

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)

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 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/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis? Yes No
- Is member free from illicit substance abuse for at least 6 months? **(submit labs last 30 days)** Yes No
- Is member free from alcohol abuse for at least 6 months? **(submit labs 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)

FOR GENOTYPE 2:

Trial and failure of Interferon + Ribavirin (please submit progress notes if failed in past)

Approval for Sovaldi® will **not** be considered **before** trial and failure of an Interferon + Ribavirin therapy and Table A is filled out.

Treatment Experienced with 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:

- Liver biopsy confirming:
 - METAVIR sc
ore 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 8.7kPa (1.70 m/s) (F3) OR 10.4kPa (1.86m/s) (F4)
- Shear wave (VTTQ) Siemens score of greater \geq 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	
<input type="checkbox"/> Neutrophils	<750/ μ L within the past 3 months
<input type="checkbox"/> ANC	<500 within the past 3 months
<input type="checkbox"/> Hgb	Baseline within past month <7g/dL
<input type="checkbox"/> Platelets	<50,000 within past 3 past months
<input type="checkbox"/> Autoimmune hepatitis	<input type="checkbox"/> YES OR <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 OR <input type="checkbox"/> NO
<input type="checkbox"/> Suicidal within last 3-6 months AND documented evidence of > 3 medication adjustments to control symptoms within the past 12months of psychosis, etc.	<input type="checkbox"/> YES OR <input type="checkbox"/> 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: 5/16/2014; 5/22/2014; 6/5/2014; 7/16/2014; 11/5/2014; 2/4/2015; 5/22/2015; 10/15/15; 10/20/2015; 12/29/2015; 6/6/2016; 12/20/2016; 8/17/2017