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. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Hepatitis-C Antiviral (HCV) Drugs

PREFERRED		
❑ sofosbuvir/velpatasvir **(ABA Epclusa)**	❑ ledipasvir/sofosbuvir **(ABA Harvoni)**	❑ **Mavyret™** (glecaprevir/piprentasvir)
NON-PREFERRED		
❑ **Epclusa®**	❑ **Harvoni®**	❑ **Sovaldi®**
❑ **Viekira Pak**	❑ **Vosevi®**	❑ **Zepatier®**

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable**: _____

- **Optima Health coverage criteria for the new direct-acting agents is based on careful consideration of the evidence-based guidance of professional specialty societies, published guidelines, and physician subject matter expert specialists.**
- **Coverage criteria will be assessed for members diagnosed with HCV F0-F4 Fibrosis score**
- **ONE TIME APPROVAL FOR ANY and ALL DIRECT-ACTING ANTIVIRAL (DAA) PER LIFETIME**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ **If** requesting a **non-preferred** medication member must have trial and failure, intolerance or contraindication to **BOTH** of the following **(verified by pharmacy paid claims or submitted chart notes)**
  - ❑ Mavyret (prior authorization required)
  - ❑ ABA Epclusa or ABA Harvoni (prior authorization required)
- ❑ Medication must be prescribed by one of the following provider types:
  - ❑ Gastroenterologist
  - ❑ Hepatologist
  - ❑ Infectious Disease Specialist
  - ❑ Transplant Specialist

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- ❑ Provider **must submit documentation** (chart notes, laboratory values, test results) to confirm **ALL** of the following information for assessment of appropriate treatment duration: *(reference dosing table below)*
  Note: the following information will not be used to determine approval or denial outcome
  - ❑ Diagnosis
    - ❑ Genotype: _____
  - ❑ HCV treatment history
    - ❑ Treatment-Naïve
    - ❑ Relapsed, previous therapy/treatment: _____
    - ❑ Treatment Experienced, previous therapy/treatment: _____
  - ❑ Existence of cirrhosis
    - ❑ No Cirrhosis
    - ❑ Compensated Cirrhosis
    - ❑ Decompensated Cirrhosis
    - ❑ Hepatocellular Carcinoma
    - ❑ Awaiting Liver Transplant
  - ❑ Liver assessment
    - ❑ Liver biopsy
    - ❑ Transient elastography (FibroScan)
    - ❑ FibroTest (FibroSure)
    - ❑ Shear wave elastography (ElastPQ)
    - ❑ Shear wave (SWE supersonic tech)
    - ❑ Shear wave (VTTQ) Siemens
  - ❑ Alcohol/toxicology screening **(collected the same day as the liver assessment)**
  - ❑ Blood test results
    - ❑ Complete Blood Count (CBC)
    - ❑ Basic Metabolic Panel (BMP)
    - ❑ HCV RNA viral load **(collected within the previous 6 months)**
  - ❑ If member is less than 18 years of age, please submit current weight: _____

*****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.****

Member 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:** 10/1/2017
REVISED/UPDATED: ~~10/5/2017; 12/30/2017; (REFORMATTED) 3/21/2019; 10/22/2020; 1/10/2022;~~ **3/11/2022**;

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HCV GENOTYPE	Genotype	Patient Population	Regimen & Duration
HARVONI	Genotype 1	Treatment-naïve without cirrhosis and pre-treatment HCV RNA less than 6 million IU/mL	HARVONI 8 weeks
		Treatment-naïve without cirrhosis & pre-treatment HCV RNA more than 6 million IU/mL or with compensated cirrhosis (Child Pugh A)	HARVONI 12 weeks
		Treatment-experienced without cirrhosis	HARVONI 12 weeks
		Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
		Treatment-naïve and treatment experienced with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin 12 weeks
	Genotype 1 or 4	Treatment-naïve and treatment experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
	Genotype 4, 5, or 6	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
Mavyret	Genotype: 1,2,3,4,5, or 6	Treatment naïve and no cirrhosis or compensated cirrhosis (Child-Pugh A)	MAVYRET 8 weeks
	1	Treatment Experienced: An NS5A[1] inhibitor1 without prior treatment with an NS3/4A protease inhibitor (PI): without or compensated cirrhosis (Child-Pugh A)	16 weeks
		Treatment Experienced: An NS3/4A PI[2] without prior treatment with an NS5A inhibitor: without or compensated cirrhosis (Child-Pugh A)	12 weeks
	1, 2, 4, 5, or 6	Treatment Experienced: PRS[3]: no cirrhosis	8 weeks
		Treatment Experienced: PRS[3]: Compensated cirrhosis (Child-Pugh A)	12 weeks
	3	Treatment Experienced: PRS[3]: without or compensated cirrhosis (Child-Pugh A)	16 weeks
EPCLUSA	1,2, 3, 4, 5, 6	Treatment-naïve and treatment experienced , without cirrhosis and with compensated cirrhosis (Child-Pugh A)	12 weeks
		Treatment-naïve and treatment experienced a, with decompensated cirrhosis (Child-Pugh B and C)	12 weeks + ribavirin 12 weeks
Zepatier	Package insert		
Vosevi	Package insert		
Viekira Pak	Package insert		

1. Treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with (peg) interferon and ribavirin.
2. Treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with (peg) interferon and ribavirin.
3. PRS=Prior treatment experience with regimens containing (peg) interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.