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: Mavyret™ (glecaprevir/piprentasvir) ***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**
  The patient is: ❑ treatment naïve ❑ relapse ❑ treatment experienced
- Please indicate prior therapy:
  ❑ Incivek® ❑ Olysio™ ❑ Victrelis® ❑ Sovaldi® ❑ peginterferon alfa ❑ ribavirin ❑ Harvoni®
- 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? ❑ 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
- 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	

(continued on next page)

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	❑ Knodell fibrosis score (last #-reported separately)
❑ Ishak stage	❑ Batts-Ludwig stage

- ❑ 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)

Treatment Naïve Patients:

HCV Genotype	**Treatment Duration**	
	No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**
1, 2, 3, 4, 5, or 6	8 weeks	12 weeks

Treatment Experienced Patients:

		Treatment Duration	
HCV Genotype	**Patients Previously Treated With a Regimen Containing:**	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5, or 6	PRS[3]	8 weeks	12 weeks
3	PRS[3]	16 weeks	16 weeks

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.
3. PRS=Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

*****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:** 10/1/2017
REVISED/UPDATED: 10/5/2017