

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)

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
- The patient is: treatment naïve relapse treatment experienced
- Please indicate prior therapy: DAA _____ peginterferon alfa ribavirin
- Patient has a diagnosis of chronic HCV genotype. 1 2 3 4 5 6 (**Labs must be included**)
- A documented viral load (HCV RNA) taken within 6 months of beginning therapy (**Include labs**)
- Is member co-infected with hepatitis B (**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/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis? (**Include labs**) (**If Yes, Epclusa® will not be approved**) 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**)
- **Does the patient have extrahepatic manifestations defined as:** Mixed cryoglobulinemia Cryoglobulinemic vasculitis Sjögren’s (sicca) syndrome Lymphoproliferative disorders Porphyria cutanea tarda Membranoproliferative glomerulonephritis other: _____ (**will NOT be approved**)

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 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:

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 ≥ 8.7 kPa (1.70 m/s) (F3) OR 10.4kPa (1.86m/s) (F4)
- Shear wave (VTTQ) Siemens score of greater ≥ 1.55 m/s (F3) OR 1.80m/s(F4)

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 #: _____ Member Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Phone Number: _____ Fax Number: _____

DEA/NPI #: _____

*Approved by Pharmacy and Therapeutics Committee: 7/21/2016

REVISED/UPDATED: 8/3/2016; 9/20/2016; 12/16/2016; 9/19/2017.