PRIOR AUTHORIZATION POLICY

POLICY: Hepatitis C – Viekira Pak Prior Authorization Policy
- Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets [co-packaged] – AbbVie)

REVIEW DATE: 09/02/2020

OVERVIEW

Viekira Pak is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV).[1] Viekira Pak is indicated in patients with genotype 1b without cirrhosis or with compensated cirrhosis or with genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. Viekira Pak contains ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, ritonavir, a cytochrome P450 (CYP)3A inhibitor and dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor.

The recommended dose of Viekira Pak is two co-formulated ombitasvir/paritaprevir/ritonavir tablets once daily (in the morning) and one dasabuvir tablet twice daily (morning and evening). When administered with Viekira Pak, the recommended dose of ribavirin is weight-based. For patients with HCV/human immunodeficiency virus (HIV)-1 co-infection the recommendations are the same as for those without co-infection. Of note, product labeling notes that some patients with genotype 1a with cirrhosis may be treated for 12 weeks with Viekira Pak + weight-based ribavirin based on data from the TURQUOISE-II trial. In liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤ 2) the recommended duration of therapy with Viekira Pak is 24 weeks, irrespective of HCV genotype 1 subtype.

Table 1. FDA-Approved Regimens and Treatment Duration for Viekira Pak.[1,5]

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira Pak + WBR	12 weeks
Genotype 1a, with cirrhosis	Viekira Pak + WBR	24 weeks**
Genotype 1b, with or without cirrhosis	Viekira Pak	12 weeks

* Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection; WBR – Weight-based ribavirin; ** A 12 week treatment duration may be considered for some patients based on prior treatment history.

Guidelines

Viekira Pak is not addressed in the American Association for the Study of Liver Diseases (AASLD) Guidelines recommended (or alternative) regimens are detailed in the Hepatitis C Virus Direct-Acting Antivirals Therapy Class Summary.[2] Viekira Pak is only recognized in the guidelines as not recommended for use in patients with decompensated cirrhosis (Child-Pugh B or C).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Viekira Pak. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Viekira Pak as well as the monitoring required for adverse events and efficacy, approval requires Viekira Pak to be prescribed by or in consultation with a physician who specialized in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Viekira Pak is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1a.** Approve for the duration noted if the patient meets the following criteria (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed in combination with ribavirin; AND
   - **C)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient does not have cirrhosis: Approve for 12 weeks; OR
     - **ii.** Patient has cirrhosis: Approve for 24 weeks; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 1b.** Approve for 12 weeks if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

3. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1.** Approve for 24 weeks if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Viekira Pak is prescribed in combination with ribavirin; 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.

4. **Patient Has Been Started on Viekira Pak.** Approve Viekira Pak for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course of therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Viekira Pak is not recommended in the following situations:

1. **Hepatitis C Virus (HCV), Child-Pugh Class B or Child-Pugh Class C Liver Disease (Moderate or Severe Hepatic Impairment).** Viekira Pak is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh Class B or C).[1] The AASLD recommend *against* the use of Viekira Pak in patients with chronic hepatitis C virus (HCV) with decompensated cirrhosis (Child-Pugh Class B or C). On October 22, 2015 the FDA issued a safety communication about the risk of serious liver injury when Viekira Pak or Technivie® (paritaprevir/ritonavir/ombitasvir tablets) are used in patients with moderate or severe hepatic impairment.[3] Hepatic decompensation and liver failure in patients with underlying liver cirrhosis have been reported with the use of Viekira Pak and Technivie. Some of these events have resulted in liver transplant or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment. Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to the FDA Adverse Event Reporting System (FAERS) were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended. Among these 26 cases 5 were reported in the US.[4]

2. **Hepatitis C Virus (HCV) [Any Genotype], Combination with Any Other Direct-Acting Antivirals (DAAs) Not Including Ribavirin.** Viekira Pak provide a complete antiviral regimen for patients with genotype 1 HCV. Viekira Pak is indicated with ribavirin for some patients. In the opinion of a specialist physician reviewing the data we have adopted this criterion.

3. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment.[2] According to AASLD guidance, the panel continues to recommend treatment for all patients with chronic HCV infection, *except* those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

5. **Pediatric Patients (Age < 18 Years).** The safety and efficacy of Viekira Pak have not been established in pediatric patients < 18 years of age.[1]

6. **Retreatment with Viekira Pak in Patients Who Have Previously Received Viekira Pak, Viekira XR, or Technivie** (e.g., retreatment in prior null responders, prior partial responders, prior relapse patients, patients who have not completed a course of therapy due to an adverse reaction or for other reasons). Technivie, Viekira Pak, and Viekira XR contain the same active ingredients; Viekira Pak and Viekira XR additionally contain dasabuvir.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Viekira Pak™ tablets [prescribing information]. North Chicago, IL: AbbVie, Inc.; December 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated November 6, 2019. Accessed on August 24, 2020.
3. Food and Drug Administration (FDA). FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie. October 22, 2015. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm. Accessed on August 24, 2020.
4. Zeuzem S, Jacobson IM, Baykal T, et al. Retreatment of HCV with ABT-450/r-ombitasvir and dasabuvir with ribavirin. *N Engl J Med*. 2014;370:1604-1614.