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: **Zepatier™** (elbasvir/grazoprevir) - ***(COMMERCIAL ONLY - 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 ❑ relapser ❑ prior partial responder ❑ prior null responder
- Patient has a diagnosis of CHC with HCV **genotype 1 or genotype 4:** ***(Has patient failed Harvoni®)*** ❑ Yes ❑ No
- Please list all recent HCV TREATMENTS: _____
- Has member previously tried: ❑ NS3/4A Protease Inhibitor ❑ NS5B Inhibitor ❑NS5A Inhibitor ❑ Yes ❑ No
- Testing prior to medication: Provide NS5A Resistance test for Genotype 1a ***(must submit)***
- Is patient co-infected HIV? ❑ Yes ❑ No
- Is patient co-infected HBV ❑ Yes ❑ No
- Does patient have hepatocellular carcinoma awaiting a liver transplant? ❑ Yes ❑ No
- Does patient have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C])? ***This must be verified by biopsy.*** ❑ Yes ❑ No
- Is member free from illicit substance abuse for at least 6 months? ***(submit labs within last 30 days)*** ❑ Yes ❑ No
- Is member free from alcohol abuse for at least 6 months***? (submit labs within last 30 days)*** ❑ 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	

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

(continued on next page)

Submit a Liver assessment documenting stage 3 or stage 4 hepatic fibrosis including *one (1)* of the following: (*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)

Please send all recent labs for HCV

Duration of Approval (IDSA Guidelines)

Patient Population	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced[1], without baseline NS5A polymorphisms[2]	ZEPATIER™	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced[1] with baseline NS5A polymorphisms[2]	ZEPATIER™ + RBV[3]	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced[1]	ZEPATIER™	12 weeks
Genotype 1a[4] or 1b: PegIFN/RBV/PI-experienced[5]	ZEPATIER™ + RBV[3]	12 weeks
Genotype 4: Treatment-Naïve	ZEPATIER™	12 weeks
Genotype 4: PegIFN/RBV-experienced[1]	ZEPATIER™ + RBV[3]	16 weeks

1. Patients who have failed treatment with peginterferon alfa (PegIFN) + ribavirin (RBV).
2. NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.
3. For patients with CrCl greater than 50 mL per minute, the recommended dosage of ribavirin is weight-based (less than 66 kg = 800 mg per day, 66 to 80 kg = 1000 mg per day, 81 to 105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day) administered in two divided doses with food. For patients with CrCl less than or equal to 50 mL per minute, including patients receiving hemodialysis, refer to the ribavirin tablet prescribing information for the correct ribavirin dosage.
4. The optimal ZEPATIER-based treatment regimen and duration of therapy for PegIFN/RBV/PI-experienced genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at positions 28, 30, 31, and 93 has not been established.
5. Patients who have failed treatment with PegIFN + RBV + HCV NS3/4A protease inhibitor (PI): boceprevir, simeprevir, or telaprevir.

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:** 3/16/2016
REVISED/UPDATED: ~~4/26/2016; 5/4/2016; 5/27/2016; 6/6/2016; 12/20/2016;~~ **9/24/2017**