UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2054-14
Program	Prior Authorization/Medical Necessity
Medication	Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
P&T Approval Date	4/2015, 11/2015, 8/2016, 12/2016, 9/2017, 11/2018, 2/2019, 3/2020, 5/2021, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

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. Coverage Criteria[a]:

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

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

-AND-

2. Patient is not post liver transplant

-AND-

3. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

4. Used in combination with ribavirin

-AND-

5. **One** of the following:

a. Patient is without cirrhosis

-OR-

b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

7. 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-

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

-AND-

9. **One** of the following:

a. **All** of the following:

(1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-AND-

(2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

-AND-

(3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-AND-

(4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

-OR-

b. Patient is currently on Viekira Pak therapy

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 **all** of the following criteria:

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

-AND-

2. Patient is not post liver transplant

-AND-

3. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

4. **One** of the following:

   a. Patient is treatment-naïve

   -OR-

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

-AND-

5. Used in combination with ribavirin

-AND-

6. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

7. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

8. 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-

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

-AND-

10. **One** of the following:

    a. **All** of the following:

        (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

        -AND-

        (2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

        -AND-

        (3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

        -AND-

        (4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

        -OR-

    b. Patient is currently on Viekira Pak therapy

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 **all** of the following criteria:

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

-AND-

2. Patient is not post liver transplant

-AND-

3. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

4. **One** of the following:

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

   -OR-

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

-AND-

5. Used in combination with ribavirin

-AND-

6. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

7. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

8. 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-

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

-AND-

10. **One** of the following:

    a. **All** of the following:

       (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir)

therapy

-AND-

(2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

-AND-

(3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-AND-

(4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

-OR-

b. Patient is currently on Viekira Pak therapy

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 **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1b infection

-AND-

2. Patient is not post liver transplant

-AND-

3. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

4. **One** of the following:

a. Patient is without cirrhosis

-OR-

b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. 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-

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

-AND-

8. **One** of the following:

   a. **All** of the following:

      (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

      -AND-

      (2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

      -AND-

      (3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

      -AND-

      (4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

      -OR-

   b. Patient is currently on Viekira Pak therapy

Authorization will be issued for 12 weeks.

E. For the treatment of chronic hepatitis C genotype 1 infection regardless of subgenotype in

patients who are without cirrhosis or have compensated cirrhosis and a liver transplant recipient, **Viekira Pak** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient is a liver transplant recipient

-AND-

3. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

4. Used in combination with ribavirin

-AND-

5. **One** of the following:

   a. Patient is without cirrhosis

   -OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

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

-AND-

8. **One** of the following:

   a. **All** of the following:

      (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-AND-

(2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

-AND-

(3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-OR-

b. Patient is currently on Viekira Pak therapy

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 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 April 3, 2023.

Program	Prior Authorization/Medical Necessity – Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
Change Control	
4/2015	Coverage requirement for State of New Jersey effective 5/18/2015.
9/2015	Administrative change, Oxford New Jersey effective date reference added onto separate line.
11/2015	Changed program title to include all lines of business and updated language regarding documentation of liver fibrosis.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Added Epclusa to step therapy requirement; added Viekira XR to program.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria.

9/2017	Revised step therapy criteria based on new product availability, included NY prescriber requirement, removed treatment readiness screening tools and removed medical record submission requirements.
11/2018	Annual review with no changes to the criteria. Updated references.
2/2019	Removed Viekira XR due to market withdrawal. Revised step therapy requirement to include Zepatier. Updated references.
3/2020	Annual review. Clarification to compensated cirrhosis to match label. Updated background and references.
5/2021	Removed prescriber requirement. Updated references.
5/2022	Added requirement of not being post liver transplant in sections A-D. Updated references.
5/2023	Annual review. Updated references.