New York State Medicaid Preferred Drug Program Fax Number: (800) 268-2990

Viekira Pak™ and Viekira XR™ Prior Authorization Worksheet

| Enrollee Information | | |
| --- | --- | --- |
| enrollee Name: | | |
| enrollee medicaid Id number (2 letters, 5 numbers, 1 letter): | enrollee date of birth: | gender:  Female Male |

| Prescriber Information | | |
| --- | --- | --- |
| prescriber Name: | | |
| Contact person: | | |
| 10-digit Npi number: | office Phone Number:  (     )      - | office Fax number:  (     )     - |
| Are you a gastroenterologist, hepatologist, transplant physician or infectious disease specialist?  Yes  No | | |
| If no, are you working in collaboration with a specialist listed above?  Yes  No | | |
| If no, do you have clinical experience with the management and treatment of hepatitis c virus (HCV) infection?  Yes  No  *Clinical experience is defined as the management AND treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months.* | | |

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| Clinical Criteria |
| MEDICAL STATUS |
| Diagnosis (Please check all that apply):  Chronic Hepatitis C Infection  Yes  No  HCV Genotype:  1a 1b  Has documentation confirming genotype been submitted?  Yes  No  Has the patient had a baseline quantitative HCV RNA level completed?  Yes  No  Baseline quantitative HCV RNA       IU/mL Date completed:  Has the patient had hepatic laboratory testing including direct bilirubin levels completed at baseline?  Yes  No  Does the patient have moderate (Child-Pugh B) to severe hepatic impairment (Child-Pugh C)?  Yes  No  *(Viekira Pak/Viekira XR are contraindicated in patients with moderate (Child-Pugh B) to severe hepatic impairment (Child-Pugh C))*  Was screening for evidence of current or prior Hepatitis B virus (HBV) infection?  Yes  No  *Health care professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with DAAs, and monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up* |
| PREGNANCY |
| For female patients of child bearing potential: Has a negative pregnancy test been collected  within 30 days prior to initiation of therapy OR medical record submitted documenting pregnancy status?  Yes  No |
| **TREATMENT HISTORY** |
| |  |  | | --- | --- | | Was the current Viekira Pak/Viekira XR regimen initiated at another healthcare facility or  previously covered by another health plan?  Yes  No  IF YES, how many weeks of previous therapy have been completed prior to the date of this request?  Please check the box that best describes the patient’s HCV treatment status: | | | Treatment-naïve  Yes  No  Treatment-experienced  Yes  No  If treatment-experienced, is the patient a non-responder to:  pegylated interferon + ribavirin  Yes  No  other: | |
| Please provide previous HCV therapy completed prior to the date of this request (IF APPLICABLE):  DRUG:       DOSAGE FORM:       STRENGTH:       DIRECTIONS:  DRUG:       DOSAGE FORM:       STRENGTH:       DIRECTIONS:  DRUG:       DOSAGE FORM:       STRENGTH:       DIRECTIONS:  How many weeks of previous therapy have been completed prior to the date of this request? |
| **TREATMENT READINESS** |
| Please indicate which of the following scales/assessment tools was used to evaluate the readiness of the patient (only one is required):  SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools – Available at: <http://www.integration.samhsa.gov/clinical-practice/screening-tools#drugs>  If checked, please provide the name of SAMSHA-HRSA drug and alcohol screening tool used (required):  Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) – Available at: [www.prepc.org](http://www.prepc.org)  **Has the patient demonstrated treatment readiness, including the ability to adhere to the  prescribed treatment regimen?**  **Yes  No** |

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| **CONTINUATION OF THERAPY REQUESTS *\*\*This portion is not required for initial therapy requests*** | | | |
| Week 4 ( ±2 weeks) HCV RNA Level: |  | Date Taken: |  |
| Week 4 ( ±2 weeks) Hepatic laboratory testing including direct bilirubin |  | Date Taken: |  |
| Week 12 ( ±2 weeks) HCV RNA Level: |  | Date Taken: |  |
| Has HCV RNA level decreased since initiation of Viekira Pak/Viekira XR therapy?  Yes  No | | | |
| Has the patient completed all HCV evaluation appointments and procedures and demonstrated compliance to their treatment regimen?  Yes  No | | | |

| **CURRENT TREATMENT REGIMEN** |
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| **Please indicate the Viekira Pak/Viekira XR treatment regimen that is being prescribed:**   |  |  |  |  | | --- | --- | --- | --- | | **Diagnosis** | | **Treatment Regimen\*** | **Length of Authorization** | |  | Genotype 1a, without cirrhosis | Viekira Pak/Viekira XR + ribavirin | 12 weeks | |  | Genotype 1a, with compensated cirrhosis (Child-Pugh A) | Viekira Pak/Viekira XR + ribavirin | 24 weeks\*\* | |  | Genotype 1b, with or without compensated cirrhosis (Child-Pugh A) | Viekira Pak /Viekira XR | 12 weeks |   \*Follow the genotype 1a dosing recommendations in patients with either an unknown subtype or mixed genotype 1 infection.  \*\*Viekira Pak/Viekira XR administered with ribavirin for 12 weeks may be considered for some patients based on prior treatment history; see Viekira Pak/Viekira XR prescribing information.  HCV/HIV-1 co-infected patients should follow the treatment regimens provided in the table above.  In liver transplant recipients with normal hepatic function and Metavir fibrosis score ≤2), the recommended duration of Viekira Pak/Viekira XR with ribavirin is 24 weeks regardless of genotype 1 subtype.  Please provide dosing information for the treatment regimen selected above:  Viekira Pak STRENGTH:       DIRECTIONS:       QUANTITY:       REFILLS:  Viekira XR STRENGTH:       DIRECTIONS:       QUANTITY:       REFILLS:  Ribavirin  Other Ribavirin Product       STRENGTH:       DIRECTIONS:       QUANTITY:       REFILLS:  Other       STRENGTH:       DIRECTIONS:       QUANTITY:       REFILLS: |

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| |  |  |  | | --- | --- | --- | | **Please answer the following questions if requesting a non-preferred ribavirin product as part of treatment:** | | | | Patient has experienced a treatment failure with a preferred drug. | | Yes  No | | Patient has experienced an adverse drug reaction with a preferred drug. | | Yes  No | | There is a documented history of successful therapeutic control with a nonpreferred drug and transition to a preferred drug is medically contraindicated. | | Yes  No | |  | Other (Please specify the clinical reason the patient is unable to use a preferred agent in the same drug class. If necessary, fax additional pages): | | |  |  | | | **Please provide any additional information that should be considered in the space below:** | | | | |

I attest that this is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by New York Medicaid.

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| Prescriber’s signature |  | date |

**Ombitasvir, Paritaprevir and Ritonavir Tablet; Dasabuvir Tablet (Viekira Pak™) and Dasabuvir, Ombitasvir, Paritaprevir and Ritonavir Tablet (Viekira XR™)**

Viekira Pak™ consists of ombitasvir, paritaprevir and ritonavir (OMV/PTV/r), a fixed-dose combination tablet that is co-packaged with a dasabuvir (DSV) tablet. Viekira XR is a fixed-dose combination, extended-release tablet of DSV/OMV/PTV/r. The combination is approved for the treatment of chronic hepatitis C virus (HCV) genotype 1a and 1b infection in adults including those with compensated cirrhosis (Child-Pugh A).1-2 Viekira Pak™ and Viekira XR™ consist of ombitasvir (OMV), a HCV NS5A inhibitor, paritaprevir (PTV), a HCV NS3/4A protease inhibitor, ritonavir, a cytochrome P450 (CYP) 3A inhibitor and dasabuvir (DSV), a HCV non-nucloside NS5B palm polymerase inhibitor. The product consists of three direct acting antiviral (DAA) agents, OMV, PTV and DSV. Ritonavir is an HIV-1 protease inhibitor and has no activity against HCV; it is a potent inhibitor of CYP 3A metabolic enzymes and increases the overall drug exposure (i.e., area under the curve [AUC]) of paritaprevir. Patients co-infected with HIV-1 should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

Viekira Pak™ and Viekira XR™ must be given with ribavirin (RBV) for all patients with HCV genotype 1a and for all patients with HCV genotype 1b the Viekira Pak™ and Viekira XR™ can be given without RBV.

**Advantages of ombitasvir, paritaprevir and ritonavir tablet; dasabuvir tablet**

The recommended oral dose of Viekira Pak™ is two OMV/PTV/r fixed dose combination tablets taken once daily in the morning, and one DSV tablet twice daily (morning and evening) with a meal.1 The recommended oral dose of Viekira XR™ is three tablets once daily given with a meal.2 The treatment duration depends on the patient’s genotype and the presence or absence of cirrhosis (see below). The products are also approved for patients co-infected with human immunodeficiency virus (HIV-1) and for liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤2).

Published phase 3 trials have demonstrated the efficacy of OMV/PTV/r, a fixed dose combination tablet, co-packaged with DSV in patients with HCV genotype 1a or 1b infection. The primary endpoint was defined as HCV RNA less than the lower level of quantification (<25 IU/mL) at 12 weeks post-treatment (SVR12).

**Published phase III trials:**

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| **Trial** | **Population** | **Study Arms (study size [n])** | **SVR (study size [n])** |
| **SAPPHIRE-13** | GT1a and 1b TN\* without cirrhosis for 12 weeks | ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV (n=473) | Overall = 96.2%   * GT1a (n=322) = 95.3% * GT 1b (n=151) = 98.0% |
| Placebo (n=158) | N/A |
| **SAPPHIRE-24** | GT1a and 1b TE\*\* without cirrhosis for 12 weeks | ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV (n=297) | Overall = 96.3%   * Prior relapsers (n=86) = 95.3% * Prior partial responders (n=65) = 100.0% * Prior null responders (n=146) = 95.2% |
| Placebo (n=97) | N/A |
| **PEARL-II5** | GT1b TE without cirrhosis for 12 weeks | ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV (n=88) | GT 1b (n=88) = 96.6% |
| ombitasvir, paritaprevir and ritonavir; dasabuvir (n=91) | GT 1b (n=91) = 100.0% |
| **PEARL-III and PEARL- IV6** | GT1a and 1b TN without cirrhosis for 12 weeks | ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV (n=310) | GT1a (n=100) = 97.0%  GT1b (n=210) = 99.5% |
| ombitasvir, paritaprevir and ritonavir; dasabuvir (n=414) | GT1a (n=205)= 90.2%  GT1b (n=209)= 99.0% |
| **TURQUOISE-II7** | GT 1a and 1b TN and TE with cirrhosis | ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV for 12 weeks (n=208) | Overall = 91.8%   * GT1a (n=140) = 88.6% * GT1b (n=68) = 98.5% |
| ombitasvir, paritaprevir and ritonavir; dasabuvir and RBV for 24 weeks (n=172) | Overall = 95.9%   * GT1a (n=121) = 94.2% * GT1b (n=51) = 100.0% |
| **TURQUOISE-III8** | GT 1b TN and TE with cirrhosis | ombitasvir, paritaprevir and ritonavir; dasabuvir for 12 weeks (n=60) | Overall = 100% (n=60) |

GT=Genotype; N/A=not applicable; RBV=ribavirin; TN=treatment naïve; TE=treatment experienced

\*Treatment naïve was defined as patients that had not received any prior HCV treatment

\*\*Treatment experienced was defined as: prior relapsers, prior partial responders or prior null responders to pegylated interferon/ RBV treatment

**Cautions1**

* Prior to initiating therapy with any HCV direct acting antiviral (DAA) agent, all patients should be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs) and hepatitis B core antibody (anti-HBc). In patients with serologic evidence of HBV infection, monitor for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with a DAA agent and during post-treatment follow-up.
* The products are contraindicated in patients with moderate hepatic impairment (Child-Pugh B) and in patients with severe hepatic impairment (Child-Pugh C).
* Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes have been identified in post-marketing surveillance reports. For patients with cirrhosis it is recommended to monitor for clinical signs and symptoms of hepatic decompensation and conduct hepatic laboratory testing, including direct bilirubin levels at baseline, during the first 4 weeks of therapy, and then as clinically indicated. Therapy should be discontinued if the patient develops evidence of hepatic decompensation.
* Paritaprevir and ritonavir are primarily metabolized by CYP3A enzymes and dasabuvir is metabolized by the CYP2C8 enzyme. Co-administration of the product with drugs that are highly dependent on CYP3A for clearance, strong inducers of CYP3A or CYP2D8, and strong inhibitors of the CYP2D8 enzyme are contraindicated.
* In clinical trials, elevation of alanine transaminase (ALT) up to ≥5 times the upper limit of normal (ULN) occurred in approximately 1% of the population. ALT elevation occurred more frequently in women taking ethinyl estradiol-containing medications. Patients should discontinue their ethinyl estradiol-containing medication prior to starting therapy and an alternative method of contraception should be used. Ethinyl estradiol-containing medications can be restarted approximately 2 weeks following the completion of their HCV treatment.
* Liver function tests should be performed at baseline and during the first 4 weeks of therapy. The product should be discontinued if ALT >10 times ULN occurs or if the patient experiences signs or symptoms of liver inflammation or an increase in their conjugated bilirubin, alkaline phosphatase (ALP), or international normalized ratio (INR).
* No dose adjustment is required in patients with mild, moderate or severe renal impairment. The product has not been studied in patient undergoing dialysis.
* Patients co-infected with HIV-1 must be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance that could occur from exposure to ritonavir.
* Viekira Pak™ and Viekira XR™ are pregnancy category B and should be used in pregnant women only if the benefit justifies the risk to the fetus. Safety and effectiveness of the product has not been established in patients < 18 years of age and patients with decompensated cirrhosis. When given in combination with RBV, the combination is contraindicated in pregnant women due to teratogenicity of RBV.
* Viekira XR™ tablets should not be split, crushed or chewed. The tablet must be swallowed whole. For optimal release of DSV, alcohol should not be consumed within 4 hours of taking Viekira XR™.

**Where does ombitasvir, paritaprevir and ritonavir tablet; dasabuvir tablet fit into therapy and how should it be used?**

In January 2014, The American Association for the Study of Liver Diseases and Infectious Diseases Society of America, in collaboration with the International Antiviral Society – USA, launched [www.hcvguidelines.org](http://www.hcvguidelines.org) for the purpose of disseminating expert opinion on management of CHC as newer HCV DAA become available and treatment evidence emerges. There are no comparative efficacy data available to date for the HCV DAA, but it is likely that guidelines for optimal regimens will continue to evolve and will need to integrate patient-specific as well as economic factors.

Many patient-specific factors must be taken into consideration when deciding to initiate therapy and baseline host and viral factors will affect relapse rates and treatment duration. The goal of treatment is undetectable HCV RNA 12 weeks post-treatment (SVR12).

**Viekira Pak™ and Viekira XR™ treatment regimen and duration recommendations.**

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| **Patient Population** | **Treatment** | **Recommended Treatment Duration** |
| Genotype 1a without cirrhosis | OMV/PTV/r; DSV +RBV  OR  DSV/ OMV/PTV/r + RBV | 12 weeks |
| Genotype 1a with compensated cirrhosis (Child-Pugh A) | OMV/PTV/r; DSV +RBV  OR  DSV/ OMV/PTV/r + RBV | 24 weeks§ |
| Genotype 1b with/ without compensated cirrhosis (Child-Pugh A) | OMV/PTV/r; DSV  OR  DSV/ OMV/PTV/r | 12weeks |

DSV/OMV/PTV/r = dasabuvir/ ombitasvir/paritaprevir/ritonavir [Viekira XR™]; OMV/PTV/r; DSV = ombitasvir/paritaprevir/ritonavir; dasabuvir [Viekira Pak]; RBV= ribavirin

§Viekira Pak™ or Viekira XR™ with RBV for 12 weeks can be considered in treatment-naïve patients with compensated cirrhosis (Child-Pugh A).

For liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤2), the recommended duration of Viekira Pak™ and Viekira XR™ with RBV is 24 weeks.

**References:** **1.** Viekira™ prescribing information. AbbVie, 2014. **2.** Viekira XR™ prescribing information. AbbVie. 2016. **3.** Feld, J. et al. N Engl J Med. 2014; 370: 1594-1603. **4.** Zeuzem, S, et al. N Engl J Med. 2014;370: 1604-14. **5.** Andreone, P, et al. Gastro. 2014; 04: 359-65. **6.** Ferenci, P. et al. N Engl J Med. 2014; 370: 1983-1991.  
**7.** Poordad, F. et al. N Engl J Med. 2014; 370: 1973-92. **8.** Feld, J. et al. Hepatology.2016; 301-7.

**Ombitasvir/ Paritaprevir/Ritonavir Tablet; Dasabuvir Tablet (Viekira Pak™) and Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Viekira XR™)**

**Initiation and Monitoring**

Once patient readiness for chronic hepatitis C virus (HCV) treatment has been determined, the algorithm below outlines key decision points for initiating and monitoring of Viekira Pak™ and Viekira XR. Prior to initiating HCV DAA therapy, all patients should be tested for evidence of HBV infection by measuring HBsAg, anti-HBs, and anti-HBc.

*Note: Ribavirin is contraindicated in pregnancy; therefore all female patients of childbearing age (or female partners of male patients) should confirm they are not pregnant prior to beginning treatment and should use 2 methods of non-hormonal birth control throughout treatment. Also note, HCV RNA testing should be conducted using a sensitive assay.*

Has the patient been diagnosed with HCV genotype (GT) 1a or 1b and received quantitative HCV RNA testing?

Seek alternative treatment options or conduct testing prior to treatment

No

GT1b with/ without compensated cirrhosis

Viekira Pak or Viekira XR for 12 weeks

GT1a with compensated cirrhosis

Viekira Pak or Viekira XR with RBV for 24 weeks\*

Obtain HCV RNA level 12 weeks after the end of treatment to determine sustained virological response (SVR 12)

Does the patient have GT 1b?

Does the patient have GT1a?

GT1a without cirrhosis

Viekira Pak or Viekira XR with RBV for 12 weeks

GT=genotype; RBV=ribavirin

\* Viekira Pak™ and Viekira XR™ with RBV for 12 weeks can be considered in treatment-naïve patients with compensated cirrhosis (Child-Pugh A).

\*\*For liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤2), the recommended duration of Viekira Pak™ and Viekira XR with RBV is 24 weeks.