UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1150-8
Program	Prior Authorization/Notification
Medication	Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
P&T Approval Date	12/2014, 2/2015, 2/2016, 8/2016, 4/2018, 2/2019, 2/2020, 2/2021
Effective Date	5/1/2021; Oxford only: N/A

1. Background:

Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):

- genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin
- genotype 1b without cirrhosis or with compensated cirrhosis

Viekira Pak includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.[1, 2]

2. Coverage Criteria:

A. For the treatment of chronic hepatitis C genotype 1a or mixed genotype 1 infection in patients without cirrhosis and not post liver transplant, **Viekira Pak** will be approved based on the following criteria:

1. **Viekira Pak** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection

   -AND-

   b. Used in combination with ribavirin

   -AND-

   c. Patient is without cirrhosis

   -AND-

   d. Patient has not experienced failure with Viekira, Sovaldi (sofosbuvir) or a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

-AND-

e. Patient is not receiving Viekira Pak in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir)]

Authorization will be issued for 12 weeks.

B. For the treatment of chronic hepatitis C genotype 1a or mixed genotype 1 infection in patients with compensated cirrhosis and who are treatment naïve or treatment experienced with a prior relapse to interferon-based therapy and not post liver transplant, **Viekira Pak** will be approved based on the following criteria:

1. **Viekira Pak** will be approved based on **all** of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection

-AND-

b. Used in combination with ribavirin

-AND-

c. **One** of the following:

i. Patient is treatment-naive

ii. Patient is a previous relapser to interferon-based therapy

-AND-

d. Patient has compensated cirrhosis (e.g., Child-Pugh A)

-AND-

e. Patient is without decompensated liver disease (e.g., Child-Pugh B or C)

-AND-

f. Patient has not experienced failure with Viekira, Sovaldi (sofosbuvir) or a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

-AND-

g. Patient is not receiving Viekira Pak in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir)]

Authorization will be issued for 12 weeks.

C. For the treatment of chronic hepatitis C genotype 1a or mixed genotype 1 infection in patients with compensated cirrhosis and who are treatment experienced with a prior partial response or null response to interferon-based therapy and not post liver transplant, **Viekira Pak** will be approved based on the following criteria:

1. **Viekira Pak** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection

   -AND-

   b. Used in combination with ribavirin

   -AND-

   c. **One** of the following:

      i. Patient is a previous partial responder to interferon-based therapy

      ii. Patient is a previous null responder to interferon-based therapy

   -AND-

   d. Patient has compensated cirrhosis (e.g., Child-Pugh A)

   -AND-

   e. Patient is without decompensated liver disease (e.g., Child-Pugh B or C)

   -AND-

   f. Patient has not experienced failure with Viekira, Sovaldi (sofosbuvir) or a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

   -AND-

   g. Patient is not receiving Viekira Pak in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir)]

Authorization will be issued for 24 weeks.

D. For the treatment of chronic hepatitis C genotype 1b infection in patients who are without cirrhosis or have compensated cirrhosis and not post liver transplant, **Viekira Pak** will be approved based on the following criteria:

1. **Viekira Pak** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1b infection

   -AND-

   b. **One** of the following:

      (1) Patient is without cirrhosis

      (2) Patient has compensated cirrhosis (e.g., Child-Pugh A)

   -AND-

   c. Patient has not experienced failure with Viekira, Sovaldi (sofosbuvir) or a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

   -AND-

   d. Patient is not receiving Viekira Pak in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir)]

Authorization will be issued for 12 weeks.

E. For the treatment of chronic hepatitis C genotype 1 infection regardless of subtype in patients without cirrhosis and are post liver transplant, **Viekira Pak** will be approved based on the following criteria:

1. **Viekira Pak** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1 infection following liver transplantation

   -AND-

   b. Patient has mild fibrosis (e.g., Metavir fibrosis score less than or equal to F2)

   -AND-

   c. Used in combination with ribavirin

   -AND-

   d. Patient is not receiving Viekira Pak in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir)]

Authorization will be issued for 24 weeks.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply Limits, step therapy and medical necessity may be in place.

4. References:

1. Viekira Pak [package insert]. North Chicago, IL: AbbVie, Inc.; December 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed January 9, 2021.

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Change Control	
12/2014	New program.
2/2015	Review alignment.
2/2016	Annual review with no clinical changes. References update.
8/2016	Added Viekira XR to the program.
4/2018	Updated criteria for chronic hepatitis C genotype 1b to align with label, removing requirement of concomitant ribavirin in patients with compensated cirrhosis.
2/2019	Removed Viekira XR based on market withdrawal.
2/2020	Annual review. Added clarification to coverage criteria, with no change to clinical intent.
2/2021	Annual review with no changes to coverage criteria. Updated references.