Washington State Health Care Authority

Washington Medicaid Hepatitis C Policy January 2018

Medical policy no. 12.35.30-99

Policy criteria:

Medical necessity

Washington State Health Care Authority (HCA) determines medical necessity for the treatment of chronic hepatitis C virus (HCV) infection based on criteria 1-4. HCA will approve coverage for all patients with chronic HCV infection regardless of fibrosis scoring.

Prior authorization:

1. Patient has chronic HCV infection defined by:
    a. Liver fibrosis score ≥ F1 and a detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months; **OR**
    b. Liver fibrosis score < F1; **AND**
        i. Positive (i.e. reactive) HCV antibody test that is at least six months old **and** has a detectable and quantifiable HCV RNA (>15 IU/mL) six months after date of positive HCV antibody test; **OR**
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least six months apart; **AND**

2. Prescriber is:
    a. Specialist in one of the following areas:
        i. Gastroenterology
        ii. Hepatology
        iii. HIV
        iv. Infectious disease; **OR**
    b. Participating and consulting with Project ECHO or one of the specialists listed above (requires consultation note or documentation of phone call); **OR**
    c. Other specialty or non-specialist provider who works in coordination with an organized system of care, has received training in chronic HCV diagnosis, staging, and treatment protocols, and has ready access to specialists who treat HCV (requires letter of endorsement and prior clearance by HCA); **AND**

3. Required documentation and lab tests:
    a. HCV Antibody test administered at least 6 months before request for treatment.
    b. HCV Genotype.
    c. Current HCV RNA Viral Load.
    d. Fibrosis staging test (e.g. FibroScan® or FibroSURE®) to determine liver fibrosis level required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis and/or decompensation may require longer treatment and/or ribavirin). Fibrosis staging test results must be less than 2 years old.
    e. Documentation of decompensation (or previous episodes of decompensation) if fibrosis level is F4 or stage 4 or cirrhosis.
    f. Documentation of treatment-experienced status including prior treatment regimen, length of treatment, response, and dates of treatment.
    g. Lab reports, if available, documenting presence or absence of resistant mutations in treatment-experienced patients.

4. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who:
    a. Are taking medications that are contraindicated with or that have a severe drug interaction with the prescribed HCV treatment.
    b. Are pregnant or planning on becoming pregnant.
    c. Have severe end organ disease and are not eligible for transplantation (e.g. heart, lung, kidney)
    d. Have decompensated liver disease with CPT >12 or MELD >20.
    e. Have a clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment.
    f. In the professional judgment of the primary treating clinician, would not achieve a long-term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure, receiving palliative care, with significant pulmonary or cardiac disease, or with malignancy outside of the liver not meeting oncologic criteria for cure).
    g. Have a MELD score <20 and one of the following:
        i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
        ii. Malignancy outside the liver not meeting oncologic criteria for cure
        iii. Hepatocellular carcinoma with metastatic spread
        iv. Intrahepatic cholangiocarcinoma
        v. Hemangiosarcoma
        vi. Uncontrolled sepsis.

Approval

Preferred products:

1. *Mavyret* is preferred for all treatment-naïve genotypes and certain treatment-experienced genotypes. *Mavyret* is considered not medically necessary under the following circumstances:
    a. Relapse after completion of regimen(s) containing both an NS5A inhibitor and an NS3/4A protease inhibitor.
    b. Moderate or severe hepatic impairment (**ANY** history of decompensation).
    c. Concurrent atazanavir, rifampin, or any medication that reduces *Mavyret* effectiveness.
    d. Unmonitored HBV coinfection.

2. *Epclusa* is preferred for all treatment-naïve genotypes and all treatment-experienced genotypes. *Epclusa* is considered not medically necessary under the following circumstances:
    a. Relapse after completion of a regimen containing an NS5A inhibitor.
    b. Genotype 1a or 3 relapse after completion of a regimen containing sofosbuvir.
    c. Severe renal impairment or end stage renal disease (eGFR <30 mL/min).
    d. Concurrent amiodarone, proton pump inhibitor therapy > 20 mg of omeprazole, or any medication that reduces *Epclusa* effectiveness.
    e. Unmonitored HBV coinfection.

3. *Vosevi* is preferred for all genotypes if relapsed on a completed regimen containing an NS5A inhibitor and for genotypes 1a and 3 if relapsed on a completed regimen containing sofosbuvir. *Vosevi* is considered not medically necessary under the following circumstances:
    a. Relapse due to incomplete regimen.
    b. Moderate or severe hepatic impairment (**ANY** history of decompensation).
    c. Severe renal impairment or end stage renal disease (eGFR <30 mL/min).
    f. Concurrent rifampin, amiodarone, proton pump inhibitor therapy > 20 mg of omeprazole, or any concurrent medication that reduces *Vosevi* effectiveness.
    d. Unmonitored HBV coinfection.

Other products:

All other agents will be considered on a case-by-case basis.

HCA-accepted diagnostic tests and scores to stage liver fibrosis

Metavir Score	Biopsy	Fibroscan	Elastography (ARFI/PSWE)	FibroSure	APRI	Other Imaging
F4	F4	≥ 12.5 kPa	≥ 2.34 m/s	≥ 0.75	≥ 2.0	Cirrhosis
F3	F3	9.6 – 12.4 kPa	2.01 – 2.33 m/s	0.58 – 0.74	1.5 – 1.9	
F2	F2	7.1 – 9.5 kPa	1.38 – 2.0 m/s	0.49 – 0.57	1.0 – 1.4	
F1	F1	≤ 7.0 kPa	≤ 1.37 m/s	0.23 - 0.48	≤ 0.9	
F0	F0			≤ 0.22		

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