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) ***COMMERCIAL ONLY***

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 below:
  ❑ **Mavyret™** ❑ Incivek® ❑ Olysio™ ❑ Victrelis® ❑ Sovaldi® ❑ peginterferon alfa ❑ ribavirin
- Patient has a diagnosis of chronic HCV genotype. ❑1 ***(Include labs)*** ❑4 ***(Include labs)*** ❑5 ***(Include labs)*** ❑6 ***(Include labs)***
- 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, Harvoni® 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, Harvoni® 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 ❑ Porphyria cutanea tarda
  ❑ Cryoglobulinemic vasculitis ❑ Sjögren's (sicca) syndrome ❑ Lymphoproliferative disorders
  ❑ 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

(continued on next page)

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
  - ❑ Ishak stage score of F4 –F6
  - ❑ Knodell fibrosis score (last #-reported separately) F 3-4
  - ❑ 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)

Genotype 1	Treatment-naïve without cirrhosis 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

***Harvoni for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL**

RBV dosing:

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

*****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; 4/26/2016; 5/4/2016; 12/19/2016; 9/21/2017;~~ **10/6/2017**