## Rebecca Buck

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**Sent:** Tuesday, January 31, 2017 8:06 AM
**To:** Jane Kitchel
**Cc:** Gustafson, Cory; Nolan Langweil; McPherson, Darcy; Rebecca Buck
**Subject:** DVHA Response - Guidelines for coverage of hepatitis C treatments
**Attachments:** wa-apple-health-hepatitis-c-clinical-policy.pdf

Senator Kitchel,

On behalf of DVHA, below is information on Drug Effectiveness Review Project (DERP) and guidelines for coverage of hepatitis C treatments.

**What is DERP:**

- DERP is a collaborative of 13 state Medicaid pharmacy programs. Paid membership to DERP allows access to comparative, evidence-based research that assist pharmacy decision-makers with Medicaid drug coverage decisions. DERP focuses on specialty and other high-impact drugs.
- DERP reports evaluate clinical efficacy, effectiveness, and safety of drugs.
- These reports are presented to member states, after which each state presents to its own Pharmacy and Therapeutics Committee (P&T) or Drug Utilization Review Board (DURB).

**Hepatitis C guidelines & experiences from states that participate in DERP:**
Washington:

- DERP provides a comprehensive clinical review but does not make recommendations regarding coverage of the Hep C drugs. It is left up to the states to perform financial impact analysis and devise a recommendation for Medicaid coverage.
- Attached is Washington state Medicaid policy for coverage of hepatitis C treatments.

Idaho:

- DERP provides the participating states with the best clinical evidence and then allows the states to use that evidence to make their own policy decisions – "Globalize the evidence and localize the decision". The participating states have input into what questions the would like DERP to investigate and sometimes the answer comes back that there is no evidence.

**VT Medicaid & Comparative Effectiveness Research:**

- DVHA evaluated whether or not to join the DERP several years ago. Since DVHA currently contracts with its PBM (Change Healthcare) to provide this evidence-based research, it was felt unnecessary and costly to purchase a similar service with DERP.
- Change Healthcare has been doing an excellent job with new drug reviews, as well as providing guidance on specialty and high-impact drug coverage decisions.
- Change Healthcare employs three physicians in the areas of Infectious Disease, Psychiatry, and Hematology/Oncology who provide expertise and present at all of DVHA's DURB meetings.

Thank you,
Lindsay

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# Washington Apple Health: Hepatitis C Treatment Policy (June 17, 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 liver fibrosis score ≥ F1 and a detectable and quantifiable HCV RNA (> 15 international units/ML) tests within the last 12 months; **OR**
    b. a liver fibrosis score < F1; **AND**
        i. 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**
        ii. 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); **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
    d. Laboratory tests (e.g. APRI score or FibroSure) 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;
        i. If patient has cirrhosis must document if patient is compensated, currently decompensated, or has had previous episodes of decompensation.

* Exceptions may be made for other specialties or 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.

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 after failure of an interferon based treatment will be approved based on AASLD guidelines unless listed in the exceptions section below.
    b. Re-treatment after all- DAA regimen:
        i. All cases will be considered individually.
    c. Must provide prior treatment regimen including treatment regimen, length of treatment, response and date of treatment.
    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.

**PREFERRED TREATMENT REGIMEN**

*Harvoni®* is the preferred agent and should be used first-line unless there are contraindications to its use. *Sovaldi®* is the preferred agent for the treatment of HCV genotype 2 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 (Child-Pugh B/C/D) after failure of or intolerance to *Harvoni®* (ledipasvir/sofosbuvir), or if patients creatinine clearance (CrCl) 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 HCV genotype 3.

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 (Child-Pugh B/C/D) 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 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; **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. The patient does NOT have moderate to severe liver disease (Child-Pugh B/C/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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