

# 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:** Olysio® (simeprevir) (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

**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  prior partial responder  prior null responder
- Patient has a diagnosis of CHC with HCV genotype  1
- **For Genotype 1, has the patient had a trial and failure for Harvoni®? (If No, send documentation for contraindications or adverse effects)**  Yes  No
- If so, did the patient test positive for the NS3 Q80K polymorphism?  Yes  No  
*If the patient tested positive for the NS3 Q80K polymorphism, the request will be denied.*
- Does the patient have hepatocellular carcinoma awaiting a liver transplant?  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.  Yes  No
- Does the patient have severe renal impairment (eGFR < 30ml/min/1.73m<sup>2</sup>) or end stage renal disease (ESRD) requiring hemodialysis?  Yes  No
- Is member free from illicit substance abuse for at least 6 months? (submit labs within last 30 days) (Medicaid Excluded)  Yes  No
- Is member free from alcohol abuse for at least 6 months? (submit labs within last 30 days)(Medicaid Excluded)  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 *two (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 (*Medicaid Excluded*): (*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  $\geq 0.59$  (F3) or  $\geq 0.75$  (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  $\geq 8.7$ kPa (1.70 m/s) (F3) OR 10.4kPa (1.86m/s) (F4)
- Shear wave (VTTQ) Siemens score of greater  $\geq 1.55$ m/s (F3) OR 1.80m/s (F4)

**Alternative treatment requiring interferon-free regimen**

**Please submit progress notes and labs for contraindication of Interferon, *one (1)* of the following needs to apply:**

TABLE A	
<input type="checkbox"/> Neutrophils	<750/ $\mu$ L within the past 3 months
<input type="checkbox"/> ANC	<500 within the past 3 months
<input type="checkbox"/> Hgb	Baseline within past month <10g/dL
<input type="checkbox"/> Platelets	<50,000 within past 3 past months
<input type="checkbox"/> Autoimmune hepatitis	<input type="checkbox"/> YES <b>OR</b> <input type="checkbox"/> NO
<input type="checkbox"/> Hepatic decompensation <input type="checkbox"/> Bleeding varices <input type="checkbox"/> Ascites <input type="checkbox"/> Encephalopathy <input type="checkbox"/> Jaundice	<input type="checkbox"/> YES <b>OR</b> <input type="checkbox"/> NO
<input type="checkbox"/> Suicidal within last 3-6 months <b>AND</b> documented evidence of > 3 medication adjustments to control symptoms within the past 12months of psychosis, etc.	<input type="checkbox"/> YES <b>OR</b> <input type="checkbox"/> NO (documentation of aggressive management AND compliance is required)

***IF APPROVED, OLYSIO® WILL BE AUTHORIZED FOR 8 WEEKS, WITH THE REMAINING 4 WEEKS OF THERAPY DEPENDENT ON RECEIPT OF AN HCV-RNA LEVEL AT WEEK 4.***

**\*\*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: 1/16/2014

REVISED/UPDATED: 2/7/2014; 7/17/2014; 8/15/2014; 11/2/2014; 2/4/2015; 5/22/2015; 12/28/2015; 6/6/2016; 12/19/2016; 2/9/2017; 8/15/2017