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: **EPCLUSA®** (sofosbuvir and velpatasvir) ***MEDICAID ONLY***

DRUG INFORMATION: Complete information below. If incomplete, authorization process will be delayed.

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**
- The patient is: ❑ treatment naïve ❑ relapse ❑ treatment experienced
- Please indicate prior therapy: ❑ DAA_____ ❑ peginterferon alfa ❑ ribavirin
- Patient has a diagnosis of chronic HCV genotype. ❑ 2 ❑ 3 ❑ 5 ❑ 6 ***(Labs must be included)***
- Patient has a diagnosis of chronic HCV genotype. ❑ 1 ❑ 4 ***(Labs must be included)*** **Has patient failed Harvoni®** ❑ Yes ❑ No
- A documented viral load (HCV RNA) taken within 6 months of beginning therapy (Include labs)
- Is member co-infected with hepatitis B ***(Please send labs)*** ❑ Yes ❑ No
- Is member co-infected with HIV-1? ❑ Yes ❑ No
- Has the patient ever been successfully treated for chronic HCV? ❑ Yes ❑ No
- Does the patient have hepatocellular carcinoma or severe cirrhosis awaiting a liver transplant? ***(If Yes, Epclusa® will not be approved)*** ❑ Yes ❑ No
- Does the patient have compensated cirrhosis? (Include labs) ❑ Yes ❑ No
- Does the patient has decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C])? **This must be verified by biopsy.** ***(Include labs)*** ❑ Yes ❑ No
- Does the patient have severe renal impairment (eGFR < 30ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis? ***(Include labs) (If Yes, Epclusa® will not be approved)*** ❑ Yes ❑ No

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 2 liver assessments with Lab values & symptoms correlating with Cirrhosis.

Genotype 1, 2, 3, 4, 5, or 6 HCV	
Patient Population	**Recommended Treatment Regimen**
Patients without cirrhosis and patients with compensated cirrhosis (Child Pugh A)	EPCLUSA for 12 weeks
Patients with decompensated cirrhosis (Child Pugh B and C)	EPCLUSA + ribavirin for 12 weeks

*****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:** 7/21/2016
REVISED/UPDATED: ~~1/31/2017;~~ ~~2/9/2017;~~ **8/12/2017**