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: **Sovaldi®** (sofosbuvir) - **MEDICAID ONLY (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.***
- ***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 ❑ prior partial responder ❑ prior null responder

  - Patient has a diagnosis of CHC with HCV **genotype** ***(check one below):***

    ❑ **1** ***(Has the patient had a trial and failure for Harvoni®? If NO, send documentation for contraindications or adverse effects)*** ❑ **2** ❑ **3** ❑ **4**
  - Does the patient have hepatocellular carcinoma awaiting a liver transplant? ❑ Yes ❑ No
  - Does the patient have 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

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	

Cirrhosis requires 2 liver assessments with Lab values & symptoms correlating with Cirrhosis.

(continued on next page)

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 <7g/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)

Duration of Approval (IDSA Guidelines)

CHC with genotype 1 or 3 or 4	Sovaldi® + peginterferon alpha + ribavirin	12 weeks of therapy
CHC with genotype 2	Sovaldi® + ribavirin	12 weeks of therapy

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: ~~1/31/2017; 2/9/2017;~~ **8/17/2017**