



## Manual Prior

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### Hepatitis C agents

Prescriber indicates diagnosis, social history, prior treatment, patient status and requested regimen on PA request form, and attests to the accuracy of the information and availability of documentation in the patient's medical chart.

#### **LAB VALUES AND PRIOR AUTHORIZATIONS:**

For all regimens HCV RNA values must be measured 1-4 days before the end of treatment weeks (TWs) 4, 8, 12, and 24 and reported on the continuation PA request.

An initial PA is approved for treatment weeks (TWs) 1-8 for all therapies when the general and regimen specific criteria have been documented on the request.

Approval of continuation requests are done for 1 month or more based on prescriber documenting the following:

- Patient has remained compliant (>85%) on all medications.
- Efficacy of regimen has been documented through lab values, copies of which are attached to the request form.

**REGIMENS SPECIFIC LAB VALUES FOR CONTINUATION OF THERAPY ARE INDICATED BELOW.**

#### **GENERAL CRITERIA FOR ALL REGIMENS:**

- Prescriber is, or has consulted with a gastroenterologist, hepatologist, ID specialist or other Hepatic specialist. Requires consult within the past year with documentation of recommended regimen.
- Documentation of counseling regarding abstinence from alcohol, IV drug use and education on how to prevent HCV transmission.
- Documentation of abstinence from drugs and alcohol for at least 6 months; negative urine drug screen required if there is a history of IV drug use.

#### **CRITERIA FOR ALL REGIMENS INCLUDING RIBOVIRON (RBV):**

For women of childbearing potential and male patients with female partners of childbearing potential (for RBV regimens only) prescriber must attest that documentation of the following exists in the patient's chart:

- Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping treatment
- Agreement that partners will use two forms of effective non-hormonal contraception during treatment and for at least 6 months after stopping treatment
- Verification that monthly pregnancy tests will be performed throughout treatment

## INF INTOLERANT CRITERIA

INF intolerance can be documented in the patient's chart by any of the following:

- Documented life-threatening side effects or potential side effects (i.e. history of suicidality)
- Decompensated cirrhosis (Child-Pugh > 6) OR Child-Pugh ≥ 6 with HIV
- Blood dyscrasias – baseline neutrophil count <1500/ $\mu$ L, baseline platelets <90,000/ $\mu$ L or baseline Hgb < 10/dL
- Pre-existing unstable or significant cardiac disease (e.g. history of MI or acute coronary syndrome)
- Other documentation provided by prescriber.

## REGIMEN SPECIFIC CRITERIA FOR INITIATING THERAPY WITH EACH AGENT:

### **HARVONI® (ledipasvir/sofosbuvir) Regimens / Criteria**

#### **H1. One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) daily for 8 weeks**

*GENOTYPE 1: Treatment naïve, W/OUT cirrhosis, pre-treatment HCV RNA < 6 million IU/mL*

#### **H2. One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) daily for 12 weeks**

*GENOTYPE 1: Treatment naïve, W/ or W/OUT cirrhosis, pre-treatment HCV RNA ≥ 6 million IU/mL*

*GENOTYPE 1: Relapsed, prior null or partial response, W/OUT cirrhosis*

#### **H3. One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) daily for 24 weeks**

*GENOTYPE 1: Relapsed, prior null or partial response, W/ cirrhosis*

#### **Lab value criteria for discontinuing Harvoni® therapy after TW 8:**

HCV RNA at **TW 4 or later** > 25 IU/mL – discontinue therapy

### **OLYSIO® (simeprevir) Regimens / Criteria**

#### **O1. 150 mg daily plus weight-based RBV plus weekly PEG for 12 weeks / Weight-based RBV plus weekly PEG for 12 weeks**

*GENOTYPE 1: Treatment naïve OR relapsed to regimen W/out protease inhibitor, W/ or W/out cirrhosis AND NS3 Q80K polymorphism negative*

#### **O2. 150 mg daily plus weight-based RBV plus weekly PEG for 12 weeks / Weight-based RBV plus weekly PEG for 36 weeks**

*GENOTYPE 1: Prior non-responder to regimen W/out protease inhibitor, W/ or W/out cirrhosis AND NS3 Q80K polymorphism negative*

#### **Lab value criteria for discontinuing Olysio® therapy after TW 8:**

HCV RNA at **TW 4 or later** > 25 IU/mL – discontinue therapy after TW 12

## **SOVALDI® (sofosbuvir) Regimens / Criteria**

### **S1. 400mg daily plus weight-based RBV plus weekly PEG for 12 weeks**

*GENOTYPE 1: Treatment naïve / relapsed (regardless of HIV co-infection)*

*GENOTYPE 2: Prior null or partial response WITH cirrhosis*

*GENOTYPE 3, 4, 5 OR 6: Regardless of prior treatment*

### **S2. 400mg daily plus weight-based RBV plus weekly PEG for 12 weeks / additional 12 weeks of PEG/RBV to follow**

*GENOTYPE 1: Prior null or partial response (w/ or w/out protease inhibitor)*

*GENOTYPE 1: HIV+, prior null or partial response to PEG/RBV PLUS a protease inhibitor*

### **S3. 400mg daily plus weight-based RBV for 12 weeks**

*GENOTYPE 2: Treatment naïve / relapsed W/OUT cirrhosis*

### **S4. 400mg daily plus weight-based RBV for 16 weeks**

*GENOTYPE 2: Treatment naïve, relapsed, or null responder, W/ cirrhosis, INF-intolerant\**

### **S5. 400mg daily plus Olysio 150mg daily w/ or w/out weight-based RBV for 12 weeks**

*GENOTYPE 1: INF-intolerant\* AND Child-Pugh < 6*

*GENOTYPE 1: HIV+, prior non-response to PEG/RBV*

### **S6. 400mg daily plus weight-based RBV for 24 weeks**

*GENOTYPE 1: INF-intolerant\* AND Child-Pugh ≥6*

*GENOTYPE 1, 2 OR 3: Re-infection of allograft liver after transplant*

*GENOTYPE 3 OR 4: INF-intolerant\**

### **S7. 400mg daily plus weight-based RBV (for up to 48 weeks or until liver transplant)**

*AWAITING LIVER TRANSPLANT: Patient has diagnosis of hepatocellular carcinoma and is awaiting transplant*

### **Lab value criteria for discontinuing Sovaldi® therapy after TW 8:**

**HCV RNA at TW 12 or later > 25 IU/mL – discontinue therapy**

## VICTRELIS® (boceprevir) Regimens / Criteria

### V1. Weight-based RBV plus weekly PEG for 4 weeks / 800 mg boceprevir orally three times daily plus weight-based RBV plus weekly PEG for 12 weeks / continued treatment beyond based on viral response

*GENOTYPE 1: Treatment naïve OR relapsed or null responder to regimen W/out protease inhibitor, W/ or W/out cirrhosis*

#### Recommended length of therapy based on response to treatment:

Treatment status	HCV RNA at TW 8	HCV RNA at TW 24	PA action
Previously untreated	Not detected	Not detected	Complete triple regimen at TW 28
	Detected	Not detected	1. Continue triple regimen an finish at TW 36; 2. Continue PEG + RBV through TW 48
Previously partial responder or relapser	Not detected	Not detected	Complete triple regimen at TW 36
	Detected	Not detected	1. Continue triple regimen an finish at TW 36; 2. Continue PEG + RBV through TW 48

#### Lab value criteria for discontinuing Victrelis® therapy after TW 8:

Discontinue therapy if:

1. HCV RNA at TW 8  $\geq$ 1000 IU/mL
2. HCV RNA at TW 12  $\geq$ 100 IU/mL
3. Confirmed detectable HCV RNA levels at TW 24

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