

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) (**PREFERRED**) (**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 PREVIOUS Hep-C therapy/treatment(s) (check all that apply):**

<input type="checkbox"/> Incivek®	<input type="checkbox"/> Victrelis®	<input type="checkbox"/> Sovaldi®	<input type="checkbox"/> Olysio™
<input type="checkbox"/> peginterferon alfa	<input type="checkbox"/> ribavirin	<input type="checkbox"/> Harvoni®	<input type="checkbox"/> Epclusa®
<input type="checkbox"/> Daklinza™	<input type="checkbox"/> Technivie™	<input type="checkbox"/> Viekira Pak™	<input type="checkbox"/> Viekira XR™
<input type="checkbox"/> Vosevi®	<input type="checkbox"/> Zepatier®		

- Patient has a diagnosis of chronic HCV genotype. 1 2 3 4 5 6 (**Labs must be included**)
- Documented viral load (HCV RNA) taken within **6 months** of beginning therapy? (**Include labs**) Yes No
- 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])? (**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. Liver assessment MUST be submitted to determine length of therapy. One of the following liver assessments MUST be submitted. (Please Note: Contra-Indication to a liver assessment would lead to an incomplete form.)

Liver biopsy confirming:

<input type="checkbox"/> METAVIR score	<input type="checkbox"/> Knodell fibrosis score (last #-reported separately)
<input type="checkbox"/> Ishak stage	<input type="checkbox"/> Batts-Ludwig stage

Transient elastography (FibroScan) score of: _____ kPa

FibroTest (FibroSure) score of: _____ (Alcohol test **MUST** be same date as FibroTest)

Shear wave elastography (ElastPQ) score of: _____ m/s

Shear wave (SWE supersonic tech) score of: _____ m/s

Shear wave (VTTQ) Siemens score of: _____ m/s

LABS need to be submitted with this request form for the following: CBC BMP

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:

HCV Genotype	Patients Previously Treated With a Regimen Containing:	Treatment Duration	
		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

- In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
- In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.
- 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; 12/30/2017.

OPTIMA HEALTH PLAN

Hepatitis C Therapy Patient Treatment Agreement

Prescriber Instructions: *Please submit the completed agreement with the initial prior authorization requests.*

Patient Instructions: By reading and signing this agreement, I acknowledge that I have been informed about the requirements of the treatment program and understand what is expected of me. I can refuse to sign this agreement, but treatment will not be started until and unless I sign this agreement.

Patient Information	Prescriber Information
Name: _____ _____	Name: _____ _____
Optima Health Member ID Number: _____	Optima Provider ID Number or NPI: _____
Date of Birth: _____	Office Contact Name: _____
Hepatitis C Medication Regimen: _____ _____	Telephone Number: _____ Fax Number: _____
1. I have been told how to take my hepatitis C medicines. I understand how to take them. I am aware of possible side effects. I understand why it is important to finish all the therapy.	
2. I will take my hepatitis C medicines like my doctor said. I understand that missing doses of medicine may cause the treatment to fail.	
3. I understand that if I miss more than 3 doses in one month, Medicaid may no longer pay for my hepatitis C medicines.	
4. I will tell my doctor and pharmacist the medicines I take. I understand there may be some medicines I cannot take with my hepatitis C medicines.	
5. I understand that Medicaid may only pay for hepatitis C medicines for a certain number weeks over my lifetime.	
6. I understand that past use of certain hepatitis C medicines may keep me from using medicines like them again.	
7. I am not currently using IV drugs or abusing alcohol.	
8. I will not use IV drugs or abuse alcohol (which could seriously damage my liver) while on treatment or after completion of treatment.	
9. I am (OR my female partner is) not pregnant.	
10. I am (OR my female partner is) not planning on getting pregnant while I am on my hepatitis C medicines and for at least 6 months after I finish them.	
11. I (OR my female partner) will use two forms of non-hormonal birth control while I am taking my hepatitis C medicines and for at least 6 months after I finish taking them.	
12. I (OR my female partner) will have monthly pregnancy testing while I am taking my hepatitis C medicines.	

I have read the above statements and understand the agreement.

Patient Signature: _____

Date: _____

Physician Signature: _____

Date: _____