Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

*FHK- Florida Healthy Kids

Ombitasvir+paritaprevir+ritonavir + dasabuvir Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Based on Genotype, Treatment status, Cirrhosis status, or Transplant status

NOTE: SC, WA, IN Medicaid are Carved Out
*****Criteria applies to Kentucky, Florida Healthy Kids, and Louisiana Medicaid only; for all other markets, please refer to market specific criteria.***

Medication	Quantity Limit
Viekira Pak (ombitasvir + paritaprevir + ritonavir + dasabuvir) Viekira XR (ombitasvir + paritaprevir + ritonavir + dasabuvir)	1 pak per 28 days 3 tablets per day

APPROVAL DURATION

Genotype and Status (HCV mono-infected or HCV/HIV-1 co-infected*[a])	Associated Treatment Regimens	Total Approval Duration of ombitasvir + paritaprevir + ritonavir + dasabuvir agents (Viekira Pak, Viekira XR)
Genotype 1b (treatment naïve or dual treatment-experienced^, with compensated cirrhosis or without cirrhosis)	Viekira Pak Viekira XR	12 weeks
Genotype 1b (treatment-naïve or dual treatment-experienced^, with compensated cirrhosis)	Viekira Pak+ ribavirin Viekira XR + ribavirin	12 weeks
Genotype 1a, unknown Genotype 1 subtype, or mixed Genotype 1 subtypes (treatment naïve or dual treatment-experienced^, without cirrhosis)	Viekira Pak+ ribavirin Viekira XR + ribavirin	12 weeks
Genotype 1a, unknown Genotype 1 subtype, or mixed Genotype 1 subtypes (treatment naïve or dual treatment-experienced^, with compensated cirrhosis)	Viekira Pak+ ribavirin Viekira XR + ribavirin	24 weeks
Genotype 1 [post-liver allograft transplant, without cirrhosis (Metavir fibrosis score ≤ 2)]	Viekira Pak+ ribavirin Viekira XR + ribavirin	24 weeks

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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^Per Viekira label, dual treatment-experienced refers to individuals who have had a prior relapse, prior partial response, or prior null response to a dual therapy regimen of peginterferon and ribavirin.

APPROVAL CRITERIA

Requests for ombitasvir + paritaprevir + ritonavir + dasabuvir (Viekira Pak, Viekira XR) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia; **AND**
III. One of the following:
   A. Documentation is provided for a diagnosis of chronic HCV Genotype 1[1]* and a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013);

   OR
   B. Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F4[2]), post-liver transplant recipients, chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016); **AND**
   C. Documentation is provided for a diagnosis of CHC infection, which includes genotypea (AASLD/IDSA 2016), a reactive HCV antibody (CDC 2013), and a subsequent positive HCV RNA result (CDC 2013);

AND
IV. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016);

AND
V. One of the following:
   A. Individual is a woman of child-bearing potential wishing to become pregnant (Use with ribavirin is contraindicated in pregnancy and pregnancy is not recommended for six months following completion of a ribavirin-based regimen)(AASLD/IDSA 2015);

   OR
   B. Individual is considered at highest risk for severe hepatitis C-related complications (AASLD/IDSA 2015):
      1. Advanced fibrosis as documented by **one** of the following (AASLD/IDSA 2015):

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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a. Liver biopsy-proven fibrosis staging score of F3 or F4 on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales[2]; **OR**
b. Liver biopsy-proven fibrosis staging score of greater than or equal to F4 on the Ishak fibrosis staging scale[2]; **OR**
c. In the absence of a liver biopsy, medical imaging-proven fibrosis staging score of F3 or F4 on IASL, Batts-Ludwig, or Metavir scales or greater than or equal to F4 on Ishak scale[2];

OR

2. Liver transplant recipient; **OR**
3. Type 2 or 3 essential cryoglobulinemia with end-organ manifestations (for example, vasculitis) (AASLD/IDSA 2015); **OR**
4. Glomerular disease [proteinuria (greater than 300 mg/day), nephrotic syndrome, or membranoproliferative glomerulonephritis] (AASLD/IDSA 2015);

AND

VI. Individual has compensated liver disease[1] (with or without cirrhosis);

AND

VII. Individual is using with **one** of the following antiviral treatment regimens:

A. As monotherapy for individuals with HCV Genotype 1b, treatment-naïve or dual treatment-experienced (peginterferon and ribavirin), and with compensated[1] cirrhosis or without cirrhosis; **AND**
B. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier or the individual has one of the following:
    1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    2. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Viekira Pak/Viekira XR; **OR**
    3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

C. In combination with ribavirin for **one** of the following:
    1. Individuals with HCV Genotype 1a or mixed/unknown Genotype1, treatment-naïve or dual treatment-experienced (peginterferon and ribavirin), and with compensated[1] cirrhosis or without cirrhosis; **AND**

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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2. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier or the individual has one of the following:
    a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Viekira Pak/Viekira XR; **OR**
    c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

3. Individuals with HCV Genotype 1b, treatment-naïve or dual treatment-experienced (peginterferon and ribavirin), and with compensated[1] cirrhosis; **AND**
4. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier, or the individual has one of the following:
    a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Viekira Pak/Viekira XR; **OR**
    c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

OR

5. Individuals with HCV Genotype 1, post-liver allograft transplant, and without cirrhosis (Metavir fibrosis score less than or equal to 2[2]).

Ombitasvir + paritaprevir + ritonavir + dasabuvir (Viekira Pak, Viekira XR) may not be approved for the following:

I. Individual has moderate to severe hepatic impairment (Child-Pugh B-C); **OR**
II. Individual has end stage renal disease (CrCl less than 15 mL/min) or requires dialysis; **OR**
III. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to the following: Strong cytochrome (CYP) 2C8 inhibitors

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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[such as but not limited to, gemfibrozil, ritonavir-boosted atazanavir], strong CYP 2C8 inducers (such as but not limited to, carbamazepine, phenobarbital, rifampin, rifabutin, rifapentine), moderate or strong CYP 3A4 inducers (such as but not limited to, phenytoin, St. Johns' Wort, efavirenz-based regimens, oxcarbazepine), or agents highly dependent on CYP3A clearance (substrates) [such as but not limited to, dronedarone, amiodarone, flecainide, propafenone, quinidine, ranolazine, lurasidone, cisapride, alfuzosin, colchicine, ergot derivatives, ethinyl estradiol-containing agents, lovastatin, simvastatin, pimozide, Revatio, triazolam, oral midazolam, ritonavir-boosted darunavir, lopinavir/ritonavir, rilpivirine-based regimens, voriconazole, salmeterol]; **OR**

IV. Individual is using in combination with a regimen containing another NS3/4A protease inhibitor [such as telaprevir, boceprevir, simeprevir, paritaprevir, or elbasvir/grazoprevir]; **OR**

V. Individual is using in combination with a regimen containing another nucleotide NS5B polymerase inhibitor [such as sofosbuvir or ledipasvir/sofosbuvir] or another non-nucleoside NS5B polymerase inhibitor; **OR**

VI. Individual is using in combination with a regiment containing another NS5A inhibitor [such as ledipasvir/sofosbuvir, ombitasvir, daclatasvir, elbasvir/grazoprevir, or sofosbuvir/velpatasvir]; **OR**

VII. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a serine NS3/4A protease inhibitor [such as simeprevir, telaprevir, boceprevir, paritaprevir (AASLD/IDSA 2016), or elbasvir/grazoprevir]; **OR**

VIII. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a NS5A inhibitor [such as ombitasvir, daclatasvir, ledipasvir/sofosbuvir, elbasvir/grazoprevir , or sofosbuvir/velpatasvir]; **OR**

IX. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir) or a regimen containing a nucleotide NS5B polymerase inhibitor [such as Sovaldi (sofosbuvir) or ledipasvir/sofosbuvir (AASLD/IDSA 2016), or sofosbuvir/velpatasvir].

***Notes**:

[a]Per label, ombitasvir/paritaprevir/ritonavir + dasabuvir agents (Viekira Pak, Viekira XR) may be used in individuals co-infected with HIV-1. Individuals co-infected with HCV/HIV-1 treated with Viekira Pak/Viekira XR should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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1. **Compensated Liver Disease**:
   According to the American Association for the Study of Liver Diseases (AASLD 2009, 2016), the specific criteria for compensated liver disease include all of the following: a total bilirubin; serum albumin; prothrombin time/INR; presence of ascites; and presence of hepatic encephalopathy. However, these criteria do not establish a comprehensive definition of compensated liver disease. In fact, the AASLD guidelines refer to compensated liver disease as Grade A based on the Child Pugh-Turcotte (CPT) classification scoring system.

Child Pugh Classification (AASLD/IDSA 2015)

Parameters			
Points Assigned	1 point	2 points	3 points
Total Bilirubin (µmol/L)	<34	34-50	>50
Serum Albumin (g/L)	>35	28-35	<28
Prothrombin time/INR	<1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)

Child Pugh Score Interpretation (AASLD/IDSA 2009, 2016)

Class A	5-6 points	Well compensated liver disease
Class B	7-9 points	Significant functional compromise (moderate hepatic impairment)
Class C	10-15 points	Uncompensated liver disease (severe hepatic impairment)

2. **Scoring Systems for Fibrosis Staging (AASLD 2009)**:

Stage (F)	**IASL***	**Batts-Ludwig**	**Metavir**
0	No fibrosis	No fibrosis	No fibrosis
1	Mild fibrosis	Fibrosis portal expansion	Periportal fibrotic expansion
2	Moderate fibrosis	Rare bridges or septae	Periportal septae 1 (septum)
3	Severe fibrosis	Numerous bridges or septae	Porto-central septae
4	Cirrhosis	Cirrhosis	Cirrhosis

*IASL = The International Association for the Study of Liver

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Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

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Stage (F)	**Ishak**
0	No fibrosis
1	Fibrosis expansion of some portal areas with or without short fibrous septa
2	Fibrous expansion of most portal areas with or without short fibrous septa
3	Fibrous expansion of most portal areas with occasional portal to portal bridging
4	Fibrous expansion of most portal areas with marked bridging (portal to portal and portal to central)
5	Marked bridging (portal to portal and portal to central) with occasional nodules (incomplete cirrhosis)
6	Cirrhosis

3. Hepatitis C virus (HCV) direct acting antiviral (DAA) agents have a black box warning for risk of hepatitis B virus (HBV) reactivation in individuals with HCV-HBV co-infection. Individuals should be tested for evidence of current or prior HBV infection prior to initiation of DAA therapy. HBV reactivation has been reported in HCV/HBV co-infected individuals currently taking or previously completed DAA therapy and not concomitantly receiving HBV antiviral therapy. Some cases of HBV reactivation have led to fulminant hepatitis, hepatic failure, and death. Individuals should be monitored for hepatitis flare or HBV reactivation during and following HCV DAA therapy. Individuals should be appropriately managed for HBV infection as indicated.

State Specific Mandates		
California Medicaid	07/2015	California has state mandated criteria; please see California specific document.
New Jersey Medicaid	7/1/2016	New Jersey Medicaid has state mandated criteria for all Direct Acting Antiviral (DAA) agents for treatment of Hepatitis C. Please see New Jersey State Criteria
New York Medicaid	7/1/2016	New York has state mandated criteria. Please see New York Specific Criteria
Nevada Medicaid	2016	Nevada has state mandated criteria; please see Nevada State Specific Criteria.
Virginia Medicaid	7/1/2016	Virginia has state mandated criteria; please see Virginia State Specific Criteria.
Maryland Medicaid	n/a	Maryland has state mandated criteria; please see Maryland State Specific Criteria.
Georgia Medicaid	10/2016	Georgia has state mandated criteria; please see Georgia State Specific Criteria.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	NA	NA	X	X	NA	NA	NA	NA	NA	NA	NA

*FHK- Florida Healthy Kids

Key References:

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