

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: **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
- 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	

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 ≥ 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 ≥ 8.7 kPa (1.70 m/s) (F3) OR 10.4kPa (1.86m/s) (F4)
- Shear wave (VTTQ) Siemens score of greater ≥ 1.55 m/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	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Decompensated (Child Pugh B or C) cirrhosis	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Post-transplant	DAKLINZA + sofosbuvir for 12 weeks
Genotype 3	Without cirrhosis	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Compensated (Child Pugh A) or decompensated (Child Pugh B or C) cirrhosis	DAKLINZA + sofosbuvir + ribavirin for 12 weeks
	Post-transplant	DAKLINZA + sofosbuvir + ribavirin for 12 weeks

****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; 12/4/2015; 12/22/2015; 3/17/16; 5/4/2016; 6/6/2016; 12/15/2016; 2/9/2017; 8/11/2017.