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: Harvoni® (ledipasvir and sofosbuvir) - ***MEDICAID 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 ❑ relapse ❑ treatment experienced
- Please indicate prior therapy:
  ❑ **Mavyret™** ❑ Incivek® ❑ Olysio™ ❑ Victrelis® ❑ Sovaldi® ❑ peginterferon alfa ❑ ribavirin
- Patient has a diagnosis of chronic HCV genotype. ***(labs MUST be included))*** ❑ **1** ❑ **4** ❑ **5** ❑ **6**
- Patient has a diagnosis of CHC with HCV **genotype 1 or genotype 4:** ❑ Yes ❑ No
  - 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? ❑ 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)*** ❑ 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.

RBV dosing:

- ❑ **F0-F3 and CTP cirrhosis: weight-based (<75kg=1000mg; ≥75kg=1200mg)**
- ❑ **CTP B and C cirrhosis: dose escalation, 600-1200mg/d**

Genotype 1	Treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	HARVONI 8 weeks
Genotype 1	Treatment-naïve without cirrhosis who have pre-treatment HCV RNA > 6 million IU/mL or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
	Treatment-naïve and treatment experienced with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 week
Severe renal impairment (eGFR <30mL/min/1.73) or ESRD		No dose recommendation

*****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:** 11/20/2014
REVISED/UPDATED: ~~2/4/2015; 2/12/2015; 5/21/2015; 10/15/15; 12/27/2015; 1/27/2016; 3/18/2016; 3/29/2016; 5/4/2016; 6/6/2016; 12/19/2016; 1/31/2017; 2/9/2017; 8/14/2017;~~ **10/5/2017**