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**
  Patient is: ❑ treatment naïve ❑ relapse ❑ prior partial responder ❑ prior null responder
- Patient has a diagnosis of CHC with HCV genotype ❑ 1
- **For Genotype1, 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^2) 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)*** ❑ 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 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: ***(Please Note: Contra-Indication to a liver assessment would lead to a denial)***

- ❑ Liver biopsy confirming:
  - ❑ METAVIR score of F3 - F4
  - ❑ Knodell fibrosis score (last #-reported separately) F 3-4
  - ❑ Ishak stage score of F4 –F6
  - ❑ 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)

(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	
❑ Neutrophils	<750/µL within the past 3 months
❑ ANC	<500 within the past 3 months
❑ Hgb	Baseline within past month <10g/dL
❑ Platelets	<50,000 within past 3 past months
❑ Autoimmune hepatitis	❑ YES **OR** ❑ NO
❑ Hepatic decompensation ❑ Bleeding varices ❑ Ascites ❑ Encephalopathy ❑ Jaundice	❑ YES **OR** ❑ NO
❑ Suicidal within last 3-6 months **AND** documented evidence of > 3 medication adjustments to control symptoms within the past 12months of psychosis, etc.	❑ YES **OR** ❑ 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; 4/4/2017;~~ **9/22/2017**