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***

Drug Requested: **Daklinza**™ (daclatasvir) ***(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.***
- ***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 ❑ relapser ❑ prior partial responder ❑ prior null responder

  - Patient has a diagnosis of CHC with HCV: ***(If No, send documentation)***
    - ❑ **Genotype 1 (*MEDICAID*: *Has the patient had a trial and failure of Harvoni®?*** ❑ Yes ❑ No
      (***COMMERCIAL*: *Has the patient had a trial and failure of Harvoni®*** ❑ Yes ❑ No

      OR

    - ❑ **Genotype 3**: ***Has the patient had a trial and failure for Sovaldi® + Peginterferon + Ribavirin® or Epclusa®?*** ❑ Yes ❑ No
  - **Please list all recent HCV TREATMENTS**:_____
  - Has the member previously tried: ❑ NS3/4A Protease Inhibitor ❑ NS5B Inhibitor ❑ NS5A Inhibitor ❑ Yes ❑ No
  - Is the patient co-infected HIV? ❑ Yes ❑ No
  - Is the patient co-infected HBV? ❑ Yes ❑ No
  - 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
  - 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

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)

Please send all recent labs for HCV

Duration of Approval (IDSA Guidelines)

	Patient Population	Treatment & Duration
Genotype 1	Without cirrhosis	DAKLINZA + sofosbuvir for 12 weeks
	Compensated (Child-Pugh A) cirrhosis	
	Decompensated (Child Pugh B or C) cirrhosis	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Post-transplant	
Genotype 3	Without cirrhosis	DAKLINZA + sofosbuvir for 12 weeks
	Compensated (Child Pugh A) or decompensated (Child Pugh B or C) cirrhosis	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Post-transplant	

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:** 8/20/2015
REVISED/UPDATED: ~~10/15/2015; 11/19/2015; 12/1/2015; 12/22/2015; 3/17/16; 5/4/2016; 6/6/2016; 12/15/2016;~~ **9/19/2017**;