MEDICA MEDICAID HEPATITIS C DRUG PRIOR AUTHORIZATION POLICY

POLICY: Medicaid Hepatitis C Drug Prior Authorization

OVERVIEW

Effective July 1, 2019, all MN Managed Care Organizations who are Medicaid Plan sponsors are required to adopt the STATE's Fee-For-Service (FFS) Preferred Drug List (PDL) preferred drugs and clinca prior authorization criteria for direct acting antiviral drugs used to treat Hepatitis C.

POLICY STATEMENT

Prior authorization is required for the direct acting antiviral drugs used to treat Hepatitis C. Prior authorization criteria is subject to change with notification from the State with a minimium of 60 days' notice to implement updated criteria or change to the preferred drugs.

AUTHORIZATION CRITERIA (EFFECTIVE 1/1/2020)

- 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.
- A tiered approach is used for genotypes where there are multiple nonpreferred treatment options.
- 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 criteria in Attachment A.
- Prior authorization requests for patients with mixed genotypes will be evaluated on a case-by-case basis.

EXCLUSION CRITERIA (APPLIES TO ALL DRUGS AND GENOTYPES)

- Clinically significant drug interactions with patient's existing medications that cannot be mitigated
- Pregnancy
- Severe end organ disease and not eligible for transplant (e.g. liver, heart, lung, kidney)
- Clinically-significant illness or any other major medical disorder that may interfere with patients' abilities to complete a course of treatment
- Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (e.g. 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)
- Decompensated liver disease with CPT > 12 or MELD > 20
- MELD ≤ 20 and one of the following:
    - Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
    - Malignancy outside the liver not meeting oncologic criteria for cure
    - Hepatocellular carcinoma
    - Intrahepatic cholangiocarcinoma
    - Hemangiosarcoma
- Contraindication to requested drug or drug combination
- Requested duration of therapy is longer or shorter than therapy duration listed in FDA-approved label of requested drug
- Indeterminate HCV genotype

CONTINUITY OF CARE (APPLIES TO ALL DRUGS AND GENOTYPES)

At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment.

GENOTYPE 1 CRITERIA – ALL DRUGS REQUIRE PRIOR AUTHORIZATION

Drugs: Sofosbuvir-velpatasvir, Epclusa, Harvoni, lepidasvir-sofosbuvir, Mavyret, Sovaldi, Vosevi, Zepatier

- **Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Zepatier Epclusa Lepidasvir-sofosbuvir Harvoni Sovaldi

- **Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 1

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:

- APRI > 1.5 OR
- FibroSURE > 0.49 OR
- Fibroscan > 9.5 kPa OR
- FIB-4 > 3.25 OR
- MR Elastography > 6 kPa OR
- Fibrospect > 42 OR
- Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 7: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 1.

NONPREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 1

For patients under the age of 18 requesting Harvoni or lepidasvir-sofosbuvir:

Patient is NOT a candidate for Mavyret **AND**

Patient has met Criteria 1 through 6 of the Preferred Drug Criteria **AND**

Patient has a diagnosis of hepatitis C, genotype 1 **AND**

Patient meets either of the following:

- Age 12 through 17 OR
- Weighs at least 35 kg

For patients over the age of 18:

Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**

Patient meets the drug specific criteria in Table 2, Tier Approach to Nonpreferred Drugs for Treatment-Naïve, Genotype 1 **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
      Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
      HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

TABLE 2. TIER APPROACH TO NONPREFERRED DRUGS FOR TREATMENT-NAÏVE PATIENTS OVER THE AGE OF 18, GENOTYPE 1

Tier	Nonpreferred Drug	PA Criteria Genotype 1, age > 18
1	Sofosbuvir-velpatasvir	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
2	Zepatier	Must meet all PA criteria for nonpreferred drugs above and have a creatinine clearance (CrCL) < 30 mL/min. The provider must supply clinical rationale as to why sofosbuvir-velpatasvir cannot be used.

3	Epclusa	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis. The prescriber must provide compelling clinical evidence of why sofosbuvir-velpatasvir cannot be used.
4	Lepidasvir-sofosbuvir	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
5	Harvoni	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. The prescriber must also provide compelling clinical evidence of why the lepidasvir-sofosbuvir cannot be used. Patient must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
6	Sovaldi	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa, Harvoni, sofosbuvir-velpatasvir, and lepidasvir-sofosbuvir cannot be used. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-EXPERIENCED PATIENTS, GENOTYPE 1

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:

    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 8: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 1 if requesting Mavyret **OR**

Criteria 9: Patient is 18 years of age or older with a diagnosis of hepatitis C, genotype 1 if requesting Vosevi.

GENOTYPE 2 CRITERIA – ALL DRUGS REQUIRE PRIOR AUTHORIZATION

Drugs: Sofosbuvir-velpatasvir, Epclusa, Mavyret, Sovaldi, Vosevi

- **Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi

- **Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 2

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 7: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 2.

NONPREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 2

For patients under the age of 18 requesting Sovaldi:

Patient is NOT a candidate for Mavyret **AND**

Patient has met Criteria 1 through 6 of the Preferred Drug Criteria **AND**

Patient has a diagnosis of hepatitis C, genotype 2 **AND**

Patient will use Sovaldi in combination with ribavirin **AND**

Patient meets either of the following:

- Age 12 through 17 OR
- Weighs at least 35 kg

For patients over the age of 18:

Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**

Patient meets the drug specific criteria in Table 3, Tier Approach to Nonpreferred Drugs for Treatment-Naïve, Genotype 2 **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

TABLE 3. TIER APPROACH TO NONPREFERRED DRUGS FOR TREATMENT-NAÏVE PATIENTS OVER THE AGE OF 18, GENOTYPE 2

Tier	Nonpreferred Drug	PA Criteria
1	Sofosbuvir-velpatasvir	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
2	Epclusa	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis. The prescriber must provide compelling clinical evidence of why sofosbuvir-velpatasvir cannot be used.
3	Sovaldi	Must meet all PA criteria for nonpreferred drug above and have a contraindication to Epclusa. Sovaldi must be used in combination with ribavirin. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently on hemodialysis.

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-EXPERIENCED PATIENTS, GENOTYPE 2

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR

- FibroSURE > 0.49 OR
- Fibroscan > 9.5 kPa OR
- FIB-4 > 3.25 OR
- MR Elastography > 6 kPa OR
- Fibrospect > 42 OR
- Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above.

Criteria 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 8: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 2 if requesting Mavyret **OR**

Criteria 9: Patient is 18 years of age or older with a diagnosis of hepatitis C, genotype 2 if requesting Vosevi.

CRITERIA FOR GENOTYPE 3 – ALL DRUGS REQUIRE PRIOR AUTHORIZATION

Drugs: Epclusa, Mavyret, Sovaldi, Vosevi, sofosbuvir-velpatasvir

- **Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi

- **Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 3

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 7: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 3.

NONPREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 3

For patients under the age of 18 requesting Sovaldi:

Patient is NOT a candidate for Mavyret **AND**

Patient has met Criteria 1 through 6 of the Preferred Drug Criteria **AND**

Patient has a diagnosis of hepatitis C, genotype 3 **AND**

Patient will use Sovaldi in combination with ribavirin **AND**

Patient meets either of the following:

- Age 12 through 17 **OR**
- Weighs at least 35 kg

For patients over the age of 18:

Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**

Patient meets the drug specific criteria in Table 4, Tier Approach to Nonpreferred Drugs for Treatment-Naïve, Genotype 3 **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)
        -

Table 4. Tier Approach to Nonpreferred Drugs for Treatment-Naïve Patients Over the Age of 18, Genotype 3

Tier	Nonpreferred Drug	PA Criteria
1	Sofosbuvir-velpatasvir	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
2	Epclusa	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis. The prescriber must provide compelling clinical evidence of why sofosbuvir-velpatasvir cannot be used.
3	Sovaldi	Must meet all PA criteria for nonpreferred drugs above and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-EXPERIENCED PATIENTS, GENOTYPE 3

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 8: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 3 if requesting Mavyret **OR**

Criteria 9: Patient is 18 years of age or older with a diagnosis of hepatitis C, genotype 3 if requesting Vosevi.

CRITERIA FOR GENOTYPE 4 – ALL DRUGS REQUIRE PRIOR AUTHORIZATION

Drugs: Sofosbuvir-velpatasvir, Epclusa, Harvoni, lepidasvir-sofosbuvir, Mavyret, Sovaldi, Vosevi, Zepatier

- **Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Zepatier Epclusa Lepidasvir-sofosbuvir Harvoni Sovaldi

- **Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 4

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3**AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above.

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the health upon request **AND**

Criteria 7: Patient is 12 years of age or older **OR** weighs at least 45 kg with a diagnosis of hepatitis C, genotype 4.

NONPREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 4

For patients under the age of 18 requesting Harvoni or lepidasvir-sofosbuvir:

Patient is NOT a candidate for Mavyret **AND**

Patient has met Criteria 1 through 6 of the Preferred Drug Criteria **AND**

Patient has a diagnosis of hepatitis C, genotype 4 **AND**

Patient meets either of the following:

- Age 12 through 17 **OR**
- Weighs at least 35 kg

For patients over the age of 18:

Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**

Patient meets the drug specific criteria in Table 5, Tier Approach to Nonpreferred Drugs for Treatment-Naïve, Genotype 4 **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

TABLE 5. TIER APPROACH TO NONPREFERRED DRUGS FOR TREATMENT-NAÏVE PATIENTS OVER THE AGE OF 18, GENOTYPE 4

Tier	Nonpreferred Drug	PA Criteria
1	Sofosbuvir-velpatasvir	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
2	Zepatier	Must meet all PA criteria for nonpreferred drugs above and have a creatinine clearance (CrCL) < 30 mL/min. The provider must supply clinical rationale as to why sofosbuvir-velpatasvir cannot be used.
3	Epclusa	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis. The prescriber must provide compelling clinical evidence of why sofosbuvir-velpatasvir cannot be used.
4	Lepidasvir-sofosbuvir	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
5	Harvoni	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. The prescriber must also provide compelling clinical evidence of why the lepidasvir-sofosbuvir cannot be used. Patient must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
6	Sovaldi	Must meet all PA criteria for nonpreferred drugs above and have a documented contraindication to Zepatier and supply clinical rationale as to why Epclusa, Harvoni, sofosbuvir-velpatasvir, and lepidasvir-sofosbuvir cannot be used. Sovaldi must be used in combination with ribavirin and Peg-IFN. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-EXPERIENCED PATIENTS, GENOTYPE 4

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR

- Fibrospect > 42 OR
- Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above

Criteria 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 8: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 4 if requesting Mavyret; **OR**

Criteria 9: Patient is 18 years of age or older with a diagnosis of hepatitis C, genotype 4 if requesting Vosevi.

GENOTYPE 5 OR 6 CRITERIA – ALL DRUGS REQUIRE PRIOR AUTHORIZATION

Drugs: Sofosbuvir-velpatasvir, Epclusa, Mavyret, Harvoni, lepidasvir-sofosbuvir, Vosevi

- **Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni

- **Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 5 or 6

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above.

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 7: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 5 or 6.

NONPREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-NAÏVE PATIENTS, GENOTYPE 5 OR 6

For patients under the age of 18 requesting Harvoni or lepidasvir-sofosbuvir:

Patient is NOT a candidate for Mavyret **AND**

Patient has met Criteria 1 through 6 of the Preferred Drug Criteria **AND**

Patient has a diagnosis of hepatitis C, genotype 5 or 6 **AND**

Patient meets either of the following:

- Age 12 through 17 **OR**
- Weighs at least 35 kg

For patients over the age of 18:

Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**

Patient meets the drug specific criteria in Table 6, Tier Approach to Nonpreferred Drugs for Treatment-Naïve, Genotype 5 or 6 **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Table 6. Tier Approach to Nonpreferred Drugs for Treatment-Naïve Patients Over the Age of 18, Genotype 5 or 6

Tier	Nonpreferred Drug	PA Criteria
1	Sofosbuvir-velpatasvir	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
2	Epclusa	Must meet all PA criteria for nonpreferred drugs above. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis. The prescriber must provide compelling clinical evidence of why sofosbuvir-velpatasvir cannot be used.
3	Lepidasvir-sofosbuvir	Must meet all PA criteria for nonpreferred drugs above and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. Patient also must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.
4	Harvoni	Must meet all PA criteria for nonpreferred drugs above and supply clinical rationale as to why Epclusa and sofosbuvir-velpatasvir cannot be used. The prescriber must

		also provide compelling clinical evidence of why the lepidasvir-sofosbuvir cannot be used. Patient must have creatinine clearance (CrCL) > 30 mL/min OR not currently be on hemodialysis.

PREFERRED DRUG PRIOR AUTHORIZATION CRITERIA FOR TREATMENT-EXPERIENCED PATIENTS, GENOTYPE 5 OR 6

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- 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 service above.

Criteria 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**

- 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**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the health plan upon request **AND**

Criteria 8: Patient is 12 years of age or older OR weighs at least 45 kg with a diagnosis of hepatitis C, genotype 5 or 6 if requesting Mavyret **OR**

Criteria 9: Patient is 18 years of age or older with a diagnosis of hepatitis C, genotype 5 or 6 if requesting Vosevi.

TABLE 1: MHCP PREFERRED DRUG LIST - HEPATITIS C DIRECT-ACTING ANTIVIRALS; ALL REQUIRE PRIOR AUTHORIZATION

(Note –Criteria above of preferred/non-preferred drugs by genotype)

- **Genotype 1 Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Zepatier Epclusa Lepidasvir-sofosbuvir Harvoni Sovaldi

- **Genotype 1 Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

- **Genotype 2 Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi

- **Genotype 2 Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

- **Genotype 3 Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi

- **Genotype 3 Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

- **Genotype 4 Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Zepatier Epclusa Lepidasvir-sofosbuvir Harvoni Sovaldi

- **Genotype 4 Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

- **Genotype 5 or 6 Treatment-Naïve Patients**

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni

- **Genotype 5 or 6 Treatment-Experienced Patients**

Preferred	Nonpreferred
Mavyret Vosevi	None

DURATION OF APPROVAL

• See the MN DHS Treatment Durations reference page at: https://mn.gov/dhs/assets/hepatitis-c-appendix-a_tcm1053-413776.pdf

QUANTITY LIMITS

• Quantity limits pursuant to the FDA-approved label will apply

REFERENCES

1. MN DHS website: https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/rx/pa-criteria/hepatitis-c-2020.jsp
2. MN DHS Treatment Durations reference: HTTPS://MN.GOV/DHS/ASSETS/HEPATITIS-C-APPENDIX-A_TCM1053-413776.PDF