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Current Effective Date: 03/27/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 01/2027
Policy Number: C12049-A

Hepatitis C Antiviral Therapy

PRODUCTS AFFECTED

Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), ledipasvir-sofosbuvir, Mavyret (glecaprevir and pibrentasvir), ribavirin, sofosbuvir-velpatasvir, Sovaldi (sofosbuvir), Viekira Pak (paritaprevir/ritonavir/ombitasvir and dasabuvir), Vosevi (sofosbuvir, velpatasvir, voxilaprevir), Zepatier (elbasvir and grazoprevir)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic Hepatitis C Infection

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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Drug and Biologic Coverage Criteria

A. FOR ALL INDICATIONS:

1. Documented diagnosis of Hepatitis C virus (HCV) infection
   AND
2. Documentation requested medication is prescribed in accordance with the current FDA approved labeling and current AASLD guideline recommendation at the dose and duration appropriate for the member
   AND
3. For chronic infection: Documentation of HCV RNA (HCV viral load) within the past 6 months [DOCUMENTATION REQUIRED]
   OR
   For acute infection (Mavyret only): Documentation of HCV RNA (HCV viral load) and negative HCV antibody within the past 6 weeks [DOCUMENTATION REQUIRED]
   AND
4. Documentation of HIV status (if positive see HIV CO- INFECTION requirements), Hepatitis B status, expected start date and end date of regimen, and cirrhosis status (e.g., Child Pugh Class, FIB-4 score, FibroScan, FibroSure, clinical evidence of cirrhosis, prior liver biopsy, etc.) [DOCUMENTATION REQUIRED]
   AND
5. FOR REGIMENS THAT INCLUDE RIBAVIRIN OR AASLD REGIMENS THAT RECOMMEND RIBAVIRIN: For exception to FDA approved or AASLD recommended regimens that contain ribavirin for Ribavirin-ineligible members, documentation of FDA labeled contraindication to Ribavirin is required: pregnancy, CrCl <30 ml/minute, Hepatic decompensation (Child-Pugh class B and C), Hemoglobin <8.5 g/dL, WBC <1,000 mm3, neutrophils <500 mm3 or Platelets <50 x 109/L
   AND
6. Documentation of adherence evaluation including review of any potential barriers to successful completion of HCV therapy including, but not limited to: compliance difficulty, missed appointments, inadequate social support, Sub-therapeutic management of comorbid physical health conditions and severe mental health conditions (e.g., psychotic disorders, bipolar disorder, major depression, PTSD), and all potential drug interactions with concomitant prescription or over-the-counter medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications). Documentation of member's current medication list and potential interactions with plan to manage the interaction(s), if applicable. (Office notes documenting this are sufficient to meet this criteria)
   AND
7. Documentation of prior HCV treatment history and if treatment-experienced, include date(s) of all HCV therapy (start and completion) and the resulting outcome or discontinuation status and reason for discontinuation.
   AND
8. Documentation of the following Resistant Associated Substitutions (RASs) testing: REQUIRED ONLY FOR REQUESTS WITH THE APPLICABLE DRUG REGIMEN AND MEMBER/TREATMENT CHARACTERISTICS DETAILED BELOW:
   a. Zepatier (elbasvir/grazoprevir): NS5A RAS testing is recommended for genotype 1a-infected, treatment-naive or -experienced patients being considered for elbasvir/grazoprevir
   b. Harvoni (sofosbuvir/ledipasvir): NS5A RAS testing can be considered for genotype 1a-infected, treatment-experienced patients with and without cirrhosis being considered for ledipasvir/sofosbuvir. If >100-fold resistance is present, a different recommended therapy should be used
   c. Epclusa (sofosbuvir/velpatasvir): NS5A RAS testing is recommended for genotype 3-

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infected, treatment-experienced patients without cirrhosis and treatment- naive patients with cirrhosis being considered for 12 weeks of sofosbuvir/velpatasvir. IfY93H is present, weight-based ribavirin should be added or another recommended regimen should be used. (AASLD I, A)

d. Daklinza (daclatasvir) plus Sovaldi (sofosbuvir): NS5A RAS testing is recommended for genotype 3-infected, treatment-experienced patients without cirrhosis being considered for 12 weeks of daclatasvir plus sofosbuvir. Indicate if baseline NS5A Y93H polymorphism is present. If Y93H is present, weight-based ribavirin should be added. (AASLD I, B) NS5A RAS testing is recommended for genotype 3-infected, treatment-naive patients with compensated cirrhosis being considered for 24 weeks of daclatasvir plus sofosbuvir. Indicate if baseline NS5A Y93H polymorphism is present. If Y93H is present, treatment should include weight-based ribavirin, or a different recommended therapy used. (AASLD I, B)

MOLINA REVIEWER NOTE: If genotype testing is not captured in another requirement, genotype testing is required for these regimen requests when the above member/treatment characteristics are met to review RAS testing per AASLD guidelines.
AND

9. FOR NON-FORMULARY/NON-PREFERRED AGENTS: Documented rationale of clinical medical necessity for the inability to utilize the FORMULARY/PREFERRED AGENTS
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
AND
10. Any condition specific requirements (listed below)

B. CHRONIC HEPATITIS C INFECTION RE-TREATMENT, RE-INFECTION:

1. Documentation of HCV genotype and subtype (obtained within the last 3 years and for current infection if re-infection) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6 [DOCUMENTATION REQUIRED]
AND
2. (a) Documentation of reason(s) for previous failure of DAA therapy (i.e., tolerability, efficacy, etc.) and if the stated reason(s) for the previous treatment failure have been addressed (e.g., re-education and understanding/agreement of treatment plan)
OR
(b) Documentation (post therapy sustained virologic response [SVR] lab) member was successfully treated with DAA therapy and has subsequently been re-infected.
NOTE: Inadequate compliance to regimen and treatment plan (including office visits, scheduled clinical tests, etc.) or non-adherence to initial/previous HCV regimen as evidenced by medical records and/or pharmacy claims should be noted and addressed
AND
3. Member adherent to previous HCV therapy as evidenced by pharmacy claims [MOLINA REVIEWER VERIFY]
AND
4. Documentation of ONE of the following:
(a) Documentation of failure to achieve a sustained virologic response (SVR) or lack of efficacy during treatment as evidenced by detectable serum HCV RNA by quantitative assay at 12 or more weeks after completing treatment; or a 10-fold increase of viral load at week 6 of treatment. [DOCUMENTATION REQUIRED: Laboratory documentation of quantitative viral load required.]
OR
(b) Documentation of adverse event that required therapy discontinuation as evidenced by laboratory results (e.g., CBC, LFTs, etc.) and/or clinical presentation, AND no improvement of adverse effect after proper clinical management

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OR

(c) Documentation of re-infection (i.e., report of high-risk behavior since previous treatment)

AND

5. Requested regimen is the highest-rated regimen per AASLD Guidelines for member's condition [by viral subtype, previous therapy, presence or absence or cirrhosis, and presence or absence of resistance-associated variants (RAVs)]

AND

6. There is evidence that such re-treatment will improve member outcomes according to AASLD guidelines OR at least a Class IIa rating (weight of evidence and/or opinion is in favor of usefulness and efficacy) or higher per AASLD Guidelines

C. HEPATITIS C INFECTION, PEDIATRICS:

1. (a) Documentation of HCV genotype and subtype (obtained within the last 3 years) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6 [DOCUMENTATION REQUIRED]

OR

(b) Request is for an AASLD regimen for children or adolescents recommended with any genotype

AND

2. Requested regimen must meet the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America Present HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis: HCV in Children AND the most recent FDA labeled indications

D. HEPATITIS C INFECTION, HIV COINFECTION:

1. Documented diagnosis of HIV-1

AND

2. Documentation of HCV genotype and subtype (obtained within the last 3 years) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6 [DOCUMENTATION REQUIRED]

E. DECOMPENSATED CIRRHOSIS (CHILD PUGH B OR C)

1. Documentation of decompensated liver disease confirmed by ONE of the following (dated within the past 30 days):
   (a)Child-Turcotte-Pugh Score (CTP): 7-15 class B/C
   (b)Model for End-Stage Liver Disease (MELD): ≤ 20
   (c) Ascites, hepatic encephalopathy, variceal bleeding, or jaundice
   NOTE: Ombitasvir, Paritaprevir and Ritonavir; Dasabuvir tablets (Viekira Pak) will not be authorized for CTP score B or C

   AND

2. Documentation of HCV genotype and subtype (obtained within the last 3 years) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6 [DOCUMENTATION REQUIRED]

F. HEPATOCELLULAR CARCINOMA AWAITING LIVER TRANSPLANT:

1. Documentation of diagnosis of Stage I-III hepatocellular carcinoma (HCC) confirmed by image testing (ultrasound, tomography, MRI, laparoscopy), or biopsy
   NOTE: It is reasonable to treat HCV in a member with HCC or a history of HCC after the HCC has been treated successfully, with follow-up imaging demonstrating locoregional control. Patients with HCC should be assessed for DAA therapy on a case-by-case basis and, ideally, managed with input from a Tumor Board or specialty care. Patients with extensive or progressive HCC (e.g., vascular invasion or metastatic disease) are less likely to benefit from DAA therapy.

   AND

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2. Member meets all criteria for authorization of a liver transplant as indicated in Molina Healthcare MCP-114: Liver Transplantation Adult & Pediatric
   AND
3. Documentation of HCV genotype and subtype (obtained within the last 3 years) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6 [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:
For new to Molina Members, authorization should be entered to allow completion of regimen up to appropriate AASLD duration - 8,12,16, or 24 weeks.
For re-treatment - Review as new authorization
Acute treatment - NA

DURATION OF APPROVAL:
Per appropriate AASLD regimen 8, 12, 16, or 24 weeks

PRESCRIBER REQUIREMENTS:
ACUTE OR CHRONIC HEPATITIS C INFECTION, TREATMENT NAÏVE, WITHOUT CIRRHOSIS: No prescriber requirement
HEPATITIS C INFECTION, HIV COINFECTION: Prescribed by or in consultation with an infectious disease specialist.
ALL OTHER INDICATIONS: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease, or transplant medicine specialist
[If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
Acute infection Mavyret only: 3 years of age and older
18 years of age and older with the exceptions found under CHRONIC HEPATITIS C INFECTION, PEDIATRICS section

QUANTITY:
Max quantity is a 28 day supply per dispense. The number of dispenses are allowed up to the approved duration.

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Hepatitis C Agents

FDA-APPROVED USES:
EPCLUSA (sofosbuvir/velpatasvir) is indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis OR with decompensated cirrhosis for use in combination with ribavirin

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HARVONI (ledipasvir/sofosbuvir) is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, genotype 1 infection with decompensated cirrhosis in combination with ribavirin, genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis in combination with ribavirin.

MAVYRET (glecaprevir and pibrentasvir) is indicated for the treatment of adult and pediatric patients 3 years and older with acute or chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND indicated for the treatment of adult and pediatric patients 3 years and older with HCV 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.

Ribavirin: indicated in combination with interferon alfa-2b (pegylated and nonpegylated) for the treatment of Chronic Hepatitis C (CHC) in patients 3 years of age or older with compensated liver disease.
Patients with the following characteristics are less likely to benefit from re-treatment after failing a course of therapy: previous nonresponse, previous pegylated interferon treatment, significant bridging fibrosis or cirrhosis, and genotype 1 infection.

SOVALDI (sofosbuvir) is indicated for the treatment of adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen AND pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

VIEKIRA PAK (paritaprevir/ritonavir/ombitasvir and dasabuvir) is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) with genotype 1b without cirrhosis or with compensated cirrhosis AND genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

VOSEVI (sofosbuvir, velpatasvir, voxilaprevir) is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor AND genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

ZEPATIER (elbasvir and grazoprevir tablet) is indicated for treatment of chronic HCV 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

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State Specific Information

State Marketplace

Illinois (Source: Illinois General Assembly)

"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Appendix 1:

AASLD recommendations for patients co-infected with HIV and HCV

HIV/HCV-coinfected patients should be treated and retreated the same as patients without HIV infection, after recognizing and managing interactions with antiretroviral medications (AASLD Class I, Level B). Antiretroviral drug switches, when needed, should be done in collaboration with HIV practitioner; for HIV antiretroviral and HCV direct-acting antiviral combinations not addressed within the guideline, expert consultation is recommended (AASLD Class I, Level A)

AASLD recommendations for acute HCV infection

Persons with confirmed acute HCV infection (HCV RNA–positive) should be treated the same as those with chronic HCV infection without awaiting possible spontaneous clearance (i.e., test-and-treat approach). Findings from studies that evaluated the efficacy of an abbreviated 6 weeks of therapy for acute HCV infection with various DAA regimens, including ledipasvir/sofosbuvir, glecaprevir/pibrentasvir, and sofosbuvir/velpatasvir, have demonstrated largely inferior response rates compared with the standard of care. As such, an abbreviated course of DAA therapy is not recommended for acute HCV infection.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Risk of Hepatitis B infection reactivation with HCV Direct Acting Antivirals (DAA) 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 a 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 a HCV DAA.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of direct acting antivirals are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

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Contraindications to Epclusa (sofosbuvir/velpatasvir) include: Epclusa and ribavirin combination regimen is contraindicated in patients for whom ribavirin is contraindicated.
Contraindications to Harvoni (ledipasvir/sofosbuvir) include: If used in combination with ribavirin, all contraindications to ribavirin also apply to Harvoni combination therapy.
Contraindications to Mavyret (glecaprevir and pibrentasvir) include: Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation, coadministration with atazanavir or rifampin.
Contraindications to Ribavirin include: pregnancy and men whose female partners are pregnant, known hypersensitivity reactions such as Stevens-Johnson syndrome, toxic, epidermal necrolysis, and erythema multiforme to ribavirin or any component of the product, autoimmune hepatitis, hemoglobinopathies, creatinine clearance less than 50 mL/min, coadministration with didanosine.
Contraindications to Sovaldi (sofosbuvir) include: 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.
Contraindications to Viekira Pak (paritaprevir/ritonavir/ombitasvir and dasabuvir) include: patients with moderate to severe hepatic impairment, If Viekira Pak is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen, 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, known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome).
Contraindications to Vosevi (sofosbuvir, velpatasvir, voxilaprevir) include: coadministration with rifampin.
Contraindications to Zepatier (elbasvir and grazoprevir) include: Patients with moderate or severe hepatic impairment (Child-Pugh B or C), OATP1B1/3 inhibitors that are known or expected to significantly increase grazoprevir plasma concentrations, strong CYP3A inducers, and efavirenz, If Zepatier is administered with ribavirin, the contraindications to ribavirin also apply.

Treatment is recommended for all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy (AASLD, May 2023). Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.

Members identified as having any barriers to treatment mentioned in RMI are not appropriate candidates for therapy until issues have been resolved, or acknowledgement of actions taken by prescriber or another provider involved in the member's care to address those barriers.

Pregnancy: For women of reproductive age with known HCV infection, antiviral therapy is recommended before considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring. (AASLD, October 2022).
The safety and efficacy of DAA therapy in pregnant or lactating women have not been established for any of the currently FDA-approved agents. During pregnancy, these drugs should be used only if the benefits outweigh the risks to the fetus.
Ribavirin has labeled contraindication of pregnancy. Ribavirin capsules may cause fetal harm when administered to a pregnant woman. Ribavirin capsules are contraindicated in women who are pregnant or planning to become pregnant. If a patient becomes pregnant while taking ribavirin capsules, the patient should be apprised of the potential hazard to the fetus. It is also contraindicated in men whose female partners are pregnant. Ribavirin therapy should not be started until a report of a negative pregnancy test has been obtained immediately prior to planned initiation

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of therapy. Female patients should use effective contraception and have periodic monitoring with pregnancy tests during treatment and during the 9-month period after treatment has been stopped. Male patients and their female partners should use effective contraception during treatment and during the 6- month period after treatment has been stopped.

Severe end organ disease and is not eligible for solid organ transplant. Clinically significant illness or any other major medical disorder that may interfere with a patient's ability to complete a course of treatment. Individuals who in the professional judgment of the primary treating clinician would not achieve a long-term clinical benefit from HCV treatment, with conditions such as those: Multisystem organ failure, Receiving palliative care or are enrolled in hospice, Presence of significant pulmonary or cardiac disease, Malignancy outside of the liver not meeting oncologic criteria for cure, Decompensated liver disease with CTP score > 12or MELD > 20, OR Model For End-Stage Liver Disease (MELD) ≤ 20 and ONE (1) of the following: [ONE] Cardiopulmonary disease that cannot be correct and is a prohibitive risk for surgery, Malignancy outside of the liver not meeting oncologic criteria for cure, Hepatocellular carcinoma with metastatic spread or not listed for liver transplant, Intrahepatic cholangiocarcinoma, Hemangiosarcoma Decompensated liver disease with CTP score > 12 or MELD > 20, OR Model For End-Stage Liver Disease (MELD) ≤ 20 and ONE (1) of the following: [ONE] Cardiopulmonary disease that cannot be correct and is a prohibitive risk for surgery, Malignancy outside of the liver not meeting oncologic criteria for cure, Hepatocellular carcinoma with metastatic spread or not listed for liver transplant, Intrahepatic cholangiocarcinoma, Hemangiosarcoma

OTHER SPECIAL CONSIDERATIONS:

The AASLD/IDSA 2023 updated guidance for testing, managing, and treating Hepatitis C includes a new recommendation that addresses the management of incomplete treatment adherence. The algorithm for the management of incomplete adherence as part of DAA treatment monitoring is applicable only to DAA treatment–naïve persons and, generally, the same patient populations who are eligible for the simplified treatment algorithms. Excluded persons with incomplete adherence should be managed in consultation with a specialist in HCV management.

Recommended management of DAA treatment interruptions for treatment-naïve patients without cirrhosis or with compensated cirrhosis receiving glecaprevir/pibrentasvir or sofosbuvir/velpatasvir (Figure 2, Bhattacharya et al, 2023)

<u>Interruptions BEFORE Receiving 28 Days of DAA Therapy:</u>

- Missed ≤7 days
  - Restart DAA therapy immediately. Complete therapy for originally planned duration (8 or 12 weeks).
- Missed ≥8 days
  - Restart DAA therapy immediately. Restarting DAA takes precedence over obtaining HCV RNA level.
  - Obtain HCV RNA test as soon as possible, preferably the same day as restarting the DAA therapy.
    - See guideline for specific recommendations based on HCV RNA outcome.

<u>Interruptions AFTER Receiving ≥28 Days of DAA Therapy</u>

- Missed ≤7 days
  - Restart DAA therapy immediately. Complete therapy for originally planned duration (8 or 12 weeks).
- Missed 8-20 Consecutive Days

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- Restart DAA therapy immediately. Restarting DAA takes precedence over obtaining HCV RNA level.
- Obtain HCV RNA test as soon as possible, preferably the same day as restarting the DAA therapy.
  - See guideline for specific recommendations based on HCV RNA outcome.

- Missed ≥21 Consecutive Days
  - Stop DAA treatment and assess for sVR12. If SVR12 not achieved, retreat according to recommendations in the Retreatment Section.

Epclusa, Mavyret, Zepatier, Harvoni, Sovaldi, Vosevi, Viekira Pak have a black box warning for risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV. Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death.
Ribavirin has a black box warning for embryo-fetal toxicity, hemolytic anemia, and monotherapy not recommended.

CODING/BILLING INFORMATION

HCPCS CODE	DESCRIPTION
NA	

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

AVAILABLE DOSAGE FORMS:
Epclusa PACK 150-37.5MG
Epclusa PACK 200-50MG
Epclusa TABS 200-50MG
Epclusa TABS 400-100MG
Harvoni PACK 33.75-150MG
Harvoni PACK 45-200MG
Harvoni TABS 45-200MG
Harvoni TABS 90-400MG
Ledipasvir-Sofosbuvir TABS 90-400MG
Mavyret PACK 50-20MG
Mavyret TABS 100-40MG
Ribavirin CAPS 200MG
Ribavirin TABS 200MG
Sofosbuvir-Velpatasvir TABS 400-100MG
Sovaldi PACK 150MG
Sovaldi PACK 200MG
Sovaldi TABS 200MG
Sovaldi TABS 400MG

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REFERENCES

1. Epclusa (sofosbuvir/velpatasvir) tablets, for oral use; oral pellets [prescribing information]. Foster City, CA: Gilead Sciences Inc; April 2022.
2. Harvoni (ledipasvir/sofosbuvir) tablets, for oral use; oral pellets [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2024.
3. Mavyret (glecaprevir/pibrentasvir) tablets, for oral use; oral pellets [prescribing information]. North Chicago, IL: AbbVie Inc; June 2025.
4. Ribavirin capsules, for oral use [prescribing information]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.
5. Sovaldi (sofosbuvir) tablets, for oral use; oral pellets [prescribing information]. Foster City, CA: Gilead Sciences; December 2024.
6. Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2019.
7. Vosevi (sofosbuvir, velpatasvir, voxilaprevir) tablets, for oral use [prescribing information]. Foster City, CA: Gilead Sciences, Inc; November 2019.
8. Zepatier (elbasvir and grazoprevir) tablets, for oral use[prescribing information]. Rahway, NJ: Merch Sharp & Dohme LLC; May 2022.
9. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [31 October 2022].
10. Terrault, N. A., McCaughan, G. W., Curry, M. P., Gane, E., Fagiuoli, S., Fung, J., Agarwal, K., Lilly, L., Strasser, S. I., Brown, K. A., Gadano, A., Kwo, P. Y., Burra, P., Samuel, D., Charlton, M., Pessoa, M. G., & Berenguer, M. (2017). International Liver Transplantation Society Consensus Statement on Hepatitis C Management in Liver Transplant Candidates. Transplantation, 101(5), 945–955. https://doi.org/10.1097/TP.0000000000001708
11. Bhattacharya, D., Aronsohn, A., Price, J., Lo Re, V., & AASLD-IDSA HCV Guidance Panel. (2023). Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America, ciad319. https://doi.org/10.1093/cid/ciad319
12. American Association for the Study of Liver Diseases AASLD and Infectious Diseases Society of America IDSA. (2022, October 24). Management of Acute HCV Infection | HCV Guidance. Retrieved from www.hcvguidelines.org website: https://www.hcvguidelines.org/unique-populations/acute-infection

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Appendix Contraindications/Exclusions/Discontinuation References	Q1 2026

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REVISION- Notable revisions: Required Medical Information Prescriber Requirements Age Restrictions FDA-Approved Uses References	Q4 2025
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Quantity Contraindications/Exclusions/Discontinuation	Q1 2025
REVISION- Notable revisions: Products Affected Required Medical Information FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Prescriber Requirements FDA- Approved Uses Appendix Contraindications/Exclusions/Discontinuation References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file

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