Hepatocellular carcinoma<br>
4. Intrahepatic cholangiocarcinoma<br>
5. Hemangiosarcoma<br>
H. Contraindication to requested drug or drug combination<br>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>3. Hepatitis C Genotype 2 - Treatment Naive</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 2 - Treatment Naive</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)</td><td>Sofosbuvir/Velpatasvir<br><br>Epclusa (sofosbuvir/velpatasvir)<br><br>Sovaldi (sofosbuvir) tablet, pellet</td></tr>
</table>
Mavyret (glecaprevir/pibrentasvir) will be approved when ALL of the following criteria are met:<br><br>
1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen AND
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney) |



 

| Module | Clinical Criteria for Approval |
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| | D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines<br><br>**Epclusa** (sofosbuvir/velpatasvir)<br><br>**Sofosbuvir/Velpatasvir**<br><br>**Sovaldi** (sofosbuvir) tablet<br><br>**Sovaldi** (sofosbuvir) pellet will be approved when ALL of the following criteria are met:<br><br>1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR** |



 

| Module | Clinical Criteria for Approval |
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| | B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND** |



 

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<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>11. If the request for the nonpreferred drug is due to a non-mitigatable drug interaction with the preferred drug, the prescriber must conduct and submit a comprehensive review of the patient's entire drug therapy regimen (such as, all drugs prescribed by all prescribers and dispensed to the patient) clearly identifying the interacting drug(s) at the time of request (comprehensive review submission required) AND<br>12. The prescriber provides clinical rationale why the preferred agent Mavyret cannot be used AND<br>13. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>Length of Approval: As determined in FDA-approved label or appropriate guidelines</td></tr>
<tr><td>4. Hepatitis C Genotype 2 - Treatment Experienced</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 2 - Treatment Experienced</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>None</td></tr>
</table>
Mavyret (glecaprevir/pibrentasvir)<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be approved when ALL of the following criteria are met:<br><br>1. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced OR<br>B. Patient has Hepatitis B, or HIV co-infection, or both OR<br>C. Patient has undergone liver transplantation OR<br>D. Patient has liver cancer OR<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 OR<br>2. FibroSURE greater than 0.49 OR<br>3. Fibroscan greater than 9.5 kPa OR<br>4. FIB-4 greater than 3.25 OR<br>5. MR Elastography greater than 6 kPa OR<br>6. Fibrospect greater than 42 OR<br>7. Liver Biopsy greater than F3 AND<br>2. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)</td></tr>
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| Module | Clinical Criteria for Approval |
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| | B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above **AND**<br>3. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>4. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>5. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>6. Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines |



 

| Module | Clinical Criteria for Approval |
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| 5. Hepatitis C Genotype 3 - Treatment Naive | |

| TARGET DRUGS - Hepatitis C Genotype 3 - Treatment Naive | |
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| **Preferred Agent(s)** | **Non-Preferred Agent(s)** |
| Mavyret (glecaprevir/pibrentasvir) | Sofosbuvir/Velpatasvir<br><br>Epclusa (sofosbuvir/velpatasvir)<br><br>Sovaldi (sofosbuvir) tablet, pellet |

**Mavyret** (glecaprevir/pibrentasvir) will be approved when ALL of the following criteria are met:

1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**
2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:
    A. Patient is treatment-experienced **OR**
    B. Patient has Hepatitis B, or HIV co-infection, or both **OR**
    C. Patient has undergone liver transplantation **OR**
    D. Patient has liver cancer **OR**
    E. Patient has severe liver disease defined as:
        1. APRI greater than 1.5 **OR**
        2. FibroSURE greater than 0.49 **OR**
        3. Fibroscan greater than 9.5 kPa **OR**
        4. FIB-4 greater than 3.25 **OR**
        5. MR Elastography greater than 6 kPa **OR**
        6. Fibrospect greater than 42 **OR**
        7. Liver Biopsy greater than F3 **AND**
3. If the patient has a substance use disorder or IV drug use, the patient must:
    A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**
    B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:
        1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
            A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
            B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
            C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)
            D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**
        2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**
4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting



 

| Module | Clinical Criteria for Approval |
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| | treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines<br><br>**Epclusa** (sofosbuvir/velpatasvir)<br><br>**Sofosbuvir/Velpatasvir**<br><br>**Sovaldi** (sofosbuvir) tablet<br><br>**Sovaldi** (sofosbuvir) pellet will be approved when ALL of the following criteria are met: |



 

| Module | Clinical Criteria for Approval |
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| | 1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy |



 

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<tr><td></td><td>
C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>
D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>
E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>
F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>
G. MELD less than or equal to 20 and ONE of the following:<br>
1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>
2. Malignancy outside the liver not meeting oncologic criteria for cure<br>
3. Hepatocellular carcinoma<br>
4. Intrahepatic cholangiocarcinoma<br>
5. Hemangiosarcoma<br>
H. Contraindication to requested drug or drug combination<br>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. If the request for the nonpreferred drug is due to a non-mitigatable drug interaction with the preferred drug, the prescriber must conduct and submit a comprehensive review of the patient's entire drug therapy regimen (such as, all drugs prescribed by all prescribers and dispensed to the patient) clearly identifying the interacting drug(s) at the time of request (comprehensive review submission required) AND<br>
12. The prescriber provides clinical rationale why the preferred agent Mavyret cannot be used AND<br>
13. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>6. Hepatitis C Genotype 3 - Treatment Experienced</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 3 - Treatment Experienced</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>None</td></tr>
</table>
Mavyret (glecaprevir/pibrentasvir)<br><br>
Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be approved when ALL of the following criteria are met:<br><br>
1. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>
A. Patient is treatment-experienced OR
</td></tr>
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| Module | Clinical Criteria for Approval |
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| | B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>2. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above **AND**<br>3. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>4. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>5. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>6. Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, |



 

<table>
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<tr><td></td><td>patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype AND<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>Length of Approval: As determined in FDA-approved label or appropriate guidelines</td></tr>
<tr><td>7. Hepatitis C Genotype 4 - Treatment Naive</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 4 - Treatment Naive</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)</td><td>Zepatier (elbasvir/grazoprevir)<br><br>Sofosbuvir/Velpatasvir<br><br>Epclusa (sofosbuvir/velpatasvir)<br><br>Ledipasvir/Sofosbuvir<br><br>Harvoni (ledipasvir/sofosbuvir) tablet, pellet<br><br>Sovaldi (sofosbuvir) tablet, pellet</td></tr>
</table>
<br>Mavyret (glecaprevir/pibrentasvir) will be approved when ALL of the following criteria are met:<br><br>1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen AND<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced OR<br>B. Patient has Hepatitis B, or HIV co-infection, or both OR<br>C. Patient has undergone liver transplantation OR</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
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| | D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure) |



 

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| | F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines<br><br>**Epclusa** (sofosbuvir/velpatasvir)<br><br>**Sofosbuvir/Velpatasvir**<br><br>**Harvoni** (ledipasvir/sofosbuvir) tablet<br><br>**Harvoni** (ledipasvir/sofosbuvir) pellet<br><br>**Ledipasvir/Sofosbuvir**<br><br>**Sovaldi** (sofosbuvir) tablet<br><br>**Sovaldi** (sofosbuvir) pellet<br><br>**Zepatier** (elbasvir/grazoprevir) will be approved when ALL of the following criteria are met:<br><br>1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must: |



 

| Module | Clinical Criteria for Approval |
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| | A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination |



 

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<tr><td></td><td>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. If the request for the nonpreferred drug is due to a non-mitigatable drug interaction with the preferred drug, the prescriber must conduct and submit a comprehensive review of the patient's entire drug therapy regimen (such as, all drugs prescribed by all prescribers and dispensed to the patient) clearly identifying the interacting drug(s) at the time of request (comprehensive review submission required) AND<br>
12. The prescriber provides clinical rationale why the preferred agent Mavyret cannot be used AND<br>
13. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>8. Hepatitis C Genotype 4 - Treatment Experienced</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 4 - Treatment Experienced</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)<br><br>Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>None</td></tr>
</table>
<br>
Mavyret (glecaprevir/pibrentasvir)<br><br>
Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be approved when ALL of the following criteria are met:<br><br>
1. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>
A. Patient is treatment-experienced OR<br>
B. Patient has Hepatitis B, or HIV co-infection, or both OR<br>
C. Patient has undergone liver transplantation OR<br>
D. Patient has liver cancer OR<br>
E. Patient has severe liver disease defined as:<br>
1. APRI greater than 1.5 OR<br>
2. FibroSURE greater than 0.49 OR<br>
3. Fibroscan greater than 9.5 kPa OR<br>
4. FIB-4 greater than 3.25 OR<br>
5. MR Elastography greater than 6 kPa OR<br>
6. Fibrospect greater than 42 OR<br>
7. Liver Biopsy greater than F3 AND<br>
2. If the patient has a substance use disorder or IV drug use, the patient must:<br>
A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR<br>
B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND ONE of the following:
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
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| | 1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above **AND**<br>3. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>4. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**<br>5. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>6. Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND** |



 

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<tr><td></td><td>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>Length of Approval: As determined in FDA-approved label or appropriate guidelines</td></tr>
<tr><td>9. Hepatitis C Genotype 5 or 6 - Treatment Naive</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 5 or 6 - Treatment Naive</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)</td><td>Sofosbuvir/Velpatasvir<br><br>Epclusa (sofosbuvir/velpatasvir)<br><br>Ledipasvir/Sofosbuvir<br><br>Harvoni (ledipasvir/sofosbuvir) tablet, pellet</td></tr>
</table>
<br>Mavyret (glecaprevir/pibrentasvir) will be approved when ALL of the following criteria are met:<br><br>
1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen AND<br>
2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>
A. Patient is treatment-experienced OR<br>
B. Patient has Hepatitis B, or HIV co-infection, or both OR<br>
C. Patient has undergone liver transplantation OR<br>
D. Patient has liver cancer OR<br>
E. Patient has severe liver disease defined as:<br>
1. APRI greater than 1.5 OR<br>
2. FibroSURE greater than 0.49 OR<br>
3. Fibroscan greater than 9.5 kPa OR<br>
4. FIB-4 greater than 3.25 OR<br>
5. MR Elastography greater than 6 kPa OR<br>
6. Fibrospect greater than 42 OR<br>
7. Liver Biopsy greater than F3 AND<br>
3. If the patient has a substance use disorder or IV drug use, the patient must:<br>
A. Be enrolled in a substance use disorder treatment program and provider’s attestation of enrollment is provided at time of request OR<br>
B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND ONE of the following:<br>
1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>
A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
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| | B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**<br>5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**<br>6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**<br>7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**<br>8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request **AND**<br>9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) **AND**<br>10. Patient does NOT have ANY of the following exclusion criteria:<br>A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>B. Pregnancy<br>C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>G. MELD less than or equal to 20 and ONE of the following:<br>1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>2. Malignancy outside the liver not meeting oncologic criteria for cure<br>3. Hepatocellular carcinoma<br>4. Intrahepatic cholangiocarcinoma<br>5. Hemangiosarcoma<br>H. Contraindication to requested drug or drug combination<br>I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>J. Indeterminate HCV genotype **AND**<br>11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>**Length of Approval:** As determined in FDA-approved label or appropriate guidelines |



 

| Module | Clinical Criteria for Approval |
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| | **Epclusa** (sofosbuvir/velpatasvir)<br><br>**Sofosbuvir/Velpatasvir**<br><br>**Harvoni** (ledipasvir/sofosbuvir) tablet<br><br>**Harvoni** (ledipasvir/sofosbuvir) pellet<br><br>**Ledipasvir/Sofosbuvir** will be approved when ALL of the following criteria are met:<br><br>1. A primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist may prescribe the regimen **AND**<br>2. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:<br>A. Patient is treatment-experienced **OR**<br>B. Patient has Hepatitis B, or HIV co-infection, or both **OR**<br>C. Patient has undergone liver transplantation **OR**<br>D. Patient has liver cancer **OR**<br>E. Patient has severe liver disease defined as:<br>1. APRI greater than 1.5 **OR**<br>2. FibroSURE greater than 0.49 **OR**<br>3. Fibroscan greater than 9.5 kPa **OR**<br>4. FIB-4 greater than 3.25 **OR**<br>5. MR Elastography greater than 6 kPa **OR**<br>6. Fibrospect greater than 42 **OR**<br>7. Liver Biopsy greater than F3 **AND**<br>3. If the patient has a substance use disorder or IV drug use, the patient must:<br>A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**<br>B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:<br>1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:<br>A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)<br>B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)<br>C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)<br>D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**<br>2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above. **AND**<br>4. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND** |



 

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5. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death AND<br>
6. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration AND<br>
7. Pretreatment detectable HCV RNA viral load measured value, within 1 year of treatment start date, is provided at time of request AND<br>
8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request AND<br>
9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) AND<br>
10. Patient does NOT have ANY of the following exclusion criteria:<br>
A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>
B. Pregnancy<br>
C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>
D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>
E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>
F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>
G. MELD less than or equal to 20 and ONE of the following:<br>
1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>
2. Malignancy outside the liver not meeting oncologic criteria for cure<br>
3. Hepatocellular carcinoma<br>
4. Intrahepatic cholangiocarcinoma<br>
5. Hemangiosarcoma<br>
H. Contraindication to requested drug or drug combination<br>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. If the request for the nonpreferred drug is due to a non-mitigatable drug interaction with the preferred drug, the prescriber must conduct and submit a comprehensive review of the patient's entire drug therapy regimen (such as, all drugs prescribed by all prescribers and dispensed to the patient) clearly identifying the interacting drug(s) at the time of request (comprehensive review submission required) AND<br>
12. The prescriber provides clinical rationale why the preferred agent Mavyret cannot be used AND<br>
13. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>Hepatitis C Genotype 5 or 6 - Treatment Experienced</td><td>
<table>
<tr><th colspan="2">TARGET DRUGS - Hepatitis C Genotype 5 or 6 - Treatment Experienced</th></tr>
<tr><th>Preferred Agent(s)</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td>Mavyret (glecaprevir/pibrentasvir)</td><td>None</td></tr>
</table>
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
|---|---|

| | |
|---|---|
| Vosevi (sofosbuvir/velpatasvir/voxilaprevir) | |

**Mavyret** (glecaprevir/pibrentasvir)

**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) will be approved when ALL of the following criteria are met:

1. If the patient has any ONE of the following, a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist must prescribe the regimen:
    A. Patient is treatment-experienced **OR**
    B. Patient has Hepatitis B, or HIV co-infection, or both **OR**
    C. Patient has undergone liver transplantation **OR**
    D. Patient has liver cancer **OR**
    E. Patient has severe liver disease defined as:
        1. APRI greater than 1.5 **OR**
        2. FibroSURE greater than 0.49 **OR**
        3. Fibroscan greater than 9.5 kPa **OR**
        4. FIB-4 greater than 3.25 **OR**
        5. MR Elastography greater than 6 kPa **OR**
        6. Fibrospect greater than 42 **OR**
        7. Liver Biopsy greater than F3 **AND**
2. If the patient has a substance use disorder or IV drug use, the patient must:
    A. Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request **OR**
    B. Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request **AND** ONE of the following:
        1. Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
            A. Condom distribution (for example, written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
            B. Access to sterile syringes (for example, written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
            C. Naloxone training and distribution (for example, written prescription for naloxone, copy of current naloxone training protocol etc.)
            D. Medication-assisted treatment options (for example, provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) **OR**
        2. Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above **AND**
3. The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**
4. Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**
5. Clinical documentation of patient's liver cirrhosis status (for example, no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**



 

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
6. Clinical documentation of patient's prior treatment including drug name and date(s) of therapy AND<br>
7. Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request AND<br>
8. Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 or upon request AND<br>
9. Patient must meet the FDA-approved indication for the requested drug (including age and weight limit, if applicable) AND<br>
10. Patient does NOT have ANY of the following exclusion criteria:<br>
A. Clinically significant drug interactions with patient's existing medications that cannot be mitigated<br>
B. Pregnancy<br>
C. Severe end organ disease and not eligible for transplant (such as, liver, heart, lung, kidney)<br>
D. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment<br>
E. Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (for example, patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)<br>
F. Decompensated liver disease with CPT greater than 12 or MELD greater than 20<br>
G. MELD less than or equal to 20 and ONE of the following:<br>
1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery<br>
2. Malignancy outside the liver not meeting oncologic criteria for cure<br>
3. Hepatocellular carcinoma<br>
4. Intrahepatic cholangiocarcinoma<br>
5. Hemangiosarcoma<br>
H. Contraindication to requested drug or drug combination<br>
I. Requested duration of therapy is longer or shorter than the therapy duration listed in FDA-approved label of requested drug<br>
J. Indeterminate HCV genotype AND<br>
11. At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment<br><br>
Length of Approval: As determined in FDA-approved label or appropriate guidelines
</td></tr>
<tr><td>New to market Hepatitis C agents</td><td>
New to Market Hepatitis C Target Agents (This section will be populated when there are new recently FDA approved hepatitis C agents)<br><br>
<table>
<tr><th>Requested agent/regimen</th><th>Genotype</th><th>Preferred Agents*~</th></tr>
<tr><td>TBD</td><td>TBD</td><td>TBD</td></tr>
</table>
<br>
* HCV/HIV-1 co-infection, follow recommendations in table above<br><br>
~ Offer only those preferred agents that are indicated for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
</td></tr>
</table>



 

| Module | Clinical Criteria for Approval |
|---|---|

| Brand (generic) | GPI | Multisource Code |
|---|---|---|
| TBD | TBD | TBD |

**New to market Hepatitis C agents** will be approved when ALL of the following criteria are met:

1. The patient has an FDA approved diagnosis for the requested agent **AND**
2. The requested agent is FDA approved for treatment of the patient's genotype **AND**
3. If FDA labeling for the requested agent requires patients are tested for hepatitis B viral (HBV) infection prior to starting treatment with the requested agent, BOTH of the following:
   A. The prescriber has screened the patient for current or prior HBV **AND**
   B. If the HBV screening was positive for current or prior HBV, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis **AND**
6. ONE of the following:
   A. The requested agent is a preferred agent **OR**
   B. Information has been provided indicating that the patient has been treated with the non-preferred agent in the past 30 days **OR**
   C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **AND**
7. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) **AND**
8. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) **AND**
9. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) (e.g., patient is currently taking the requested agent) **AND**
10. The prescriber has provided documentation that ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
11. The dose is within the FDA labeled dose **AND**
12. The requested agent will be used in a treatment regimen noted in Table 1 (FDA approved labeling) **AND**
13. The length of therapy requested is recommended for the patient's diagnosis and genotype noted in Table 1 (FDA approved labeling)

**Length of Approval:** Up to the duration of treatment as determined in Table 1



 

| Module | Clinical Criteria for Approval |
|---|---|
| | **Table 1: New to Market Hep C Treatment Recommendations based on FDA approved labeling** |

| Agent(s) | FDA approved indication(s) | Genotype | Treatment Regimen | FDA labeled dose | Treatment Duration |
|---|---|---|---|---|---|
| TBD | TBD | TBD | TBD | TBD | TBD |



 