



# Louisiana

## **Treatment of Hepatitis C with ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak™/Viekira XR™)**

**Policy #** 00462

**Original Effective Date:** 02/18/2015

**Current Effective Date:** 12/14/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Treatment of Hepatitis C with Dual Therapy (Ribavirin Plus Pegylated Interferon Alfa) is addressed separately in medical policy 00374.*

*Note: Pegylated Interferons (Pegasys® , PegIntron®) ‡ for Other (Non-Hepatitis C) Uses is addressed separately in medical policy 00375.*

*Note: Treatment of Hepatitis C with a sofosbuvir (Sovaldi®) ‡ Based Regimen is addressed separately in medical policy 00397.*

*Note: Treatment of Hepatitis C with sofosbuvir/ledipasvir (Harvoni®) ‡, Authorized Generic) is addressed separately in medical policy 00455.*

*Note: Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie®) ‡ is addressed separately in medical policy 00478*

*Note: Treatment of Hepatitis C with daclatasvir (Daklinza™) ‡ and sofosbuvir (Sovaldi®) ‡ is addressed separately in medical policy 00479.*

*Note: Treatment of Hepatitis C with elbasvir and grazoprevir (Zepatier™) ‡ is addressed separately in medical policy 00509.*

*Note: Treatment of Hepatitis C with sofosbuvir and velpatasvir (Epclusa®) ‡, Authorized Generic) is addressed separately in medical policy 00514.*

*Note: Treatment of Hepatitis C with glecaprevir/pibrentasvir (Mavyret™) ‡ is addressed separately in medical policy 00593.*

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*Note: Treatment of Hepatitis C with sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)‡ is addressed separately in medical policy 00594.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### Chronic Hepatitis C Virus

Based on review of available data, the Company may consider ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak™/Viekira XR™)‡ for the treatment of individuals with chronic hepatitis C virus (HCV) to be **eligible for coverage**.\*\*

### Patient Selection Criteria

Based on review of available data, the Company may consider ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak/Viekira XR) when ALL of the following criteria are met:

- Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 1; AND
- Patient does NOT have decompensated cirrhosis; AND
- Patient has NOT received prior therapy with a protease inhibitor (e.g., Olysio, Incivek, Victrelis); AND
- Patient has NOT received prior therapy with a sofosbuvir containing regimen (e.g., Sovaldi, Harvoni, Epclusa, Vosevi, or their authorized generics); AND
- Patient will take Viekira Pak/Viekira XR with or without ribavirin as noted below in the chart; AND
- There is clinical evidence or patient history that suggests the use of sofosbuvir/velpatasvir (Epclusa), sofosbuvir/ledipasvir (Harvoni), or glecaprevir/pibrentasvir (Mavyret) will be ineffective or will cause an adverse reaction to the patient; AND

*Note that failure to meet this criterion, which is an additional company requirement, will result in a denial of not medically necessary\*\**

- Patient meets the following definitions and adheres to the timeframes for treatment:

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Patient Population	Drugs	Duration
Genotype 1a withOUT cirrhosis	Viekira Pak/Viekira XR PLUS ribavirin	12 weeks
Genotype 1a with cirrhosis (treatment naïve, prior relapser, prior partial responder)	Viekira Pak/Viekira XR PLUS ribavirin	12 weeks**
Genotype 1a with cirrhosis (prior null responder)	Viekira Pak/Viekira XR PLUS ribavirin	24 weeks
Genotype 1b, withOUT cirrhosis	Viekira Pak/Viekira XR only	12 weeks
Genotype 1b with cirrhosis	Viekira Pak PLUS ribavirin OR Viekira XR only	12 weeks
Genotype 1 liver transplant recipient with normal hepatic function and mild fibrosis (Metavir ≤2)	Viekira Pak/Viekira XR PLUS ribavirin	24 weeks

*\*\*This will be denied as not medically necessary if 24 weeks is requested. See package insert for more info.\*\**

### Chart Definitions

#### Cirrhotic:

- Metavir Stage 4; OR
- Ishak score of 5 or 6; OR
- FibroTest/FibroSure score of more than 0.75; OR
- APRI of greater than 2; OR
- FibroScan results greater than 12.5kPA

## **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak/Viekira XR) in the absence of clinical evidence or patient history that suggests the use of sofosbuvir/velpatasvir (Epclusa), sofosbuvir/ledipasvir (Harvoni), or glecaprevir/pibrentasvir (Mavyret) will be ineffective or will cause an adverse reaction to the patient to be **not medically necessary**.\*\*

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Based on review of available data, the Company considers the use of ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak/Viekira XR) for a genotype 1a, cirrhotic patient that is treatment naïve, a prior relapser, or a prior partial responder for more than 12 weeks of treatment to be **not medically necessary**.\*\*

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak/ Viekira XR) for the treatment of individuals with chronic hepatitis C virus (HCV) when patient selection criteria are not met (with the exception of those denoted in the patient selection criteria above as **not medically necessary**\*\*\*) to be **investigational**.\*

## Background/Overview

Viekira Pak and Viekira XR contain 4 ingredients. Ombitasvir is a HCV NS5A inhibitor, paritaprevir is a hepatitis C virus NS3/4A protease inhibitor, ritonavir is a CYP3A inhibitor, and dasabuvir is a HCV non-nucleoside NS5B palm polymerase inhibitor. Viekira Pak/ Viekira XR are both indicated for the treatment of patients with genotype 1 chronic HCV infection, including those with compensated cirrhosis. This product also carries an indication for HIV/HCV co-infection. Viekira Pak and Viekira XR need to be used in combination with ribavirin in most of its indications.

### Hepatitis C

Hepatitis C is the most common blood borne pathogen. In the US, there are approximately 3.2 million people chronically infected with hepatitis C. Hepatitis C, a single-stranded ribonucleic acid (RNA) virus, is genetically complex with several recognized genotypes. Genotypes 1, 2, and 3 are the most frequently encountered genotypes worldwide. Type 1a is most frequently found in Northern Europe and North America, while 1b is most common in Japan and Southern and Eastern Europe.

Drug regimens have evolved quite a bit over the past few years in this class. It is beyond the scope of this policy to delve into the entire timeline of approvals, however a brief overview will provide an idea of the evolution of these drugs. The earlier regimens contained ribavirin and

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interferon/pegylated interferons. The next wave of products brought NS3/4A protease inhibitors to market such as Incivek and Victrelis. After that, an NS5B polymerase inhibitor was approved (Sovaldi). Following the release of Sovaldi, a drug was approved that contained a combination NS5A inhibitor and NS5B polymerase inhibitor combination (Harvoni). Drugs approved up until that point in time mainly treated genotype 1 hepatitis C virus. After these drugs were approved, a multitude of other drugs were approved (Viekira/XR, Zepatier, Daklinza, etc). As drugs continue to be FDA approved in this space, the range of genotypes that can be treated increases. The latest wave of drugs includes pangenotypic products such as Epclusa, Mavyret, and Vosevi. For more information on each individual drug, please see the product's package insert or refer to their respective medical policy.

Viekira Pak and Viekira XR have been integrated into the AASLD (American Association for the Study of Liver Diseases) guidelines in various scenarios for the treatment of HCV, however it should be noted that these guidelines are receiving constant updates as new products are approved.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Viekira Pak was approved in late 2014 for the treatment of patients with genotype 1 chronic hepatitis C virus infection, including those with compensated cirrhosis. Viekira XR was approved in mid-2016 for the same indication.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy and safety of Viekira Pak was evaluated in six randomized, multicenter, clinical trials in 2,308 subjects with genotype 1 chronic HCV infection.

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### **Subjects with Chronic HCV GT1a Infection without Cirrhosis**

Subjects with chronic hepatitis C virus genotype 1a infection without cirrhosis were treated with Viekira Pak with ribavirin for 12 weeks in SAPPHIRE-I and -II and in PEARL-IV. The overall SVR12 in SAPPHIRE-I was 96%, PEARL-IV was 97% and SAPPHIRE-II was 96%.

### **Subjects with Chronic HCV GT1b Infection without Cirrhosis**

Subjects with chronic HCV genotype 1b infection without cirrhosis were treated with Viekira Pak with or without ribavirin for 12 weeks in PEARL-II and -III. The SVR rate for HCV genotype 1b infected subjects without cirrhosis treated with Viekira Pak without RBV for 12 weeks in PEARL-II and PEARL-III was 100%.

### **Subjects with Chronic HCV GT1a or GT1b Infection with Cirrhosis**

TURQUOISE-II was an open-label trial that enrolled 380 chronic HCV genotype 1a and 1b-infected subjects with cirrhosis and mild hepatic impairment (Child-Pugh A) who were either treatment-naïve or did not achieve SVR with prior treatment with peginterferon/ribavirin. Subjects were randomized to receive Viekira Pak in combination with ribavirin for either 12 or 24 weeks of treatment. The overall SVR in those patients with genotype 1b was 99% in the 12 week group. The overall SVR in patients with genotype 1a was 95% in the 24 week treatment group vs. 89% in the 12 week treatment group. If the treatment experienced patients are broken out and examined, there was a 100% SVR in the partial responders for 12 weeks of treatment (11/11), 93% in the relapsers (14/15), and 80% in the null responders (40/50). In the 24 week group, the partial responders had a 100% SVR (10/10), the relapsers had a 100% SVR (13/13), and the null responders had a 93% SVR (39/42). This data shows that the 24 week regimen is more appropriate than the 12 week regimen for those with genotype 1a and cirrhosis that were prior null responders. Based on the 12 week data, the package insert states that 12 weeks may be considered based on prior treatment history.

### **Select Liver Transplant Recipients OR HIV/HCV Co-infection**

Viekira Pak with ribavirin was administered for 24 weeks to 34 chronic HCV genotype 1-infected liver transplant recipients who were at least 12 months post transplantation at enrollment with normal hepatic function and mild fibrosis (Metavir fibrosis score F2 or lower). The initial dose of ribavirin was left to the discretion of the investigator with 600 to 800 mg per day being the most frequently selected dose range at initiation of Viekira Pak and at the end of treatment. Of the 34 subjects (29 with genotype 1a infection and 5 with genotype 1b infection) enrolled, (97%) achieved SVR12 (97%

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in subjects with GT1a infection and 100% of subjects with GT1b infection). One subject with HCV GT1a infection relapsed post-treatment.

In an open-label clinical trial 63 subjects with chronic HCV genotype 1 infection co-infected with HIV-1 were treated for 12 or 24 weeks with Viekira Pak in combination with ribavirin. Subjects were on a stable HIV-1 antiretroviral therapy (ART) regimen that included tenofovir disoproxil fumarate plus emtricitabine or lamivudine, administered with ritonavir boosted atazanavir or raltegravir. The SVR12 rates were 91% (51/56) for subjects with genotype 1a infection and 100% (7/7) for those with genotype 1b infection. Of the 5 subjects who were non-responders, 1 experienced virologic breakthrough, 1 discontinued treatment, 1 experienced relapse and 2 subjects had evidence of HCV re-infection post-treatment. One subject had confirmed HIV-1 RNA >400 copies/mL during the post-treatment period. This subject had no evidence of resistance to the ART regimen. No subjects switched their ART regimen due to loss of plasma HIV-1 RNA suppression.

## References

1. Viekira Pak [package insert]. Abbvie Inc., North Chicago, Illinois. Updated December 2014.
2. Viekira XR [package insert]. Abbvie Inc., North Chicago, Illinois. Updated July 2016.
3. Recommendations for Testing, Managing, and Treating Hepatitis C. American Association for the Study of liver diseases. Updated September 2017.

## Policy History

Original Effective Date: 02/18/2015

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- 02/05/2015 Medical Policy Committee review
- 02/18/2015 Medical Policy Implementation Committee approval. New policy.
- 02/04/2016 Medical Policy Committee review
- 02/17/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 02/02/2017 Medical Policy Committee review
- 02/15/2017 Medical Policy Implementation Committee approval. Integrated the new dosage form (Viekira XR) into the medical policy.
- 11/02/2017 Medical Policy Committee review

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- 11/15/2017 Medical Policy Implementation Committee approval. Changed from Harvoni first to Epclusa, Harvoni, or Mavyret first. Updated background info.
  - 11/08/2018 Medical Policy Committee review
  - 11/21/2018 Medical Policy Implementation Committee approval. No change to coverage.
  - 11/07/2019 Medical Policy Committee review
  - 11/13/2019 Medical Policy Implementation Committee approval. Updated the policy referral section to include mention of the authorized generics in the policy titles for Harvoni and Epclusa. Removed reference to policies 00373, 00396, and 00457 as they are retired.
  - 11/05/2020 Medical Policy Committee review
  - 11/11/2020 Medical Policy Implementation Committee approval. No change to coverage.
- Next Scheduled Review Date: 11/2021

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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