Effective Date: 11/01/2018
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Policy Number: C18433-A

Hepatitis C Antiviral Therapy, IL Medicaid Only

PRODUCTS AFFECTED

Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), ledipasvir-sofosbuvir, Sovaldi (sofosbuvir), 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.

FOR ALL INDICATIONS:

A. The member is 12 years of age or over and has a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5 or 6 confirmed by lab documentation and quantitative baseline HCV-RNA.
AND
B. Documentation provided of the member's Metavir/fibrosis score. The Metavir/fibrosis score can be determined based on Liver Biopsy, Transient Elastography (FibroScan®), Fibro

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Test®/FibroSure®, or FibroMeter™.
AND

C. Documentation of the following lab test reports, completed within 3 months prior to the request for prior approval, unless otherwise noted:
    1. Baseline quantitative HCV RNA level (within 1 year)
    2. ALT and AST
    3. CBC
    4. GFR
    5. INR, albumin, and bilirubin (for stage 4 fibrosis only)
    6. Negative HBV screen (or, if positive, quantitative HBV DNA and verification of treatment regimen)

AND

D. Prescriber must provide clinic or consultation notes from specialist consultation (see requirement J).
AND

E. Provider attestation that the member is able to make appropriate decisions about treatment, comply with dosing and other instructions, and is capable of completing therapy as prescribed.
AND

F. The prescriber must provide a copy of a signed patient commitment letter for all hepatitis C treatment regimens.
AND

G. The treatment regimen prescribed is not for an indication outside of the FDA approved labeling, and no contraindications or significant drug interactions to treatment exist as specified in the product labeling.
AND

H. Documentation showing the prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate).
AND

I. The member has no history of an incomplete course of treatment with DAAs. (Prior treatment with telaprevir, boceprevir, and DAA regimens used in combination with interferons is not taken into consideration for purposes of this criterion.) Molina will review requests and pertinent clinical information for an additional course of DAA, after previous such therapy, on a case-by-case basis, considering whether the person has received counseling for or otherwise addressed the cause of non-adherence, where applicable.
AND

J. The prescriber is any practitioner licensed to prescribe or licensed to prescribe in collaboration with a physician who holds a current unrestricted license to practice medicine. If the prescriber is NOT a gastroenterologist, hepatologist, transplant hepatologist, or infectious disease specialist, the prescriber must engage in a one-time consultation with one of these specialists within the 3 months prior to the request for prior authorization. This one-time consultation may be via telephone, videoconference, or tele-health technology. The records containing a specialist recommendation for treatment with a DAA regimen must be submittedwith the request for prior approval.
AND

K. The prescriber agrees to submit HCV RNA levels to Molina Healthcare for member's prescribed DAAs within 8 weeks after beginning treatment, 12 weeks post treatment, and 24 weeks post treatment. If at any point the member's viral load is undetectable, the prescriber is not required to submit any subsequent test. member's failure to submit a lab report in a timely fashion due to member's non- cooperation may result in denial of re-treatment, should that situation arise. However, situations beyond the control of the prescriber or the member will not result in a denial of re-treatment under this criterion.
AND

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L. FOR NON-PREFERRED AGENTS/NON-FORMULARY AGENTS: Prescriber to provide clinical reason member is not an appropriate candidate for the preferred agents (e.g. genotype, hepatic function, transplant status, renal function).

DURATION OF APPROVAL:
Per appropriate AASLD regimen – 8,12, 16 or 24 weeks
MOLINA REVIEWER/STAFF: Communicate the following points to the Prescriber upon initial authorization regarding the required criteria for re-authorization of treatment/regimen.

Non-adherence with the regimen (> 7 days) or member's failure to obtain refills in a timely manner may result in discontinuation of current prior approval. Non-adherence or failure to obtain refills that result from situations that are beyond the member's control will not result in discontinuation of a prior approval.

Requests for exceptions to these criteria can be made when the services are medically necessary to meet the medical needs of the member. Requests for exceptions to these criteria can be made on theprior approval form itself and will be reviewed on a case-by-case basis.

PRESCRIBER REQUIREMENTS:
None. Consultation is required as referenced in requirement J.

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
Expected therapy start and end date must be verified with the prescriber before the authorization is provided. MAX QUANTITY IS A 28 DAYS SUPPLY PER DISPENSE. THE NUMBER OF DISPENSES ARE ALLOWED UP TO 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, in combination with ribavirin.

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 30kg. Zepatier is indicated for use with ribavirin in certain patient populations.

HARVONI® (ledipasvir/sofosbuvir) is indicated for the treatment of chronic hepatitis C virus (HCV) in adult 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

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combination with ribavirin, genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

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.

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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

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)

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 FDAhas 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.

OTHER 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)

Interruptions BEFORE Receiving 28 Days of DAA Therapy:

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- 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.

Interruptions AFTER Receiving ≥28 Days of DAA Therapy:

- Missed ≤7 days
  - Restart DAA therapy immediately. Complete therapy for originally planned duration (8 or 12 weeks).
- Missed 8-20 Consecutive 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.
- Missed ≥21 Consecutive Days
  - Stop DAA treatment and assess for sVR12. If SVR12 not achieved, retreat according to recommendations in the Retreatment Section.

Epclusa, Zepatier, Harvoni, Sovaldi, and Vosevi 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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

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 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 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.

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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. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert. (AASLD, October 2022)

Members identified 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.

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 > 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 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.

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
Sovaldi PACK 150MG
Sovaldi PACK 200MG
Sovaldi TABS 200MG
Sovaldi TABS 400MG
Vosevi TABS 400-100-100MG
Zepatier TABS 50-100MG

REFERENCES

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1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs January 1, 2026.
2. Illinois Medicaid Preferred Drug List, Effective January 1, 2026.
3. Illinois Department of Healthcare and Family Services, Criteria for Prior Approval of Direct-Acting Antivirals (DAAs) for Hepatitis C, Updated November 2018. Available at: https://hfs.illinois.gov/content/dam/soi/en/web/hfs/sitecollectiondocuments/hfshepcdaacriteriawordfinal11012018.pdf
4. Epclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; April 2022.
5. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; March 2020.
6. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences; March 2020.
7. Vosevi (sofosbuvir, velpatasvir, voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; November 2019.
8. Zepatier (elbasvir and grazoprevir) tablets [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].

SUMMARY OF REVIEW/REVISIONS	DATE
Off-Cycle Updates: Products Affected Available Dosage Forms References	02/2026
Annual review: Products Affected Available Dosage Forms References	07/2025
Annual updates: Drug Information Appendix Background Other Considerations References	07/2024
Annual updates: Products Affected Available Dosage Forms References	07/2023
Annual updates: References	05/2022

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