MEDICAL MUTUAL®

Drug Policy

Policy:	Viekira PAK (ombitasvir/paritaprevir/ritonavir; dasabuvir tablets, co-packaged)	Annual Review Date: 11/16/2023 Last Revised Date: 11/16/2023

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).

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POLICY STATEMENT

This policy involves the use of Viekira. Prior authorization is recommended for pharmacy benefit coverage of Viekira. Criteria are based on the guidance issued by American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)/International Antiviral Society-USA (IAS-USA), prescribing information, clinical data, and expert review. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Viekira as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Viekira be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Viekira 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)** The medication is prescribed in combination with ribavirin; AND
   - **C)** The medication 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).

Approval. See above criteria.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Viekira has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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).

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.

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

5. **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.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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