Pharmacy Drug Policy & Procedure

Policy Name:	Hepatitis C Treatment	Policy #:	567P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of peg-interferon (PEG) and direct-acting antiviral (DAA) agents in the treatment of Hepatitis C. The criteria below were developed using guidelines from the AASLD/IDSA.

Statement of the Policy

The following medications are addressed within this policy:

Medication Class/Mechanism of Action	Medication Name
Single-Drug Products	
Peg-Interferon	PegIntron and Pegasys
NS5B Inhibitor	Sovaldi (sofosbuvir)
Multi-Drug Combination Products	
NS5B Inhibitor-NS5A Inhibitor-NS3/4A Protease Inhibitor	Viekira (dasabuvir-ombitasvir-paritaprevir) Vosevi (sofosbuvir-velpatasvir-voxilaprevir)
NS5A Inhibitor-NS5B Inhibitor	Harvoni (ledipasvir-sofosbuvir) Epclusa (velpatasvir-sofosbuvir)
NS5A Inhibitor-NS3/4A Protease Inhibitor	Zepatier (elbasvir-grazoprevir) Mavyret (pibrentasvir-glecaprevir)

Criteria

1. Inclusion Criteria

1.1 Prescribed by a gastroenterologist (stomach doctor), infectious disease specialist or hepatologist (liver doctor),

1.2 Documented diagnosis of chronic Hepatitis C infection

1.3 Patients with a liver fibrosis measurement equivalent to a METAVIR score of F0 to F4

- Measure of scar tissue in the liver. Occurs when the liver attempts to repair and replace damaged cells.

1.4 Provider attestation that the patient has been counseled on direct acting antiviral therapy, has no barriers to treatment, and is committed to being compliant with treatment as evidenced in chart notes or in a separate commitment form between patient and provider

1.5 If evidence or known diagnosis of cancer of any body organ diagnosed within the last 12 months is noted, or currently receiving or planning to receive cancer treatment or radiation therapy, the request for a Hepatitis C treatment regimen will be reviewed by a Medical Director for a medical exception

1.6 If member meets all above requirements for treatment and approval is made, referral to care coordination and/or a health coach should be made to ensure that the member has access to any needed resources and is supported through treatment including addressing any barriers, scheduling regular follow ups, refill adherence, necessary labs, etc.

- If evidence of recent substance abuse diagnosis or treatment is found, reference AASLD's recommended strategies for patients with recent history of IV drug use or alcohol abuse which includes counseling and education and referring for services (mental health services, medications for opioid use disorder, and syringe service programs)

2. Covered Treatment Regimens for patients that are treatment naïve to Direct-Acting Antiviral therapy

2.1 Any treatment regimen recommended by AASLD guidelines that contains only preferred products (Epclusa, Harvoni, Mavyret). If a preferred product has not yet been incorporated into the AASLD guidelines, the covered regimens will be those listed in the medication's package insert.

2.2 Treatment regimens recommended by AASLD guidelines that contain non-preferred products will only be covered with documentation of severe intolerance or contraindication to all regimens with preferred products.

3. Covered Treatment Regimens for patients that are treatment experienced with Direct-Acting Antiviral Therapy for select genotypes and previous therapies

3.1 Requests for re-treatment require the following:

- Patient meets all criteria under section inclusion criteria under section 1 of this policy
- Documentation that patient did not achieve SVR12 (sustained virologic response 12 weeks post treatment) after the previous treatment was completed and that re-treatment at this time is necessary.
- Provider has addressed any factors contributing to member not achieving SVR
- Documentation or claims data showing the patient completed a full treatment regimen and was compliant with refills with no more than 2 days' worth of medication missed
- Documentation that the patient has an infection with the same genotype previously treated.

3.2 Re-treatment regimens will follow duration and products recommended by AASLD guidelines

4. Patients with Hepatocellular carcinoma

4.1 Patients with Hepatocellular carcinoma (liver cancer) will be approved for treatment if they meet all of the following requirements:

- Patient meets Milan criteria
- Defined as having tumor size of 5cm or less in diameter with single hepatocellular carcinomas or 3 tumor nodules or less, each 3cm or less in diameter with multiple tumors
- No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor,
- Patient is currently awaiting a liver transplant.

4.2 Covered treatment regimen(s)

- Any treatment regimen recommended by AASLD guidelines that contains only preferred products (Epclusa, Harvoni, Mavyret). If a preferred product has not yet been incorporated into the AASLD guidelines, the covered regimens will be those listed in the medication's package insert.
- Treatment regimens recommended by AASLD guidelines that contain non-preferred products will only be covered with documentation of severe intolerance or contraindication to all regimens with preferred products

5. Approval Period

5.1 Eight to Sixteen (8 to 16) weeks within a 6 month approval duration, depending upon treatment regimen recommendation made by AASLD guidelines or as listed in the product package insert if the medication has not yet been incorporated in the AASLD guidelines.

5.2 Only one regimen (treatment or re-treatment) will be covered per year

6. Exclusion Criteria

6.1 Evidence or known diagnosis of cancer of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive cancer therapy or radiation therapy. Coverage will be excluded for all cases determined not to be medically necessary based off medical director review.

6.2 Re-approval for lost/stolen medications.

6.3 Providers not willing to complete and submit the Health Alliance Hepatitis C Patient Commitment form.

6.4 Retreatment requests will not be covered if documentation submitted indicates a change in genotypes from previous treatment. These requests will be determined to be new treatment requests for the genotype in question.

6.5 Vosevi is not indicated for use in treatment-naïve patients.

6.6 Re-treatment with Vosevi or Mavyret in unstudied previous treatments as listed in the product package insert.

CPT Codes	

HCPCS Codes	

References

1. Bhattacharya D, Aronsohn A, Price J, et al. Hepatitis C Guidance 2023 Update: American Association for the Study of Liver Diseases– Infectious Diseases Society of America recommendations for testing, managing, and treating hepatitis c virus infection. Clinical Infectious Diseases. Last updated December 19, 2023.
2. Tran A, Shili-Masmoudi S, Moga L, et al. Non-invasive diagnosis and follow-up of chronic infection with Hepatitis C Virus. Clin Res Hepatol Gastroenterol. 2022 Jan;46(1):101771.
3. American Society of Addiction Medicine: Public Policy Statement on Hepatitis C Infection; April 2017.
4. Borchardt RA, Torres HA. "Challenges in managing hepatitis C virus infection in cancer patients." World Journal of Gastroenterology. 2014 March 21; 20(11): 2771–2776.
5. Torres HA, McDonald GB. "How I treat hepatitis C virus infection in patients with hematologic malignancies." 2016. 128:1449–1457.

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