Clinical Policy: Hepatitis C Agents

Reference Number: NH.PHAR.200
Effective Date: 11.23
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Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Policy for Hepatitis C Agents FDA-approved to treat Hepatitis C Virus (HCV) infection.

FDA Approved Indication(s)
Hepatitis C Virus Infection

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Treatment naïve patients are exempt from prior authorization when a preferred drug that is FDA-approved for treatment naïve patients is prescribed.

It is the policy of health plans affiliated with Centene Corporation® that Hepatitis C Agents are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Chronic Hepatitis C Infection (must meet all)**:**

1. Diagnosis of chronic HCV infection as evidenced by detectable serum HCV RNA levels by quantitative assay in the last 6 months;
   a) Document genotype for treatment-experienced patients;
   b) Document if additional diagnosis of human immunodeficiency virus (HIV) and/or cirrhosis (Child-Pugh A status);
2. Patient is ≥ 18 years of age or otherwise specified by package insert;
3. Patient has been tested for hepatitis B infection by measuring HBsAg and anti-HBc;
4. Member must use Preferred Agents **(Mavyret, Sofosbuvir/velpatasvir (authorized generic for Epclusa), or ledipasvir-sofosbuvir (authorized generic for Harvoni))** unless contraindicated or clinically significant adverse effects are experienced;
5. If cirrhosis is present, confirmation of Child-Pugh A status;
6. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V. Recommended Treatment Section if a preferred agent is contraindicated or clinically significant adverse effects are experienced*);
7. Dose does not exceed FDA -dosing recommendations.

Approval duration: up to 24 weeks*
*(*Approved duration should be consistent with a regimen in Section V Recommended Treatment)*

A. Other diagnoses/indications (must meet all)**:**

1. Member must use preferred agents **(Mavyret, Sofosbuvir/velpatasvir (authorized generic for Epclusa), or ledipasvir-sofosbuvir (authorized generic for**

Harvoni)), if applicable for the requested indication, unless clinically significant adverse effects are experienced or both are contraindicated;

2. One of the following (a or b):
    a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
        i. For drugs on the PDL, the no coverage criteria policy CP.PMN.225 or
        ii. For drugs NOT on the PDL, the non-formulary policy CP.PMN.16.
    b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy: CP.PMN.53.

II. Continued Therapy

1. Chronic Hepatitis C Infection (must meet all)**:**

1. Member meets one of the following (a, b, or c):
    a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
    b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
    c. Both of the following (i and ii):
        i. Documentation supports that member is currently receiving Hepatitis C Agents for chronic HCV infection and has recently completed at least 60 days of treatment with Hepatitis C Agents;
2. Member is responding positively to therapy;
3. Member must use Preferred **Agents (Mavyret, Sofosbuvir/velpatasvir (authorized generic for Epclusa), or ledipasvir-sofosbuvir (authorized generic for Harvoni))** unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed FDA dosing limits.

Approval duration: up to a total treatment duration of 24 weeks*

*(*Approved duration should be consistent with a regimen in Section V Recommended Treatment)*

2. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the PDL, the no coverage criteria policy CP.PMN.255; or
    b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16.
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

1. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy: CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
FDA: Food and Drug Administration
HBV: hepatitis B virus

HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDSA: Infectious Diseases Society of America

V. Recommended Treatments and Alternative Treatments by Genotype

Any Genotype – Simplified Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	N/A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	N/A
	with compensated cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	N/A
		sofosbuvir/velpatasvir (Epclusa®) (except genotype 3 with Y93H present)	12	P (generic)	N/A

Genotype 1a – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®) For patients who are HIV-uninfected and whose HCV RNA level is < 6 million IU/mL.	8	P (generic)	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A B
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A

Genotype 1a – Alternative Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Naïve	**without** cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A
	with compensated cirrhosis	elbasvir/grazoprevir (without baseline NS5A RASs for elbasvir) (Zepatier®)	12	NP	Class I, Level A

Genotype 1b – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment- Naïve	**without** cirrhosis	elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		ledipasvir/sofosbuvir (Harvoni®) For patients who are HIV-uninfected and whose HCV RNA level is < 6 million IU/mL.	8	P (generic)	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A

Genotype 2 – Recommended Treatments	

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B

Genotype 3 – Recommended Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A

Genotype 3 – Alternative Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Naïve	**with compensated** cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (for patients with baseline NS5A RAS Y93H))	12	NP	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) with weight-based ribavirin for patients with baseline NS5A RAS Y93H)	12	NP	Class IIa, Level A

Genotype 4 – Recommended Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Naïve	**without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		elbasvir/grazoprevir (Zepatier®)	12	NP	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class I, Level A
	with compensated cirrhosis	sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level A
		glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level B
		elbasvir/grazoprevir (Zepatier®)	12	NP	Class IIa, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B

Genotype 5/6 – Recommended Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Naïve	**without or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®)	8	P	Class I, Level A
		sofosbuvir/velpatasvir (Epclusa®)	12	P (generic)	Class I, Level B
		ledipasvir/sofosbuvir (Harvoni®)	12	P (generic)	Class IIa, Level B

Sofosbuvir-Based Treatment Failures – Recommended Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Experienced	**with or without** cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	NP	Class I, Level A

Sofosbuvir-Based Treatment Failures – Alternative Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
Treatment-Experienced	**with or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®) (except for NS3/4 protease inhibitor inclusive combination DAA regimen failures) *Not for genotype 3 infection with sofosbuvir/NS5A inhibitor experience	16	P	Class I, Level A

Glecaprevir/Pibrentasvir-Based Treatment Failures – Recommended Treatments

Treatment Experience	Cirrhosis status	Treatment	Max Duration of Approval (weeks)	PDL status	Rating
		glecaprevir/pibrentasvir (Mavyret®)	16	P	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)	12	NP	Class IIa, Level B

Treatment-Experienced	**with or without** cirrhosis	sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (compensated cirrhosis, addition of weight-based ribavirin is recommended)	12	NP	Class IIa, Level C
Sofosbuvir/Velpatasvir/Voxilaprevir Treatment Failures – Recommended Treatments					
Treatment Experience	**Cirrhosis status**	**Treatment**	**Max Duration of Approval (weeks)**	**PDL status**	**Rating**
Treatment-Experienced	**with or without** cirrhosis	glecaprevir/pibrentasvir (Mavyret®) plus daily sofosbuvir and weight-based ribavirin	16	P/NP	Class IIa, Level B
		sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) (plus weight-based ribavirin)	24	NP	Class IIa, Level B

Grading System Used to Rate the Level of the Evidence and Strength of the Recommendation for Each Recommendation Classification

- **Class I —** conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective
- **Class II —** conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment
- **Class IIa —** weight of evidence and/or opinion is in favor of usefulness and efficacy
- **Class IIb —** usefulness and efficacy are less well established by evidence and/or opinion
- **Class III —** conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful

Level of Evidence

- **Level A** — data derived from multiple randomized clinical trials, meta-analyses, or equivalent
- **Level B** — data derived from a single randomized trial, nonrandomized studies, or equivalent
- **Level C** — consensus opinion of experts, case studies, or standard of care

References available upon request.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	11.23	11.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.