DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir fixed dose combination tablets copackaged with dasabuvir tablets – AbbVie)
Duration Limit

DATE REVIEWED: 08/03/2021

OVERVIEW

Viekira Pak is indicated with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) infection.[1] Viekira Pak is an all-oral combination antiviral treatment regimen composed of the nucleotide analog non-serine NS5A protease inhibitor ombitasvir coformulated with the ritonavir-boosted NS3/4A protease inhibitor paritaprevir (ritonavir is a cytochrome P450 (CYP)3A inhibitor), and these work together with the copackaged separate tablet of the non-nucleoside NS5B palm polymerase inhibitor dasabuvir. The efficacy of Viekira has been established, and Viekira is FDA-labeled for use in patients with hepatitis C virus (HCV) genotype 1 infection, including those with compensated cirrhosis. Viekira Pak is used with or without ribavirin for certain patient populations.

The current web-based treatment recommendations by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in collaboration with the International Antiviral Society–USA (IAS–USA) provide guidance for treating patients and give recommendations regarding patients who are most in need of immediate therapy.[3] Consult the guidance for the most up-to-date information.

This Drug Quantity Management Policy has been developed to complement the coverage provided by *Express Scripts Viekira Prior Authorization Policy*. Consult the *Express Scripts Hepatitis C - Viekira Prior Authorization Policy* for detailed information about evidence-supported approved treatment regimens and durations.[2]

Viekira Pak Maximum quantity per 365 days = Three treatment packs (112 tablets = one treatment pack per 28 days)

Viekira is available as a 28-day treatment pack that contains 112 tablets. At minimum, each patient will take 4 tablets per day: two combination tablets, taken together once daily in the morning to provide a **total** dose of 25 mg ombitasvir, 150 mg paritaprevir, and 100 mg ritonavir and two tablets of dasabuvir (250 mg each, taken twice daily, one in the morning and one in the evening). The pack does not contain ribavirin, but ribavirin should also be taken in combination with Viekira Pak for some patient populations. The recommended regimen and treatment duration for Viekira combination therapy is provided in Table 1 and is based on HCV genotype 1 subtype as well as whether the patient has cirrhosis.

Table 1. FDA-Approved Regimens and Treatment Duration for Viekira Combination Therapy[1]

	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira Pak + ribavirin	12 weeks
Genotype 1a, with cirrhosis	Viekira Pak + ribavirin	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.
**A 12 week treatment duration may be considered for some patients based on prior treatment

Viekira was studied in patients with HCV/human immunodeficiency virus (HIV)-1 co-infection and recommended treatment regimens and durations are the same as listed in Table 1 above for this patient population. In patients who have undergone liver transplantation, the recommended duration of Viekira Pak in combination with ribavirin is 24 weeks regardless of HCV genotype 1 subtype.

A quantity of three Viekira Paks per 365 days will be covered without prior authorization. This is enough drug for patients to complete a 12 week course of therapy. For coverage of additional quantities (for example, a 24 week regimen), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for indications covered by the *Express Scripts Hepatitis C - Viekira Prior Authorization Policy*.[2]

CRITERIA

1. **Chronic Hepatitis C Virus (HCV) Genotype 1. Approve 12 weeks/three additional fills** (24 weeks total duration = Viekira Pak: six treatment packs/672 tablets per 365 days) IF prior to taking Viekira , (i, and ii):
   - **i.** The patient has **genotype 1a**
   - **ii.** The patient had cirrhosis
2. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1. Approve 12 weeks/three additional fills** (24 weeks total duration = Viekira Pak: six treatment packs/672 tablets per 365 days).
3. **Patient Has Been Started on Viekira (brand or generic).** For an indication or condition addressed as an approval in the above criteria section, approve the duration described above to complete a course 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).

REFERENCES

1. Viekira Pak™ [prescribing information]. North Chicago, IL: AbbVie, Inc.; December 2019.
2. Hepatitis C - Viekira Pak prior authorization policy. Express Scripts, Inc. Updated 09/02/2020.
3. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Updated November 6, 2019. Accessed August 31, 2020.