VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

VIEKIRA

(ombitasvir, paritaprevir, ritonavir, plus dasabuvir)

Effective Date: 1/9/15

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(Archived 1/22/19)

Viekira is a prepackaged combination of an antihepaciviral, NS5A Inhibitor, Antihepaciviral, Polymerase Inhibitor, Antihepaciviral, Protease Inhibitor and Cytochrome P-450 Inhibitor. It is to be prescribed with or without Ribavirin.

Pre-Authorization Criteria:

1. **Chronic Hepatitis C (CHC) Genotype 1.** Approve for the specified duration below if patients meet all of the following criteria (A, B, C, D and E):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient does not have recurrent hepatitis C virus (HCV) post-liver transplantation (see Criteria 2); AND
   - **C)** Viekira Pak is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **D)** **According to the prescribing physician** the patient meets ONE of the following conditions (i, ii, or iii):
     - **i.** The patient has been documented as having a hepatic fibrosis score correlating with **Metavir Stage ≥F2** as assessed by an invasive (liver biopsy) OR non-invasive method (e.g., aspartate aminotransferase-to-platelet ratio index [APRI] score, fibrosis-4 index [FIB-4], FibroScan, FibroTest/FibroSURE); OR
     - **ii.** The patient has **severe extrahepatic manifestations** placing them at high risk for severe complications of their HCV (patient must meet criteria 1 or 2):
       - **(1)** Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis); OR
       - **(2)** Proteinuria, nephrotic syndrome, or membranoproliferative glomerular nephritis; OR
     - **iii.** The patient meets BOTH of the following conditions (1 and 2):
       - **(1)** The patient is at **high-risk of transmitting HCV** (patient must meet ONE of the following criteria a or b):
         - **a.** The patient is on long-term (≥ 3 months) hemodialysis; OR
         - **b.** The patient is a healthcare worker whose daily activities put them in contact with blood and/or needles; AND

(2) The patient has been counseled on ways to decrease transmission of HCV and minimize the risk of reinfection with HCV; AND

E) The patient meets ONE of the following criteria (i or ii):

i. **Approve for 12 weeks** in patients who meet ONE of the following (1 or 2):

(1) The patient has **genotype 1a** and meets ONE of the following criteria (a or b):

a. The patient does not have cirrhosis AND Viekira Pak is prescribed **in combination with ribavirin**; OR

b. The patient has cirrhosis and meets ONE of the following (i, ii, or iii) PLUS iv;

i. The patient has had a prior partial response to HCV therapy; OR

ii. The patient is a prior relapser to HCV therapy; OR

iii. The patient had not previously been treated for HCV (treatment-naïve); AND

iv. Viekira Pak is prescribed **in combination with ribavirin**.

(2) The patient has **genotype 1b** CHC and meets one of the following criteria (a or b):

a. The patient does not have cirrhosis; OR

b. The patient has cirrhosis AND Viekira Pak is prescribed **in combination with ribavirin**.

ii. **Approve for 24 weeks** in patients with **genotype 1a** who meet the following criteria (1, 2, and 3):

(1) The patient has cirrhosis; AND

(2) The patient has had a prior null-response to HCV therapy; AND

(3) Viekira Pak is prescribed **in combination with ribavirin**.

Viekira Pak with or without ribavirin (R) is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. The recommended dosing for Viekira Pak in patients with genotype 1a without cirrhosis or genotype 1b with cirrhosis is Viekira Pak in combination with weight-based ribavirin (WBR) for 12 weeks. The recommended dosing for patients with genotype 1b without cirrhosis is Viekira Pak (without WBR) for 12 weeks. The recommended dosing for patients with genotype 1a with cirrhosis is Viekira Pak in combination with WBR for 24 weeks; 12 week dosing may be considered for some patients based on prior treatment history. Patients with genotype 1a and cirrhosis and a prior null response to HCV therapy had a lower response with Viekira Pak + WBR when treated for 12 vs. 24 weeks in the TURQUOISE II trial. The response rates in patients in other populations from TURQUOISE II were similar between 12 and 24 weeks of Viekira Pak + WBR therapy.

2. **Recurrent HCV Post-Liver Transplantation Genotype 1.** Approve for 24 weeks in patients who meet the following criteria (A, B, C and D):

A) The patient is ≥ 18 years of age; AND

B) The patient has recurrent HCV after a liver transplantation; AND

C) Viekira Pak is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center[2]: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND;

D) Viekira Pak is prescribed in combination with ribavirin.

Exceptions: Treatment of Hepatitis C is considered inappropriate in patients with a limited life expectancy of less than 12 months. Use of Viekira is not recommended in patients with moderate to severe hepatic impairment (Child-Pugh class B or C). Viekira is to be avoided in HIV/HCV-coinfected patients who are not receiving HIV antiretroviral therapy.

Reauthorization/Continuation of Therapy Criteria:
1 month follow up hepatitis C virus-RNA level has decreased to non-detectable or decreased significantly. Evidence of lack of adherence or missed medical appointments may result in denial of treatment reauthorization.

Medication Guide or RX restrictions:
An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication:
Viekira Pak: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM467825.pdf

Dosing:
Chronic hepatitis C: Oral: **Note:** Regimen is a copackaged product; ombitasvir, paritaprevir, and ritonavir are a fixed-dose combination tablet; dasabuvir is an individual tablet.
Missed doses: May administer a missed dose if within 6 hours of regularly scheduled time (dasabuvir) or within 12 hours of regularly scheduled time (ombitasvir, paritaprevir, ritonavir). Otherwise, skip missed dose and resume at next scheduled time.
Genotype 1a, without cirrhosis (used with concomitant ribavirin):
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 12 weeks
Dasabuvir: 250 mg twice daily for 12 weeks
Genotype 1a, with cirrhosis (used with concomitant ribavirin):
Note: Based on prior treatment history, some patients may be considered for a duration of therapy of 12 weeks.
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 24 weeks
Dasabuvir: 250 mg twice daily for 24 weeks
Genotype 1b, without cirrhosis:
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 12 weeks
Dasabuvir: 250 mg twice daily for 12 weeks
Genotype 1b, with cirrhosis (used with concomitant ribavirin):
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 12 weeks
Dasabuvir: 250 mg twice daily for 12 weeks
Genotype 1 (unknown subtype) or Genotype 1 (mixed infection) without cirrhosis (used with concomitant ribavirin):
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 12 weeks
Dasabuvir: 250 mg twice daily for 12 weeks

Genotype 1 (unknown subtype) or Genotype 1 (mixed infection) with cirrhosis (used with concomitant ribavirin):
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 24 weeks
Dasabuvir: 250 mg twice daily for 24 weeks
Genotype 1, liver transplant recipients, Metavir fibrosis score ≤2 (normal hepatic function, mild fibrosis) (regardless of genotype 1 subtype; used with concomitant ribavirin): **Note:** If calcineurin inhibitor used concomitantly, calcineurin inhibitor dosage adjustment is needed.
Ombitasvir/paritaprevir/ritonavir tablet: Two tablets every morning for 24 weeks
Dasabuvir: 250 mg twice daily for 24 weeks

Dosing Forms:
Combination package:
Viekira Pak [28 day supply]: Tablet, oral: Ombitasvir 12.5mg, paritaprevir 75 mg, and ritonavir 50 mg
Tablet, oral: Dasabuvir 250 mg

Major Adverse reactions, warnings, contraindications:
Can cause serious hepatic injury mostly in patients with underlying advanced hepatic disease. Monitor for worsening liver disease such as ascites, hepatic encephalopathy, variceal hemorrhage, and/or increases in direct bilirubin.
Other significant reactions include fatigue, headache, insomnia, dermatitis, diarrhea, nausea, decreased hemoglobin, increased bilirubin, weakness, muscle spasm, cough.

References:
Department of Health Care Services, Treatment Policy for the Management of Chronic Hepatitis C, July 1, 2015.
UpToDate Drug Information Ombitasvir, paritaprevir, ritonavir, plus dasabuvir, 2016.
American Association of the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), "Recommendations fo Testing, Managing, and Treating Hepatitis C" found at http://www.hcvguidelines.org/full-report-view.

Policy by Dr. Catherine R. Sanders, MD and Robert Sterling, MD

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