OPTIMA HEALTH PLAN

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: ***The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.***

Drug Requested: Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) ***(NON-PREFERRED)***

DRUG INFORMATION: Complete information below. Authorization process will be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ ***ICD Code, if applicable*: _____**

- ***Optima Health coverage criteria for the new direct-acting agents are based on careful consideration of the evidence-based guidance of professional specialty societies, published guidelines, and physician subject matter experts specialists.***
- ***ONE TIME APPROVAL FOR ANY and ALL DIRECT-ACTING ANTIVIRAL (DAA) PER LIFETIME (EXCEPTION)***

CLINICAL CRITERIA: Check ALL boxes below to qualify. ALL pertinent chart notes and lab values MUST be included in this request or authorization process will be delayed.

- **Treatment is being prescribed by:** ❑ **Gastroenterologist** ❑ **Hepatologist** ❑ **ID Specialist**
  - Patient is: ❑ treatment naïve ❑ relapse ❑ treatment experienced
  - Please indicate prior therapy ***(check below that apply):***
    ❑ Incivek® ❑ Olysio™ ❑ Sovaldi® ❑ Victrelis® ❑ peginterferon alfa ❑ ribavirin ❑ Harvoni®
  - **For Genotype 1, has the patient had a trial and failure of: ❑ Harvoni® (Commercial) ❑ Harvoni® (Medicaid)?**
    (*If No, send documentation for contraindications and adverse effects*) ❑ Yes ❑ No
  - Patient has a diagnosis of chronic HCV genotype ☐ 1 ***(include labs)*** ❑ Yes ❑ No
  - A documented viral load (HCV RNA) taken within 6 months of beginning therapy ***(include labs)*** ❑ Yes ❑ No
  - Is member co-infected with hepatitis B (**If yes, *Viekira™* will *not* be approved**)? ❑ Yes ❑ No
  - Is member co-infected with HIV-1? (***If yes, please confirm Child-Pugh class A***) ❑ Yes ❑ No
  - Is member classified as Child-Pugh class A? ❑ Yes ❑ No
  - Has the patient ever been successfully treated for chronic HCV? ***(If Yes, Viekira™ will not be approved)*** ❑ Yes ❑ No
  - Does the patient have hepatocellular carcinoma or severe cirrhosis awaiting a liver transplant? ***(If Yes, Viekira™ will not be approved)*** ❑ Yes ❑ No
  - Does the patient have compensated cirrhosis? ***(include labs)*** ❑ Yes ❑ No
  - Is member free from illicit substance abuse for at least 6 months? ***(submit labs within last 30 days)*** ***(Medicaid Excluded)*** ❑ Yes ❑ No
  - Is member free from alcohol abuse for at least 6 months? ***(submit labs within last 30 days)*** ***(Medicaid Excluded)*** ❑ Yes ❑ No
  - If the answer to either of the 2 questions above is **NO**, then evidence of lack of substance abuse during therapy is required including a negative urine toxicology screening confirmation test immediately prior to DDA therapy and monthly for two months after beginning treatment ***(Results must be submitted with request)***

***For assessment of disease severity, please refer to the table below for a Fibrosis/stage score*:**

Metavir	**Scheuer/Batts, Ludwig/Tsui Stage**	**Ishak, et al: Fibrosis Scoring**	**Knodell et al: Fibrosis Scoring**
F0=no fibrosis	0=No fibrosis, normal amount of connective tissue	0=No fibrosis	0=No fibrosis
F1=portal fibrosis without septa	1=Portal/periportal fibrosis	1=Expansion of some portal areas with or without septa	1=Fibrous some portal expansion with or without septa
F2=portal fibrosis with rare septa	2=Septal fibrosis	2=Expansion of most portal areas with or without septa	2= Fibrous most portal expansion with or without septa
F3=numerous septa, not cirrhosis	3=Bridging fibrosis with architectural distortion.	3=Expansion of most portal areas with occasional portal to portal bridging	3=Bridging Fibrosis
F4=cirrhosis	4=Cirrhosis, probable cirrhosis	4=Expansion of portal areas with marked bridging (portal-portal and/or portal-central)	4=Cirrhosis
		5=Marked bridging with occasional nodules (incomplete cirrhosis)	
		6=Cirrhosis, probable or definitive	

(*continued on next page)*

Cirrhosis requires two (2) liver assessments with Lab values & symptoms correlating with Cirrhosis.

Submit a Liver assessment documenting stage 3 or stage 4 hepatic fibrosis including one (1) of the following *(Medicaid Excluded)*: (*Please Note*: *Contra-Indication to a liver assessment would lead to a denial.)*

- ❑ Liver biopsy confirming:
  - ❑ METAVIR score of F3 - F4
  - ❑ Knodell fibrosis score (last #-reported separately) F 3-4
  - ❑ Ishak stage score of F4 –F6
  - ❑ Batts-Ludwig stage 3 -4
- ❑ Transient elastography (FibroScan) score greater than or equal to 9.5 kPa
- ❑ FibroTest (FibroSure) score of greater > 0.59 (F3) or >0.75 (F4)
- ❑ Shear wave elastography (ElastPQ) score of 12.0-21.0+kPa or 2.00-2.64+m/s
- ❑ Shear wave (SWE supersonic tech) score of greater > 8.7kPa (1.70 m/s) (F3) OR 10.4kPa (1.86m/s) (F4)
- ❑ Shear wave (VTTQ) Siemens score of greater >1.55m/s (F3) OR 1.80m/s(F4)

Duration of Approval (IDSA Guidelines) Genotype 1

Patient Population	Treatment	Duration
Genotype 1a, without cirrhosis	Viekira PAK + ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis	Viekira PAK + ribavirin	24 weeks**
Genotype 1b, with or without compensated 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.

****VIEKIRA PAK administered with ribavirin for 12 weeks may be considered for**:

- ***Patients who received at least 20 weeks of PEG/RBV and achieved a ≥2 log IU/mL reduction in HCV RNA at week 12 but failed to achieve HCV RNA undetectable at the end of treatment.***
- ***Patients who received at least 36 weeks of PEG/RBV and achieved HCV RNA undetectable at the end of treatment but HCV RNA was subsequently detectable within 52 weeks of treatment follow-up*.**

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 1/15/2015
REVISED/UPDATED: ~~1/26/2015; 2/4/2015; 5/22/2015; 12/29/2015; 6/6/2016; 6/22/2016; 12/20/2016; 2/9/2017;~~ **8/20/2017**