Effective Date: 11/2018
Last P&T Approval/Version: 04/2022
Next Review Due By: 04/2023
Policy Number: C18433-A

Direct-Acting Antivirals (DAAs) for Hepatitis C Antiviral Therapy- IL Medicaid Only

PRODUCTS AFFECTED

EPCLUSA (sofosbuvir/velpatasvir), MAVYRET (glecaprevir and pibrentasvir), ZEPATIER (elbasvir and grazoprevir tablet), HARVONI® (ledipasvir/sofosbuvir) tablets, SOVALDI (sofosbuvir), VOSEVI (sofosbuvir, velpatasvir, voxilaprevir), VIEKIRA PAK (paritaprevir/ritonavir/ombitasvir and dasabuvir), Ledipasvir-Sofosbuvir TABS 90-400MG, Sofosbuvir- Velpatasvir TABS 400-100MG

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:
See FDA-approved uses

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

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 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

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).

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

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:
Therapy start date must be verified with patient and/or prescriber before the secondfill is dispensed. 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): indicated for the treatment of adult patients and pediatric patients 6 years of age and older weighing at least 17 kg 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

MAVYRET (glecaprevir and pibrentasvir): indicated for the treatment of adult patients and pediatric patients 12 years and older or weighing at least 45kg with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) and adult and pediatric patients12 years and older or weighing at least 45kg, with HCV genotype 1 infection, who previously have beentreated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both

ZEPATIER (elbasvir and grazoprevir tablet): indicated for treatment of chronic HCV genotype 1 or 4 infection in adults. ZEPATIER is indicated for use with ribavirin in certain patient populations

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

SOVALDI (sofosbuvir): 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 2or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin

VOSEVI (sofosbuvir, velpatasvir, voxilaprevir): 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 OR 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.

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
OTHER SPECIAL CONSIDERATIONS:

Pregnancy: Currently pregnant or planning on becoming pregnant in the next six months, treatment during pregnancy is not recommended due to the lack of safety and efficacy data. (AASLD, September 2017).The safety and efficacy of DAA therapy in pregnant or lactating women have not been establishedfor any of the currently FDA-approved agents. During pregnancy, these drugs should be used only if thebenefits outweigh the risks to the fetus.

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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

PRODUCT NAME
Sovaldi TABS 200MG
Sovaldi TABS 400MG
Sovaldi PACK 150MG
Sovaldi PACK 200MG
Zepatier TABS 50-100MG
Mavyret TABS 100-40MG
Mavyret PACK 50-20MG
Harvoni TABS 45-200MG
Harvoni TABS 90-400MG
Ledipasvir-Sofosbuvir TABS 90-400MG

PRODUCT NAME
Harvoni PACK 33.75-150MG
Harvoni PACK 45-200MG
Epclusa TABS 200-50MG
Epclusa TABS 400-100MG
Sofosbuvir-Velpatasvir TABS 400-100MG
Epclusa PACK 150-37.5MG
Epclusa PACK 200-50MG
Vosevi TABS 400-100-100MG
Viekira XR TB24 200-8.33-50-33.33 MG
Viekira Pak TBPK 12.5-75-50 &250MG

REFERENCES

1. Illinois Department of Healthcare and Family Services, Criteria for Prior Approval of Direct-Acting Antivirals (DAAs) for Hepatitis C, Updated November 2018
2. Epclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; June 2021.
3. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; March 2020.
4. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL: AbbVie Inc; September 2021.
5. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences; March 2020.
6. Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) [prescribing information]. North Chicago,IL: AbbVie Inc; December 2019.
7. Vosevi (sofosbuvir, velpatasvir, voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; November 2019.

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2/2022