Hepatitis C Prior Authorization Guide

1.0 Genotype and Corresponding Treatment Regimen

Treatment Regimen is determined by Genotype. After determining genotype and patient eligibility (see below, section 2), start treatment regimen based on the following table.

Status Type (HCV Mono-infected or HCV/HIV-1 Co-Infected)	Associated Treatment Regimens	Total Approval Duration for Sovaldi
Genotype 1 CHC	Sovaldi + IFN + RBV Sovaldi + Olysio ± RBV (regardless of IFN eligibility)	12 weeks
Genotype 1 CHC ineligible for an interferon-based regimen	Sovaldi + RBV Sovaldi + Olysio ± RBV	24 weeks 12 weeks
Genotype 2 CHC	Sovaldi + IFN + RBV Sovaldi + RBV	12 weeks^
Genotype 3 CHC	Sovaldi + RBV	24 weeks
Genotype 3 CHC (treatment naïve or nonresponder**)	Sovaldi + IFN + RBV	12 weeks
Genotype 4 CHC	Sovaldi + IFN + RBV	12 weeks
Genotype 4 CHC (treatment nonresponder**)	Sovaldi + RBV	24 weeks
Genotype 5 or 6 CHC (treatment naïve or prior relapser#)	Sovaldi + IFN + RBV	12 weeks
Hepatocellular Carcinoma awaiting liver transplant	Sovaldi + RBV	Up to 48 weeks*

^ In individuals who are treatment nonresponders with concurrent cirrhosis, therapy duration with Sovaldi + RBV may be extended up to 4 additional weeks for a total of 16 weeks (AASLD/IDSA 2014)

** Treatment nonresponder refers to partial or no response to previous dual therapy with interferon and ribavirin.

Prior relapser refers to an undetectable level of virus during a prior treatment course of interferon and ribavirin and relapsed.

* Therapy duration is recommended for up to 48 weeks or until the time of liver transplantation, whichever occurs first.

-For Genotype 1, 2, and 3, patients with mild liver disease (equivalent to METAVIR F0-2) are **not eligible** for Sofosbuvir- or Simeprevir-based regimens. **EXCEPTION:** If patient has serious **extra-hepatic manifestations,** may be eligible for treatment (see below, **Section 2.5**)

2.1 Required Documentation For Eligibility

*This table outlines required documents for prior authorization of Sovaldi (Sofosbuvir). The following documents **must** be presented in order to determine eligibility:*

Information Required	Document Required
Proof that patient is 18 years or older	Date of Birth on Chart Notes
Documentation of diagnosis of chronic hepatitis C (CHC) infection, which includes genotype	HCV Antibody Test
	HCV Genotypic Testing Lab
Documentation of baseline level of viremia	Baseline quantitative HCV RNA test result
Proof that patient has compensated liver disease	Child-Pugh Score less than 6

2.2 Additional Considerations For Eligibility Based on Liver Fibrosis

*In addition to the above documentation (**Section 2.1**), patients **must meet at least one** of these criteria to be considered for treatment.*

Criteria that demonstrates Advanced Fibrosis	Description	Associated Test and Results
Stage F3 (Advanced Fibrosis)	Biopsy shows numerous septa without cirrhosis.	Liver Biopsy and associated score on METAVIR, IASL, or Batts-Ludwig
F4 (Cirrhosis)	Biopsy is indicative of cirrhosis.	Liver Biopsy and associated score on METAVIR, IASL, Batts-Ludwig, or Ishak
Strong clinical suspicion of advanced fibrosis/compensated cirrhosis (Confirmed by both Physical Exam **AND** Abdominal Imaging)	Physical Exam Findings	Palpable left lobe, splenomegaly, palmar erythema **AND** low platelet count (<100,000/mm^3)
	Pertinent Abdominal Image Findings	Surface abnormalities, Portal Hypertension, Ascites
Non-invasive Serum markers of Advanced fibrosis/cirrhosis	Find Serum Markers of advanced Fibrosis/Cirrhosis using tests with corresponding values:	APRI Score of > 1.5, FIB-4 Score of > 3.25 Fibrosure/Fibrotest of > 0.58
Confirmation of Fibrosis with non-invasive imaging	Use of following imaging tests with corresponding values:	Fibroscan of >9.5 kilopascals ARFI of > 1.54 m/sec Magnetic Resonance Elastography (MRE) of > 6.47

2.3 Fibrosis Testing Methods and Labs

*These testing methods and labs **should** be considered when assessing a patient for fibrosis (**Section 2.2**).*

Testing Method/Lab to Determine Staging of Fibrosis	Description
METAVIR Score	Biopsy scoring system. Measures degree of fibrosis from 0 to 4.
IASL Score	Biopsy scoring system from International Association for the Study of the Liver. Measures degree of fibrosis from 0-4.
APRI	Non-invasive index. Measures AST to Platelet Ratio Index
FIB-4	Non-invasive scoring system. Measures age, AST and ALT levels, and platelet count.
Fibrosure/Fibrotest	Non-invasive test to diagnose fibrosis. Measures six serum markers with age and gender.
Fibroscan (Transient Elastoraphy)	Non-invasive device to measure staging of fibrosis. Measures "liver stiffness". Cannot be used on patients with ascites or who are morbidly obese.
ARFI	Non-invasive Imaging. Uses acoustic radiation force to generate images of mechanical properties of soft tissue.
Magnetic Resonance Elastography (MRE)	Non-invasive Imaging. Combines MRI imaging with sound waves to generate images of body tissue stiffness.

2.4 Screenings Prior to Treatment Initiation

*Patients **must** be undergo specific screenings and obtain results within 30 days of initiating treatment.*

- Patient must be screened for depression using PHQ-2, PHQ-9, or other screening tool. If positive, must be adequately and appropriately treated for depression prior to initiation of treatment
- Must be screened and/or vaccinated for Hepatitis A and B if not infected or exposed, and must be screened for HIV within 30 days of treatment initiation, with lab evidence. Vaccinations must occur before treatment initiation.
- When Sofosbuvir (pregnancy class B) or Simeprevir (pregnancy class C) is used in combination with ribavirin (pregnancy class X), it must NOT be started unless a report of a negative pregnancy test has been obtained.

2.5 Extra-hepatic Manifestations

Patients with extra-hepatic manifestations **do not** need to have a METAVIR score of F3 or F4. Patients can obtain eligibility with mild liver disease (**equivalent to F0-F2) AND** extra-hepatic manifestations. Manifestations can include:
- **Leukocytoclastic vasculitis (LCV**) - characterized by vascular damage caused by infiltrating neutrophils. Classically presents as palpable purpura. Less common findings include urticarial plaques, vesicles, bullae, and pustules
- **Membranoproliferative Glomerulonephritis (MPGN)** – Caused by deposits in the kidney glomerular mesangium and glomerular basement membrane (GBM) thickening. Symptoms: Blood in urine, cloudy urine, bodily swelling
- **Cryoglobulinemia** – blood contains large amounts of cryoglobulins - proteins (mostly immunoglobulins) that become insoluble at low temperatures. Symptoms: Purpura, fatigue, muscle pain, joint pain, difficulty breathing, and skin death