Washington Apple Health: Hepatitis C Treatment Policy
(June 13, 2016)

Policy

Washington Apple Health determines medical necessity for the treatment of chronic hepatitis C infection, based on criteria 1-5, except as noted in the "TREATMENT SPECIFIC EXCEPTIONS" section below. Washington Apple Health will approve coverage for all patients with chronic HCV infection regardless of fibrosis scoring.

1. Patient has chronic hepatitis C infection defined by:
    a. a positive (i.e. reactive) HCV antibody test that is at least six months old; **and** has a detectable and quantifiable HCV RNA (> 15 international units/ML) six months after date of positive HCV antibody test; **OR**
    b. two detectable and quantifiable HCV RNA (> 15 international units/ML) tests at least six months apart; **AND**

2. Prescriber is:
    a. a specialist in one of the following areas:
        i. Gastroenterologist
        ii. Hepatologist
        iii. HIV
        iv. Infectious disease; **OR**
    b. Prescriber is participating and consulting with Project ECHO or one of the specialists listed above (requires consultation note or documentation of phone call).
    NOTE: Exceptions may be made for other non-specialist providers who work in coordination with an organized system of care, have received training in hepatitis C diagnosis, staging and treatment protocols, and have ready access to specialists that treat HCV; **AND**

3. Required documentation and lab tests
    a. HCV Antibody test administered at least 6 months before request for treatment
    b. HCV Genotype
    c. HCV RNA Viral Load
        i. At least 6 months after the positive HCV antibody test; or
        ii. Within 6 months prior to the date of request for treatment if liver fibrosis score is F1;
        iii. Within 12 months prior to the date of request for treatment if liver fibrosis score is F2 or greater.
        iv. Diagnostic tests to determine liver fibrosis staging are required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis require longer treatment). Liver staging test results must be less than 2 years old;

v. If patient has cirrhosis must document if patient is compensated, currently decompensated, or has had previous episodes of decompensation.

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 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 transplant (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; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)
    g. Have a MELD < 20[16] 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

5. Retreatment Criteria
    a. Re-treatment with PEG interferon based treatment will be approved based on AASLD guidelines unless listed in the exceptions section above.
    b. Re-treatment after all- DAA regimen:
        i. All cases will be considered individually.
    c. Must provide prior treatment regimen including response and timelines
    d. Lab reports documenting presence or absence of resistant mutations
    e. Medical necessity will be based on expert recommendations that members not be re-treated with a regimen containing a drug they have failed or relapsed on:
    f. Patients having failed a regimen containing an NS3/4A protease inhibitor (boceprevir, telaprevir, simeprevir or paritaprevir) should not be re-treated with a regimen containing one of these agents. Harvoni® (Ledipasvir/sofosbuvir) is suitable for retreatment in such cases unless contraindicated.

QUANTITY AND DISPENSING LIMITS

Patients meeting the criteria above may receive HCV treatment. Approval may be limited to a 14 day supply on the original dispensing and no less than 28 days on each subsequent dispensing. Plans may limit dispensing to a single specialty pharmacy with exceptions for members without stable mailing addresses.

PREFERRED TREATMENT REGIMEN

Harvoni® is the preferred agent and should be used first-line wherever recommended by the current AASLD guidelines, unless there are contraindications to its use.

TREATMENT SPECIFIC EXCEPTIONS

The following drugs require Harvoni® failure (when appropriate)

1. The use of Viekira Pak® (paritaprevir/ritonavir/ombitasvir/dasabuvir) may be considered **medically necessary** to treat patients with the appropriate HCV genotype who do not have moderate to severe liver disease after failure or intolerance to Harvoni® (ledipasvir/sofosbuvir), or if patients creatinine clearance is < 30ml/min.
2. The use of combination Olysio® (simeprevir) and Sovaldi® (sofosbuvir) to treat HCV is considered **not medically necessary**, since there is an equally or more effective less costly alternative, Harvoni® (ledipasvir/sofosbuvir).
3. The use of Daklinza® (daclatasvir) plus Sovaldi® (sofosbuvir) +/- ribavirin may be considered **medically necessary** to treat patients with appropriate HCV genotype after failure of or intolerance to Harvoni® (ledipasvir/sofosbuvir).
4. The use of Technivie® (paritaprevir/ritonavir/ombitasvir) may be considered **medically necessary** to treat patients with the appropriate HCV genotype who do not have moderate to severe liver disease after failure of or intolerance to Harvoni® (ledipasvir/sofosbuvir), or if the CrCl is < 30 ml/min.
5. The use of Zepatier® (elbasvir/grazoprevir) may be considered **medically necessary** to treat patients with the appropriate HCV genotype who do not have without moderate to severe liver disease when ALL of the following criteria have been met:
    a. Documentation of genotype 1a resistance testing showing no NS5A resistance-associated polymorphisms (at amino acid positions 28,30,31, or 93) in treatment naïve and treatment experienced patients; **AND**
    b. The patient tried and failed Harvoni® (ledipasvir/sofosbuvir) therapy is required; **OR**
    c. the patient is NOT a suitable candidate for treatment with Harvoni® (ledipasvir/sofosbuvir) for the following reasons:
        i. CrCl < 30 mL/min; **OR**
        ii. Intolerance to Harvoni® (ledipasvir/sofosbuvir);**AND**
    d. Hepatic testing prior to therapy initiation showed no clinically significant Liver Function Test (ALT) elevations. Hepatic testing should be repeated at 8weeks for a 12 week course of therapy and at 12 weeks for a 16 week course of therapy.

6. Length of Therapy Exceptions

a. Although Harvoni® (ledipasvir/sofosbuvir) was approved by the FDA for a 12-week course of therapy, based on the clinical trials and as noted in the FDA approved label for Harvoni® (ledipasvir/sofosbuvir), an 8-week course may be considered in patients with baseline viral load less than 6 million units/mL.

i. ION-3 excluded patients with cirrhosis and investigated shortening therapy from 12 weeks to 8 weeks (with or without RBV). (Kowdley, 2014) SVR12 rate was 93% to 95% across all arms, with no difference in SVR in the intention-to-treat analysis. However, relapse rates were higher in the 8-week arms (20 of 431) regardless of RBV use compared with the 12-week arm (3 of 216). Post hoc analyses of the 2 RBV-free arms assessed baseline predictors of relapse and identified lower relapse rates in patients receiving 8 weeks of ledipasvir/sofosbuvir who had baseline HCV RNA levels below 6 million IU/mL (2%; 2 of 123), and was the same for patients with similar baseline HCV RNA levels who received 12 weeks (2%; 2 of 131). This analysis was not controlled and thus substantially limits the generalizability of this approach to clinical practice. Shortening treatment to less than 12 weeks for patients without cirrhosis should be done with caution and performed at the discretion of the practitioner.

b. All other deviations from the length of therapy recommended by the AASLD guidelines are considered **investigational.**

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