

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health Care Finance



Subject: Prior Authorization Approval Criteria for VIEKIRA PAK (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)

Policy Number: HCRA-DEP-02

Policy Scope: <i>Department- wide</i>	Number of Pages: 2
Responsible Office or Division: <i>Clinicians, Pharmacy and Acute Provider Services</i>	Number of Attachment: 2
Supersedes policy Dated N/A	Number of Effective Date: January 2015
Cross Reference and Related Policies: <i>DHCF Establishment Act of 2007</i>	Expiration Date, if any: N/A

1) PURPOSE

To establish policies and procedures governing the submission of Prior Authorization (PA) requests for Viekra Pak (ombitasvir, paritaprevir, ritonavir tablets, and dasabuvir tablets) for the District of Columbia Medicaid Fee for Service beneficiaries.

2) APPLICABILITY

This applies to all Medicaid providers and beneficiaries that participate in the DC Medicaid Fee for Service (FFS) Program.

3) AUTHORITY

The Department of Health Care Finance (DHCF) is the single state agency that has the authority to administer the District of Columbia Medicaid as set forth in the “DHCF Establishment Act of 2007” effective February 27, 2008 (DC. Law 17-109).

4) DEFINITIONS

- a) Viekira Pak contains ombitasvir (a hepatitis C virus NS5A inhibitor), paritaprevir, (a hepatitis C virus NS3/4A protease inhibitor), ritonavir, (a CYP3A inhibitor) and dasabuvir (a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor). The dose is two tablets of the fixed combination (ombitasvir, paritaprevir, and ritonavir 12.5/75/50 mg) once daily (in the morning) and one dasabuvir 250 mg tablet twice daily (morning and evening) with a meal without regard to fat or calorie content.
- b) **Prior Authorization**-Approval from the Department of Health Care Finance that is required before a service or prescription order will be reimbursed to a provider.

- c) **Drug Utilization Review (DUR) Board-** An advisory group of licensed physicians, pharmacists, and allied health professionals established by section 4401, 1927 (9g) of the Omnibus Reconciliation Act of 1990. The DUR board reviews and approves drug use criteria and standards for both retrospective and prospective drug use reviews; applies these criteria and standards in the application of DUR activities; reviews (DURs) and reports the results of DURs; recommends and evaluates educational intervention programs for covered outpatient drugs under the Medicaid Fee for Service Program.

5) **POLICY**

Effective April 1, 2015 all PA requests for Viekira Pak must be submitted on the designated Prior Authorization Request Form and completed request submission will be reviewed for approval in accordance with clinical criteria attached and incorporated by reference as attachment and developed by the District of Columbia DUR Board.

6) **PROCEDURE FOR REQUESTING VIEKIRA PAK PRIOR AUTHORIZATION**

- a) The requesting physician can obtain the following documents from <http://www.dc-pbm.com/>
 - I. Viekira Pak Prior Authorization form
 - II. The Clinical Criteria
 - III. DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications
- b) To initiate the PA, the requesting provider should submit a completed, signed, and dated Viekira Pak Prior Authorization Request Form to the Pharmacy Benefit Manager (PBM) via facsimile to 866-535-7622.
- c) Submission of the following supporting documentation is also required to complete the request:
 - i. A letter of Medical Necessity from prescriber
 - ii. Diagnostic and Lab test Results:
 - 1. showing fibrosis stage
 - 2. HCV-RNA level
 - 3. Other related tests
 - iii. DC Medicaid Beneficiary Disclosure and Commitment Form
 - 1. Signed and dated by prescriber; and
 - 2. Signed and dated by Beneficiary (patient)
- d) The requesting prescriber must submit the required supporting documentation to the Clinical Pharmacy Unit at 1-866-535-7622.
- e) The initial review of the PA form and required clinical information will be performed by the Clinical Pharmacy Unit for completeness and to address any missing information.
- f) The DUR Board members will participate in the review process and will make approval recommendations to the DHCF on the initial request.

- g) The decision for prior authorization request is anticipated to occur within ten (10) to fourteen (14) days after receipt of a completed prior authorization request and **ALL** required supporting documentations.
- h) The requesting prescriber will be notified of the disposition of the request.
- i) In the event of a denial of the Prior Authorization, the beneficiary (patient) will be notified of unmet criteria and will be advised of their right to appeal.

7) RESPONSIBILITY

Questions regarding this policy should be directed to Charlene Fairfax, Health Care Delivery Management Administration, Division of Clinician, Pharmacy, and Acute Provider Services at (202) 442-9076 or e-mail: Charlene.fairfax@dc.gov or to Gidey Amare, Pharmacist, Health Care Delivery Management Administration, Division of Clinician, Pharmacy, and Acute Provider Services at (202) 442-5952 or e-mail: gidey.amare@dc.gov.

Claudia Schlosberg
Senior Deputy Director / Medicaid Director

Date

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Benefit Coverage Criteria for Viekira Pak

I. Note to Prescribers:

Please refer to the criteria below when completing a request for prior Authorization for Viekira and be sure to include **ALL** supporting documentation with the request.

II. Approval Criteria:

A District of Columbia Fee for Service Medicaid beneficiary may qualify to receive Viekira Pak coverage if the following criteria are met:

1. The patient is at least 18 years old. Safety and effectiveness of Viekira Pak in pediatric patients less than 18 years of age have not been established;

AND

2. The beneficiary has a documented diagnosis of genotype 1 chronic hepatitis C infection, supported by clinical assessment and tests to demonstrate liver fibrosis of Metavir score of F2 or greater). Viekira Pak is not recommended for use in patients with decompensated liver disease; patients who have decompensated liver disease are not qualified for approval of Viekira Pak therapy;

AND

3. The patient is supervised by a Gastroenterologist **OR** Infectious disease specialist **OR** a physician specialized in hepatitis treatment and management **OR** a physician/midlevel practitioner working in consultation with gastroenterologist or infectious disease specialist;

AND

4. The prescribing provider has a plan to perform hepatic laboratory testing during the first 4 weeks of starting treatment and as clinically indicated thereafter (if ALT is found to be elevated above baseline levels, it should be repeated and monitored closely) and assess any conditions that warrant discontinuation of therapy;

AND

5. Viekira Pak is used:

- a. In combination with Ribavirin for HCV monoinfected or HCV/HIV1coinfected patients who are treatment naïve, genotype 1a and without cirrhosis for Twelve (12) week duration;
- b. In combination with Ribavirin for HCV monoinfected or HCV/HIV1coinfected, treatment naïve, genotype 1a and with cirrhosis for twenty four (24) week duration;
- c. For HCV monoinfected or HCV/HIV1coinfected patients who are treatment naïve, genotype 1b and without cirrhosis for Twelve (12) week duration;

- d. In combination with Ribavirin for HCV monoinfected or HCV/HIV-1 co-infected patients who are genotype 1b and with cirrhosis for Twelve (12) week duration;
- e. In combination with ribavirin for Liver Transplant Recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤ 2) for a duration of 24 weeks.

AND

- 6. Beneficiary is not taking a concomitant medication that has a contraindication or significant clinical interaction with Viekira Pak (Please refer to the FDA approved product information).
 - a. The use of Viekira Pak is contraindicated with:
 - i. Drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events;
 - ii. Drugs that are strong inducers of CYP3A and CYP2C8 and may lead to reduced efficacy of VIEKIRA PAK;
 - iii. Drugs that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation.
 - b. Ethinyl estradiol-containing medications should be discontinued prior to starting Viekira Pak (alternative contraceptive methods are recommended).

AND

- 7. The beneficiary has agreed to participate in the Hepatitis C monitoring program provided by the District's Pharmacy Benefit Manager;

AND

- 8. The beneficiary clearly understands that only one course of therapy is allowed in his/her DC Medicaid lifetime; and, unless there is legitimate documented evidence, a request for loss/stolen medication replacement will not be authorized;