UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1150-11
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, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

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]:

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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 December 22, 2023.

Program	Prior Authorization/Notification - Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
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.
2/2022	Annual review with no changes to coverage criteria. Updated references.
2/2023	Annual review with no changes to coverage criteria. Added state mandate and updated references.
2/2024	Annual review with no changes to coverage criteria.