

GOALS

ALERTS

<ul style="list-style-type: none"> ➤ Identify Hepatitis C virus (HCV) Ab+ patients. Use high sensitivity viral load (VL) test to confirm diagnosis. (e.g., Hepatitis C Viral RNA, Quantitative, Real-Time PCR) ➤ Appropriately treat eligible patients ➤ Monitor HCV patients on treatment ➤ Stop treatment as indicated (futility rules) ➤ Monitor all HCV patients for signs of cirrhosis and manage End Stage Liver Disease (ESLD). 	<p><u>HCV TREATMENT</u></p> <ul style="list-style-type: none"> • HCV treatment for all genotypes requires approval from the CCHCS HCV Oversight Committee • Closely monitor during treatment :Hgb < 10 g/dl, Hgb decrease more than 2 g/dl in 4 weeks, platelet (Pit) < 50,000/μl, absolute neutrophil count (ANC) < 750 cells/μl • DO NOT USE monotherapy with sofosbuvir, boceprevir, telaprevir, or simeprevir. <p><u>CIRRHOTICS</u></p> <ul style="list-style-type: none"> • Screen for hepatocellular carcinoma and varices • Identify decompensated cirrhosis (evidenced by encephalopathy, ascites, variceal hemorrhage, spontaneous bacterial peritonitis, hepatopulmonary or hepatorenal disease or a Child-Pugh score of ≥ 7)
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TREATMENT OPTIONS

PATIENT SELECTION: Who to treat?

- In CCHCS treatment eligibility is based on estimated disease severity.
 - Every patient with chronic HCV does **not** need treatment.
 - Only 10-20% of people with chronic HCV develop severe liver disease; only 1- 5% will die from complications of liver disease. There is no single test that can absolutely predict who will progress to severe liver disease.
 - Treatment is deferred for those with minimal liver disease or low likelihood of significant liver disease (see page 5) .
 - **All genotypes** now require treatment preapproval through the HQ CCHCS HCV Oversight Committee.
- HCV evaluation and treatment is generally not initiated in reception centers. HCV treatment, if indicated, should occur after the patient has transferred to a mainline institution.
- Patients who are recommended for deferral of treatment as recommended in this care guide may not receive pegylated interferon / ribavirin as an alternative to no treatment

TREATMENT

- Medication regimen depends on genotype and other factors: see pages 6-10; consult with CCHCS HCV Oversight Committee.

MONITORING

ALL CHRONIC HCV INFECTED PATIENTS:

- Annual clinical assessment: consider labs including platelets (Pit), INR, albumin, AST/ALT, and total bilirubin every 6-12 months to assess progression of liver disease, determine FIB4 or Child-Pugh score (page 3) as indicated.
- Vaccines: Offer and document HAV, HBV, pneumococcal vaccination. Encourage annual influenza vaccination.

HCV PATIENTS RECEIVING ANTIVIRAL THERAPY:

- See HCV treatment tracking flowsheets¹ regarding intervals for CBC, creatinine, LFT, TSH, high sensitivity HCV VL.
- Assess for depression and other side effects at each visit.
- Follow up as clinically indicated, usually every 1-4 weeks during active treatment.

CHRONIC HCV INFECTED PATIENTS WITH CIRRHOSIS

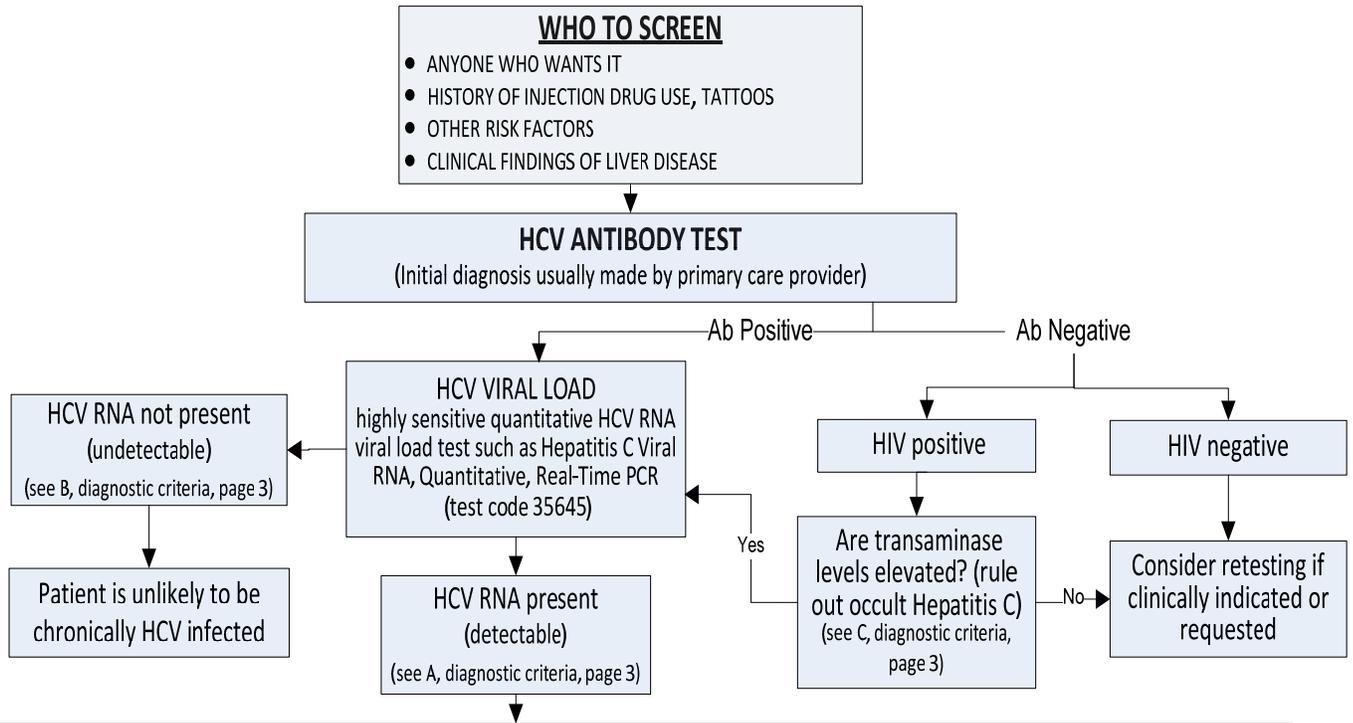
- Ultrasound every six months with clinically diagnosed or biopsy proven cirrhosis to screen for hepatocellular carcinoma, monitor Child-Pugh score (page 3) as indicated. See ESLD Care Guide.

¹All HCV Care Guide related forms are available on CCHCS Lifeline at <http://lifeline/Home/PolicyandRiskManagement/IMSPP.aspx>

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Information contained in the Care Guide is not a substitute for a health care professional's clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to "Disclaimer Regarding Care Guides" for further clarification.

DIAGNOSIS OF HEPATITIS C



Primary Care Provider:

- Provide counseling regarding HCV infection
- Obtain baseline assessment, including CBC, CMP, INR, or use values obtained within three months prior to starting treatment,
- TSH, HIV Ab, and high sensitivity quantitative HCV viral load, or use values obtained within one year prior to starting treatment
- Obtain HCV genotype if not available; repeat genotype not required
- Immunize, including HAV, HBV, pneumococcus, influenza

HCV TREATING CLINICIAN or PRIMARY CARE PROVIDER
complete CDCR Form 7413-1, CCHCS Primary Care HCV Intake/Screening*

* All HCV forms are available on CCHCS Lifeline at <http://lifeline/Home/PolicyandRiskManagement/IMSPP.aspx>

EXCLUSION CRITERIA	
Release Date Exclusion :	
Treatment Naïve:	
Genotype	Months
1, 2, 3 and 4	<5
5 and 6	<14
Interferon ineligible:	
Genotype	Months
1 and 2	<5
3, 4, 5, 6	<8
Treatment experienced:	
Genotype	Months
1a	<5
1b, 2, 3, 4, 5, 6	<8
Other Exclusion Criteria :	
<ul style="list-style-type: none"> • Poorly controlled cardiopulmonary, cerebrovascular, or thyroid disease, blood dyscrasias, seizures, cancer, diabetes mellitus (hemoglobin A1C > 8.5) • HIV infection with CD4 count < 200 cells/ml or undergoing treatment for opportunistic infection • Kidney, lung, heart transplant • Anemia, hemoglobin < 11 g/dl or hematocrit < 33% • Allergy to ribavirin • Inability to cooperate with treatment • Inability to give informed consent • Ongoing illicit drug or alcohol use • Pregnancy or inability to practice contraception 	

INTERFERON EXCLUSION CRITERIA
<ul style="list-style-type: none"> • WBC < 1,500 cells/μl or Plt < 75,000/μl • History of decompensated cirrhosis, evidenced by either variceal hemorrhage, (esophageal varices with no history of variceal hemorrhage are not a contraindication) ascites, hepatic encephalopathy, spontaneous bacterial peritonitis, hepatopulmonary disease, hepatorenal disease, or a Child-Pugh score of ≥ 7 (Child-Pugh ≥ 6 if HIV/HCV coinfectd) • Severe or acute autoimmune disease (recommend consultation) • Poorly controlled depression • Serious suicidal behavior in the past 12 months

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SELF MANAGEMENT
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DIAGNOSTIC CRITERIA

FROM PAGE 2	HCV AB	HCV RNA VIRAL LOAD	DIAGNOSIS	COMMENT
A	Pos	Pos	<ul style="list-style-type: none"> Chronic HCV (80% of those initially infected) 	<ul style="list-style-type: none"> Order genotype if no prior result available Assess for treatment eligibility
B	Pos	Neg	<ul style="list-style-type: none"> Resolved HCV (up to 20% of those infected) Acute HCV with transient viral clearing (see page 4) False positive HCV Ab 	<ul style="list-style-type: none"> Consider rechecking high sensitivity VL at 6-12 months to confirm that patient is not chronically infected
C	Neg	Pos	<ul style="list-style-type: none"> Early acute HCV (see page 4) Chronic HCV in immunosuppressed patient (e.g., HIV) False positive viral load 	<ul style="list-style-type: none"> If acute HCV, consider consultation with HCV specialist at CPHCSHCVquestions@cdcr.ca.gov and (see page 4)

DEFINITIONS OF TREATMENT RESPONSE

	NAME	DEFINITION
RVR	Rapid Viral Response	Undetectable viral load at 4 weeks
EVR	Early Viral Response	Undetectable viral load at 12 weeks
eRVR	Extended Rapid Viral Response	Undetectable viral load at 4 and 12 weeks
pEVR	Partial Early Viral Response	2 log reduction in viral load at 12 weeks (genotypes 1, 4, 5, or 6)
ETR	End of Treatment Response	Undetectable viral load at end of therapy
SVR12	Sustained Viral Response - 12 week	Undetectable viral load 12 weeks after completion of therapy – this value is replacing the SVR24
SVR24	Sustained Viral Response - 24 week	Undetectable viral load 24 weeks (6 months) after completion of therapy

DEFINITION OF TREATMENT FAILURE	
Null responder	Did not achieve pEVR (2 log drop) at 12 weeks
Partial responder	Achieved pEVR (2 log drop) at 12 weeks, but still had detectable viral load at week 24
Relapser	Achieved an ETR (undetectable HCV viral load at end of treatment), but not an SVR (undetectable 6 month post treatment viral load)

CHILD- PUGH SCORING

COMPONENT	POINTS SCORED		
	1	2	3
Encephalopathy[†]	None	Grade 1-2	Grade 3-4
Ascites	None	Mild or controlled with diuretics	Moderate or refractory despite diuretics
Albumin	> 3.5 g/dl	2.8-3.5 g/dl	< 2.8 g/dl
Total bilirubin or Modified total bilirubin[§]	< 2 mg/dl	2-3 mg/dl	> 3 mg/dl
	< 4 mg/dl	4-7 mg/dl	> 7 mg/dl
Prothrombin time (seconds prolonged) or International normalized ratio (INR)	< 4	4-6	> 6
	< 1.7	1.7-2.3	> 2.3

[†] Encephalopathy: grade 1: mild confusion, anxiety, restlessness, fine tremor, slowed coordination
 grade 2: drowsiness, disorientation, asterixis
 grade 3: somnolent but arousable, marked confusion, incomprehensible speech, incontinence, hyperventilation
 grade 4: coma, decerebrate posturing, flaccidity

[§] modified total bilirubin used to score patients who have Gilbert's syndrome or who are taking atazanavir or indinavir

ACUTE HCV: DIAGNOSIS, STAGING AND TREATMENT

DEFINITION

- Documented change in HCV antibody from negative to positive within a six month time period, OR
- A new (within the last three months) positive HCV antibody accompanied by:
 - A new elevation of AST/ALT (defined as at least five times prior baseline level obtained within the last 24 months), or
 - A five time rise above normal AST/ALT levels if no baseline labs in last 24 months, and
 - No other concomitant conditions to explain the rise in liver enzymes.

EVALUATION

- The majority of patients are asymptomatic.
- Clinical presentation may include jaundice, dark urine, right upper quadrant abdominal pain, fatigue
- High sensitivity quantitative HCV VL, HCV genotype, HIV antibody, CBC, complete metabolic panel (CMP), TSH, and INR.
- Interleukin 28B (IL28B) genotyping (CC, CT, TT) is not required or recommended for treatment planning
- Additional workup for hepatitis such as abdominal ultrasound, CT, or laboratory studies such as amylase, lipase, and urinalysis are not required for treatment of acute HCV, but may be indicated based on clinical presentation
- “Time Zero” is date of first signs and symptoms of acute hepatitis or first lab abnormalities or, if none of the above are present, most recent date of IV drug use or tattooing can be used to determine waiting time to see if HCV will spontaneously resolve.
- Confirm that HCV hasn’t resolved spontaneously by rechecking high sensitivity HCV quantitative RNA viral load 8-10 weeks after the first identified seroconversion, (plus HIV antibody if previously negative). If HCV VL is still detectable consider treatment. Consult the HCV warmline at CPHCSHCVquestions@cdc.ca.gov if the diagnosis (acute or chronic) is uncertain.
- Screen patient using exclusion criteria listed on page 2. High risk behavior that led to this seroconversion is not an absolute contraindication to treatment of acute HCV. Counsel patient regarding risk reduction.

TREATMENT

On a case by case basis, the clinician will need to balance the benefit of treating acute HCV (with its greater chance of a good response) vs. later treatment of chronic HCV infection (with concerns regarding continuation of high risk behaviors that potentially led to acute HCV)

TREATMENT FOR ACUTE HCV (ALL GENOTYPES) -

GOAL: start no later than 24 weeks after exposure

Pegylated interferon, 180 mcg subcutaneous weekly, WITH

Ribavirin weight based (see page 12 for dosing) - genotype 1, 4, 5, or 6

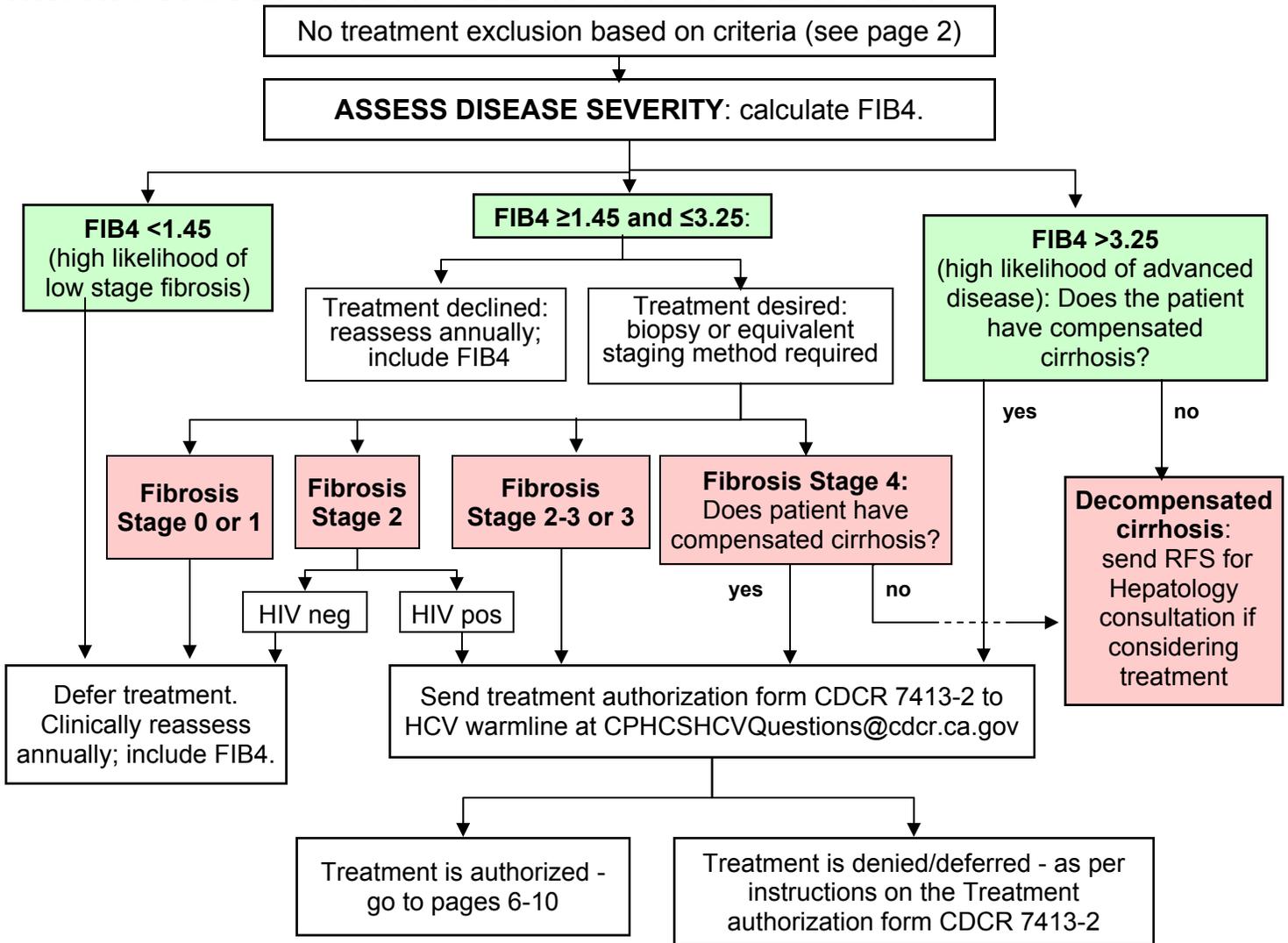
OR

Ribavirin 400 mg twice daily - genotype 2 or 3

Stopping rules

- Check high sensitivity quantitative VL at 12 weeks.
- Stop all treatment if VL does not decrease by at least 2 log.
- Total treatment duration (all genotypes): **24 weeks** for those eligible to complete treatment course.

CHRONIC HCV: PATIENT SELECTION FOR TREATMENT



***FIB4 = [Age(y) x AST(U/L)] / [PLT(10⁹/L) x ALT(U/L)^{1/2}]**

FIB4 <1.45 - unlikely to have significant fibrosis

FIB4 >3.25 - likely to have cirrhosis (Fibrosis stage 3 –4)

Vallet-Pichard, A et al, FIB-4: an Inexpensive and Accurate Marker of Fibrosis in HCV Infection. Comparison with Liver Biopsy and FibroTest. Hepatology 2007;46:32-36.

****LIVER BIOPSY**

- Adequate biopsy defined as 15 mm in length with a minimum of 6-8 portal tracts seen.
- If indicated and if treatment is being considered, repeat biopsy if stage <2 every 5 year if HIV negative, every 3 years if HIV positive. Liver biopsy is not necessary if prior biopsy stage 3 or 4 fibrosis, or if clinically cirrhotic.
- Consider calculating FIB4 prior to biopsy. If FIB4<1.45 and patient has no other comorbidities, is young, and has recently been HCV infected, patient is unlikely to have clinically significant fibrosis; advise accordingly.
- If FIB4 >3.25, patient is likely to have cirrhosis; consider a clinical evaluation for cirrhosis rather than biopsy; calculate Child Pugh score (page 3), look for clinical features consistent with advanced disease.

CHRONIC HCV TREATMENT: TREATMENT NAÏVE PROTOCOLS

Evaluation by CCHCS HCV Oversight Committee required before initiating therapy.
 Email questions to CPHCSHCVquestions@cdcr.ca.gov. See page 8 for additional details regarding these treatment protocols

GENOTYPE	MEDICATION AND DOSE	DURATION OF TREATMENT (IF PATIENT RESPONDS)
1	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir 400 mg once daily	12 weeks
2	Ribavirin 200 mg weight based ** Sofosbuvir 400 mg once daily	12 weeks 16 weeks (cirrhotics)
3	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir 400 mg once daily	12 weeks
	Ribavirin 200 mg weight based ** Sofosbuvir 400 mg once daily	24 weeks
4	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks
5 AND 6	Pegylated Interferon 180 mcg/week subQ Ribavirin weight based **	48 weeks

CHRONIC HCV TREATMENT: INTERFERON INELIGIBLE PROTOCOLS

Evaluation by CCHCS HCV Oversight Committee required before initiating therapy.
 Email questions to CPHCSHCVquestions@cdcr.ca.gov. See page 8 for additional details regarding these treatment protocols

GENOTYPE	MEDICATION AND DOSE	DURATION OF TREATMENT (IF PATIENT RESPONDS)
1 §	Simeprevir (SMV) 150 mg once daily* Sofosbuvir (SOF) 400 mg once daily +/- Ribavirin (RBV) weight based **	12 weeks
	Ribavirin (RBV) weight based** Sofosbuvir (SOF) 400 mg once daily	24 weeks
2	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks
3, 4, 5, 6	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	24 weeks

* If Genotype 1a, needs baseline testing for Q80K polymorphism. If present, consider alternate regimen.

** see page 12 for details regarding weight based ribavirin dosing

§ Consider deferring treatment unless immediate treatment is needed, as more effective IFN-free regimens for genotype 1 are expected within the next few years.

BOLD: CCHCS preferred regimen. Not bold: Alternative regimen. Please note HCV regimen will be selected during treatment authorization process based on clinical factors.

CHRONIC HCV TREATMENT: RETREATMENT PROTOCOLS

Evaluation by CCHCS HCV Oversight Committee required before initiating therapy.

Email questions to CPHCSHCVquestions@cdcr.ca.gov. See page 8 for additional details regarding these treatment protocols

GENOTYPE	MEDICATION AND DOSE	DURATION OF TREATMENT (IF PATIENT RESPONDS)
1	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks (SOF) 12-24 weeks (PEG/RBV)
	Simeprevir (SMV) 150 mg once daily* Sofosbuvir (SOF) 400 mg once daily +/- Ribavirin (RBV) weight based **	12 weeks
	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	24 weeks
1 with previous BOC or TEL failure	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks (SOF) 12-24 weeks (PEG/RBV)
2	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks 16 weeks (cirrhotics)
	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks
3	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks
	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	24 weeks
4	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks
	Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	24 weeks
5 OR 6	Pegylated Interferon (PEG) 180 mcg/week subQ Ribavirin (RBV) weight based ** Sofosbuvir (SOF) 400 mg once daily	12 weeks

*If Genotype 1a, needs baseline testing for Q80K polymorphism. If present, consider alternate regimen.

** see page 12 for details regarding weight based ribavirin dosing

BOLD = CCHCS preferred regimen.

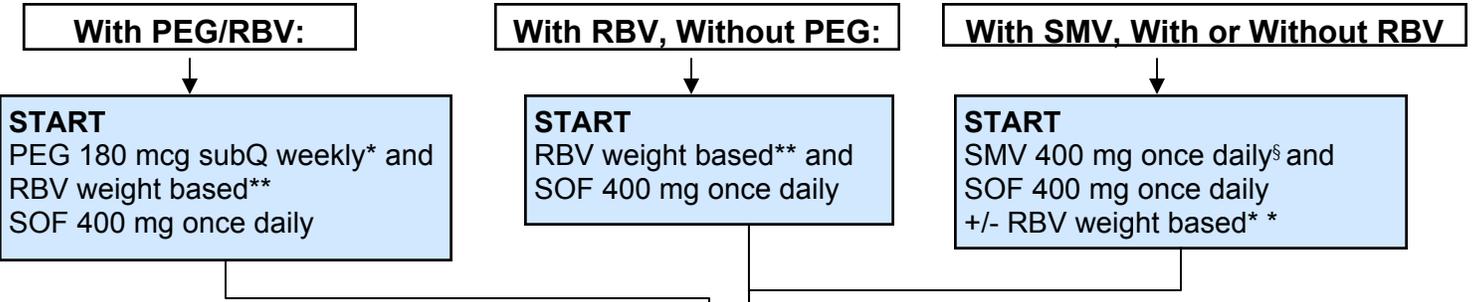
Not bold: Alternative regimen.

Please note HCV regimen will be selected during treatment authorization process based on clinical factors.

SOFOBUVIR CONTAINING REGIMENS

Evaluation by CCHCS HCV Oversight Committee required before initiating therapy.

Email questions to CPHCSHCVquestions@cdcr.ca.gov



Check page 6-7 for duration of treatment based on genotype and clinical history

**Ribavirin (RBV) weight based dosing:

Weight:	Dose: (total daily, divided two times a day)
<75 kg:	1000 mg/day
>75 kg:	1200 mg/day

✓ viral load at week 12 and 24 (if still on treatment)

Check a viral load at the end of treatment***

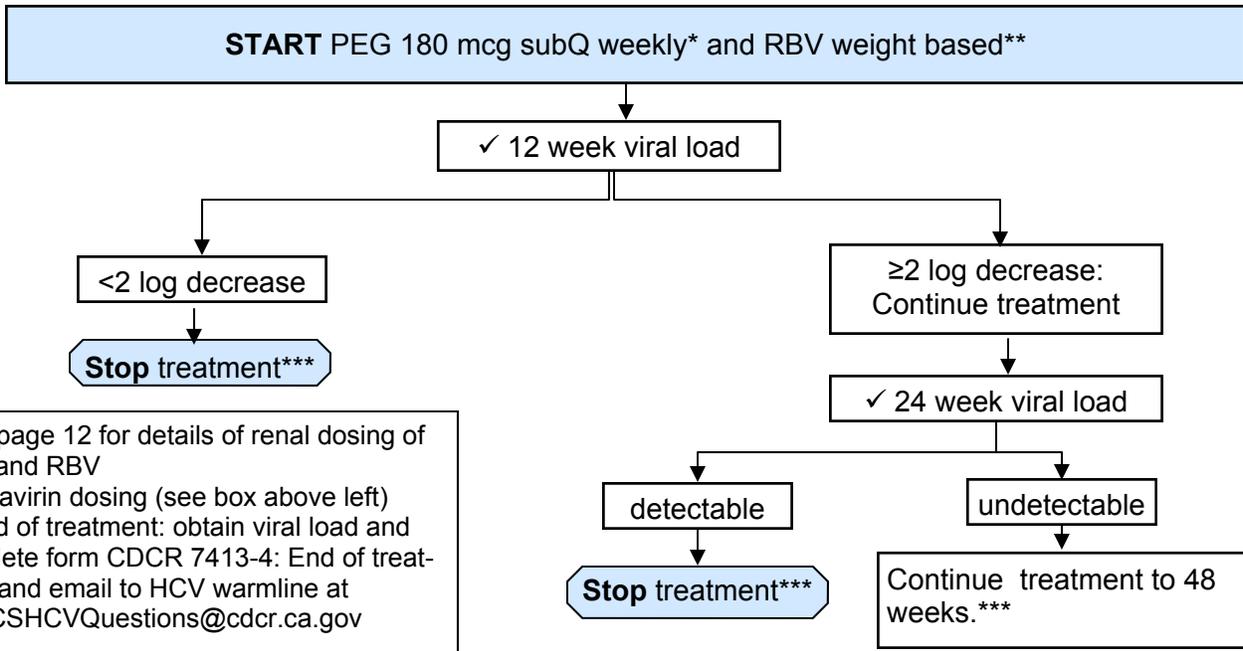
Abbreviations

PEG pegylated interferon
 RBV ribavirin
 SMV simeprevir
 SOF sofosbuvir

PEGYLATED INTERFERON AND RIBAVIRIN REGIMENS

Evaluation by CCHCS HCV Oversight Committee required before initiating therapy.

Email questions to CPHCSHCVquestions@cdcr.ca.gov



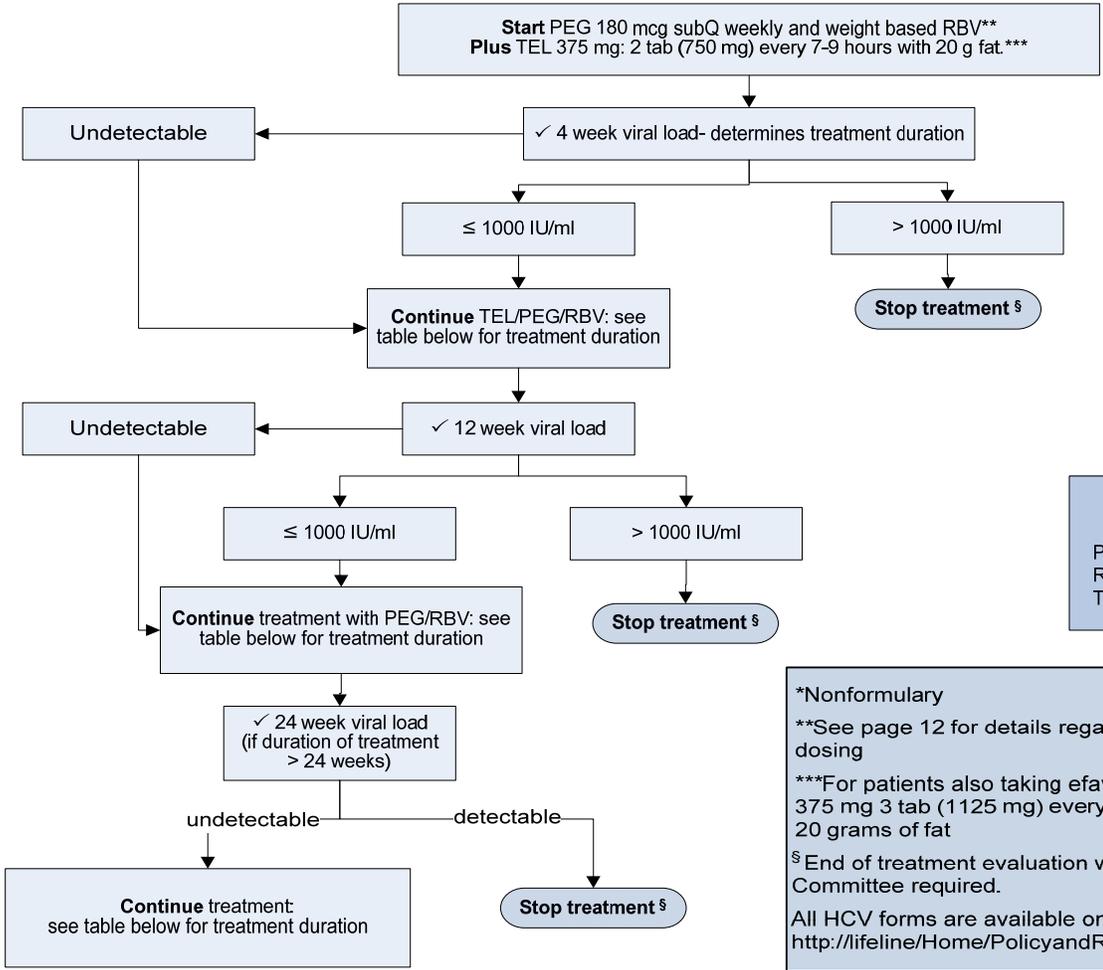
*See page 12 for details of renal dosing of PEG and RBV
 ** Ribavirin dosing (see box above left)
 ***End of treatment: obtain viral load and complete form CDCR 7413-4: End of treatment and email to HCV warmline at CPHCSHCVQuestions@cdcr.ca.gov

§ see page 13 for information about required baseline resistance testing needed before SMV is started.

TELAPREVIR* CONTAINING REGIMENS

FOR CONTINUATION ONLY: NOTE THAT BOCEPREVIR AND TELAPREVIR REGIMENS WILL NO LONGER BE STARTED IN PATIENTS RECEIVING HCV THERAPY.

Evaluation by CCHCS HCV Oversight Committee **required** before initiating therapy. E-mail questions to CPHCSHCVquestions@cdcr.ca.gov



ABBREVIATIONS
 PEG pegylated interferon
 RBV ribavirin
 TEL telaprevir

*Nonformulary
 **See page 12 for details regarding weight based ribavirin dosing
 ***For patients also taking efavirenz (EFV), the dose of TEL is 375 mg 3 tab (1125 mg) every 7-9 hours with food containing 20 grams of fat
 § End of treatment evaluation with CCHCS HCV Oversight Committee required.
 All HCV forms are available on CCHCS Lifeline at <http://lifeline/Home/PolicyandRiskManagement/IMSPP.aspx>

Telaprevir (Genotype 1)				
PATIENT TYPE	Treatment naïve or prior relapsers		Treatment naïve with cirrhosis or all HIV positive	Treatment experienced prior partial or null responders
WEEK 4 VIRAL LOAD	Undetectable	≤ 1000 IU/ml	Undetectable	≤ 1000 IU/ml
Week 4 viral load > 1000 IU/ml - Stop treatment				
WEEK 12 VIRAL LOAD	Undetectable	≤ 1000 IU/ml	Undetectable	≤ 1000 IU/ml
Week 12 viral load > 1000 IU/ml - Stop treatment				
WEEK 24 VIRAL LOAD	Undetectable	Undetectable	Undetectable	Undetectable
Week 24 viral load detectable - Stop treatment				
TREATMENT DURATION	12 weeks TEL/PEG/RBV, then additional 12 weeks PEG/RBV	12 weeks TEL/PEG/RBV, then additional 36 weeks PEG/RBV	12 weeks TEL/PEG/RBV, then additional 36 weeks PEG/RBV	12 weeks TEL/PEG/RBV, then additional 36 weeks PEG/RBV
TOTAL TREATMENT DURATION	24 weeks	48 weeks	48 weeks	48 weeks

NOTE THAT THE BOCEPREVIR AND TELAPREVIR REGIMENS WILL NO LONGER BE STARTED IN PATIENTS RECEIVING THERAPY FOR HCV

MEDICATIONS

MEDICATION/DOSE	COMMENTS/SIDE EFFECTS
<p>BOCEPREVIR (BOC) [VICTRELIS®] 200 mg capsules</p> <p>NS3/4A Protease Inhibitor</p> <p><i>For use in genotype 1 only</i></p> <p>Dose: Four capsules every 7-9 hours with food (a meal or light snack)</p>	<ul style="list-style-type: none"> ◆ ANEMIA/NEUTROPENIA: BOC is associated with an increase in anemia and neutropenia beyond that seen with PEG/RBV alone. See page 14 and 15 for management. Dose reduction of BOC is contraindicated, discontinuation may be necessary. Consultation with the CCHCS HCV warmline is strongly advised for assistance with the management of treatment associated anemia/neutropenia: CPHCSHCVQuestions@cdcr.ca.gov. ◆ GASTROINTESTINAL SIDE EFFECTS: Dysgeusia (alteration in taste), dry mouth, nausea, vomiting, diarrhea. ◆ DRUG INTERACTIONS: There are multiple drug interactions between BOC and commonly used medications. See page 12 for information regarding drug interactions. ◆ MONOTHERAPY IS CONTRAINDICATED: Do not use BOC without PEG/RBV as HCV resistance will develop within a few days. ◆ DOSING ISSUES: Dosing strategies for patients to take this medication successfully with food in CCHCS may include taking the first dose with breakfast, second with a sack lunch 7-9 hours later, and the third dose with a snack 7-9 hours after the second dose. Please note that, unlike telaprevir, there are no fat requirements for the snack that must accompany boceprevir, however the patient will need to consume food with the third dose. (e.g., one package of cheese or peanut butter cracker snack.) ◆ STORAGE ISSUES: Boceprevir can be stored refrigerated until the expiration date or at room temperature (up to 77°F) for three months. Avoid exposure to excessive heat.
<p>TELAPREVIR (TEL) [INCIVEK®] 375mg tablets</p> <p>NS3/4A Protease Inhibitor</p> <p><i>For use in genotype 1 only</i></p> <p>Dose: 750 mg (two tablets) every 7-9 hours with food (a meal or light snack with at least 20 gm fat) OR 1125 mg (three tablets) every 12 hours with food (a meal or light snack with at least 20 gm fat)</p> <p>For patients also taking efavirenz (EFV), the dose of TEL is 375 mg 3 tab (1125 mg) every 7-9 hours with food containing 20 grams of fat</p>	<ul style="list-style-type: none"> ◆ RASH: BLACK BOX WARNING REGARDING FATAL AND NONFATAL SKIN REACTIONS: Rash occurred in 56% of patients studied, and involved anorectal burning/pruritus in 11%. Antihistamines and topical corticosteroids may be of benefit; systemic corticosteroids are not advised. If the rash becomes severe (involving 50% or more of the body), or systemic symptoms develop, discontinue TEL and consult CCHCS HCV warmline. If TEL is discontinued it should not be restarted. ◆ SERIOUS SKIN REACTIONS: Drug Rash With Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS) have been reported. In the event of rash with facial edema, fever, mucosal involvement, and/or internal organ involvement, discontinue all treatment and seek urgent expert consultation. ◆ ANEMIA: TEL is associated with a more severe anemia than that seen with PEG/RBV alone. ◆ See page 14 and 15 for management. Dose reduction of TEL is contraindicated, discontinuation may be necessary. Consultation with the CCHCS HCV warmline is strongly advised for assistance with the management of treatment associated anemias. CPHCSHCVquestions@cdcr.ca.gov ◆ DRUG INTERACTIONS: There are multiple drug interactions between TEL and commonly used medications. See page 12 for information regarding drug interactions. ◆ MONOTHERAPY IS CONTRAINDICATED: Do not use TEL without PEG/RBV as HCV resistance will develop within a few days. ◆ DOSING ISSUES: Telaprevir requires food with at least 20 grams of fat taken with each dose. The usual CDCR meal meets these requirements; therefore, the first two doses can be taken with breakfast and then 7-9 hours later with a sack lunch. The third dose must be taken 7-9 hours after the second dose with a snack that contains at least 20 grams of fat. Examples of snacks that meet this requirement include a two ounce packet of peanut butter and one packet of graham crackers or three packages of cheese crackers.

MEDICATIONS

MEDICATION/DOSE		COMMENTS/SIDE EFFECTS										
RIBAVIRIN (RBV) 200 mg tablet/capsule <i>All genotypes</i>		<p>ANEMIA:</p> <ul style="list-style-type: none"> The primary clinical toxicity of ribavirin is hemolytic anemia (see anemia management, page 14). After about two weeks of ribavirin treatment, approximately 10% of people develop severe anemia. The anemia associated with ribavirin therapy may result in worsening of cardiac disease. This has led to fatal and nonfatal myocardial infarctions. <p>TERATOGENICITY (PREGNANCY):</p> <ul style="list-style-type: none"> Due to the risk of fetal malformations and fetal death with ribavirin, a negative pregnancy test is required before treatment consideration. Women of childbearing potential must use two forms of effective contraception during treatment and for six months after treatment. Men whose female partners are pregnant or may become pregnant must use barrier contraception during treatment and for six months after treatment. <p>HISTAMINE-LIKE SIDE EFFECTS: nasal stuffiness, itching, skin irritation, asthma-like syndrome.</p>										
Weight:	Dose: (total daily, divided two times a day)											
<75 kg:	1000 mg/day											
>75 kg:	1200 mg/day											
RBV DOSE ADJUSTMENT FOR RENAL IMPAIRMENT												
		<table border="1"> <thead> <tr> <th>Creatinine Clearance</th> <th>RBV Dose (daily)</th> </tr> </thead> <tbody> <tr> <td>> 50 ml/min</td> <td>No additional dosage adjustment needed</td> </tr> <tr> <td>30 to 50 ml/min</td> <td>Alternating doses, 200 mg and 400 mg every other day</td> </tr> <tr> <td>Less than 30 ml/min</td> <td>200 mg daily</td> </tr> <tr> <td>Hemodialysis</td> <td>200 mg daily</td> </tr> </tbody> </table>	Creatinine Clearance	RBV Dose (daily)	> 50 ml/min	No additional dosage adjustment needed	30 to 50 ml/min	Alternating doses, 200 mg and 400 mg every other day	Less than 30 ml/min	200 mg daily	Hemodialysis	200 mg daily
Creatinine Clearance	RBV Dose (daily)											
> 50 ml/min	No additional dosage adjustment needed											
30 to 50 ml/min	Alternating doses, 200 mg and 400 mg every other day											
Less than 30 ml/min	200 mg daily											
Hemodialysis	200 mg daily											
PEGYLATED INTERFERON (PEG) [PEGASYS®] Alfa 2a-given by subQ injection <i>All genotypes</i> Usual Dose: 180 mcg subQ once weekly		<p>♦ FLU-LIKE SYMPTOMS: fever, chills, headache, myalgia, fatigue, nausea, and anorexia. Symptoms are usually worse right after the weekly injection and can be reduced by taking analgesic medications an hour or two before each injection.</p> <p>♦ DEPRESSION AND RELATED SYMPTOMS: anxiety, irritability, insomnia, confusion, and difficulty with concentration and memory are common during treatment. While less common, other psychiatric side effects include aggressive behavior, psychosis, hallucinations, and mania; a few cases of suicide have been reported.</p> <p>♦ NEUTROPENIA AND THROMBOCYTOPENIA: see page 10 and 11 for management.</p> <p>♦ ADDITIONAL SIDE EFFECTS: Colitis, pancreatitis, vision problems, pruritus, hair loss, and injection site reactions.</p> <p>♦ WARNINGS: Pegylated interferon should not be used in those with the following conditions:</p> <ul style="list-style-type: none"> Decompensated cirrhosis Kidney, lung, or heart transplants Autoimmune hepatitis Known hypersensitivity (allergic reaction) to pegylated interferon components Major uncontrolled depression <p>Pegylated interferon should be used with caution, preferably by a specialist, in people with heart and thyroid problems, pulmonary disorders, and other autoimmune diseases.</p>										
<p>♦ DOSE ADJUSTMENT FOR RENAL IMPAIRMENT:</p> <table border="1"> <thead> <tr> <th>Creatinine Clearance</th> <th>PEG Alfa 2a dose (once weekly)</th> </tr> </thead> <tbody> <tr> <td>> 50 ml/min</td> <td>No dosage adjustment needed</td> </tr> <tr> <td>30 to 50 ml/min</td> <td>180 mcg</td> </tr> <tr> <td>Less than 30 ml/min</td> <td>135 mcg</td> </tr> <tr> <td>Hemodialysis</td> <td>135 mcg</td> </tr> </tbody> </table>			Creatinine Clearance	PEG Alfa 2a dose (once weekly)	> 50 ml/min	No dosage adjustment needed	30 to 50 ml/min	180 mcg	Less than 30 ml/min	135 mcg	Hemodialysis	135 mcg
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PEG Alfa 2b [PegIntron®] (not preferred therapy) given by subQ injection Usual dose: 1.5 mcg/kg subQ once weekly		<p>♦ DOSE ADJUSTMENT FOR RENAL IMPAIRMENT:</p> <table border="1"> <thead> <tr> <th>Creatinine clearance</th> <th>Dose reduction PEG Alfa 2b</th> </tr> </thead> <tbody> <tr> <td>> 50 ml/min</td> <td>No dosage adjustment needed</td> </tr> <tr> <td>30 - 50 ml/min</td> <td>Reduce PEG Alfa 2b dose by 25%</td> </tr> <tr> <td>10 - 29 ml/min</td> <td>Reduce PEG Alfa 2b dose by 50%</td> </tr> <tr> <td>Hemodialysis</td> <td>Reduce PEG Alfa 2b dose by 50%</td> </tr> </tbody> </table>	Creatinine clearance	Dose reduction PEG Alfa 2b	> 50 ml/min	No dosage adjustment needed	30 - 50 ml/min	Reduce PEG Alfa 2b dose by 25%	10 - 29 ml/min	Reduce PEG Alfa 2b dose by 50%	Hemodialysis	Reduce PEG Alfa 2b dose by 50%
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Bold = Formulary

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SELF MANAGEMENT
MEDICATIONS		
MEDICATION/DOSE	COMMENTS / SIDE EFFECTS	
SOFOBUVIR (SOF) [SOVALDI®] 400 mg tablet NS5B Polymerase Inhibitor <i>For use in ALL genotypes</i> Dose: one tablet once daily with or without food	FATIGUE AND HEADACHE MONOTHERAPY IS CONTRAINDICATED: Do not use SOF without the rest of the HCV combination as HCV resistance will develop. ESRD ON HEMODIALYSIS AND/OR CREATININE CLEARANCE <30 ML/MIN: SOF is contraindicated. DRUG INTERACTIONS: There are multiple drug interactions between SOF and commonly used medications. See page 16 for information regarding drug interactions	
SIMEPREVIR (SMV) [OLYSIO®] 150 mg capsule NS3/4A Protease Inhibitor <i>For use only in genotype 1</i> Dose: one 150 mg capsule once daily	NAUSEA AND MYALGIA PHOTOSENSITIVITY: Wear protective clothing and protect skin from sun. Discontinue if serious photosensitivity is noted. RASH: if severe, treatment should be discontinued DO NOT USE IN NON-GENOTYPE 1 PATIENTS. DO NOT USE IN GENOTYPE 1A PATIENTS WITH BASELINE Q80K POLYMORPHISM. SIMEPREVIR HAS NOT BEEN STUDIED IN PATIENTS WHO HAVE PREVIOUSLY FAILED BOCEPREVIR OR TELAPREVIR. TERATOGENICITY (PREGNANCY): <ul style="list-style-type: none"> • Due to the risk of fetal malformations and fetal death with ribavirin, a negative pregnancy test is required before treatment consideration. • Women of childbearing potential must use two forms of effective contraception during treatment and for six months after treatment. • Men whose female partners are pregnant or may become pregnant must use barrier contraception during treatment and for six months after treatment. MONOTHERAPY IS CONTRAINDICATED: Do not use SMV without the rest of the HCV combination as HCV resistance will develop DRUG INTERACTIONS: There are multiple drug interactions between SMV and commonly used medications. See page 16 for information regarding drug interactions.	
Colony STIMULATING FACTORS (EPOETIN ALFA AND FILGRASTIM)		
EPOETIN ALFA 10,000 units/ml, 20,000 units/ml, 40,000 units/ml, 4,000 units/ml, 3,000 units/ml, 2,000 units/ml Usual Dose: 50-100 units/kg subQ, (IV preferred if dialysis) three times weekly 150-300 units/kg subQ once weekly (maximum 40,000 units weekly) Titrate to maintain Hgb 10-12 g/dl	<ul style="list-style-type: none"> • Epoetin alfa does not have an FDA indication for the treatment of ribavirin associated anemia although it is commonly used for this complication of treatment. • Epoetin alfa is associated with significant toxicities, including pure red cell aplasia and cardiovascular risks such as thromboembolic events and strokes. • Use with caution in patients with malignancies, hypertension, cardiovascular disease, hypercoagulable conditions, sickle cell disorders and seizures. • Health care professionals who prescribe epoetin alfa to patients with anemia from causes other than cancer chemotherapy are required to provide a copy of the <i>Medication Guide</i> to each patient. Please see http://www.fda.gov/downloads/Drugs/Drugsafety/ucm088988.pdf for a copy of this medication guide. • Prior to the initiation of epoetin for the correction of anemia in the patient receiving HCV treatment, a consultation with the CCHCS HCV warmline is <i>strongly</i> recommended at CPHCSHCVquestions@cdc.ca.gov. • Frequent Hgb monitoring is required • Avoid increase of Hgb > 1g/dl over a two week period 	
FILGRASTIM 300 mcg vial 480 mcg vial Usual Dose: Dose required to reach target Absolute neutrophil count (ANC) varies, but is generally 150 to 300 mcg subQ one to three times weekly. Frequent CBC monitoring is required.	Management of Neutropenia <ul style="list-style-type: none"> • Filgrastim does not have an FDA indication for the treatment of pegylated interferon associated neutropenia. Prior to the initiation of filgrastim for the correction of neutropenia in the patient receiving HCV treatment, a consultation with the CCHCS HCV warmline is <i>strongly</i> recommended at CPHCSHCVquestions@cdc.ca.gov. • Signs/symptoms of neutropenic fever require emergent evaluation. • For <i>non-febrile patients</i>, filgrastim should be used only in consultation with a specialist and should be limited to patients who have: <ol style="list-style-type: none"> 1. Failed to respond to dose reductions of interferon (from 180 mcg/wk to 135 mcg/wk). 2. Persistent severe neutropenia. (See page 15) 3. An excellent response to therapy (as measured by HCV viral load) such that continued treatment is desirable. 4. Been counseled regarding the increased risk for infectious complications, and have signed informed consent that they desire to continue with both HCV treatment and filgrastim. 	

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SELF MANAGEMENT
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MANAGEMENT OF SIDE EFFECTS OF HEP C TREATMENT

ANEMIA - CONSIDER CONSULTATION WITH HCV WARMLINE AT CCHCSHCVQUESTIONS@CDCR.CA.GOV

HEMOGLOBIN g/dl	ACTION
< 10 g/dl in patients with no history of cardiac disease	<ul style="list-style-type: none"> Decrease ribavirin (RBV) to 600 mg/day* Recheck Hgb weekly
≥ 2 g/dl decrease during any 4 week period and history of stable cardiovascular disease	<ul style="list-style-type: none"> Decrease RBV to 600 mg/day* Recheck Hgb weekly
Hgb 8.6-9.0 g/dl	<ul style="list-style-type: none"> RBV dose reduction to 600 mg/day if not already done Weekly Hgb monitoring Consider epoetin alfa if the dose has been reduced to 600 mg/day for at least two weeks with continued drop in Hgb <ul style="list-style-type: none"> Careful review with patient of risks/benefits of epoetin alfa vs. stopping HCV treatment.** † Provide the epoetin alfa medication guide (see page 13). If the patient agrees to treatment with epoetin alfa, start at 150-300 units/kg/week <ul style="list-style-type: none"> If follow-up Hgb is 9.0-9.9 g/dl, decrease epoetin alfa to 100 units/kg once weekly and continue RBV at 600 mg/day. If follow up Hgb is 10.0 g/dl or above, stop epoetin alfa. If the next weekly Hgb remains at 10.0 g/dl or above, increase RBV by 200 mg at two week intervals until initial RBV dose is reached. Symptomatic anemia: discontinue HCV treatment** †
Hgb 8.0-8.5 g/dl	<ul style="list-style-type: none"> RBV dose reduction to 600 mg/day if not already done Weekly Hgb monitoring Careful review with patient of risks/benefits of epoetin alfa vs. stopping HCV treatment.** † If considered clinically stable to continue HCV treatment and if the patient agrees, provide epoetin alfa medication guide (see page 13) and start epoetin alfa at 150-300 units/kg/week <ul style="list-style-type: none"> If follow-up Hgb is 9.0-9.9 g/dl, decrease epoetin alfa to 100 units/kg once weekly and continue RBV at 600 mg/day. If follow-up Hgb is 10.0 g/dl or above, epoetin alfa can be discontinued. If the next weekly Hgb remains at 10.0 g/dl or above, increase RBV by 200 mg at two week intervals until the initial RBV dose is reached. Symptomatic anemia: consider inpatient management and RBC transfusion and consider discontinuing HCV treatment** †
Hgb 7.5-7.9 g/dl	<ul style="list-style-type: none"> Review with patient the risks of anemia and stopping HCV treatment vs. the risk of continuing HCV treatment and epoetin alfa.** † Provide epoetin alfa medication guide to patients starting epoetin alfa (see page 13) Stop RBV (If on DAA, discontinue medication and contact the HCV warmline) Weekly CBC monitoring If considered clinically stable and if patient agrees to continue HCV treatment and treatment with epoetin alfa, continue epoetin alfa at 150-300 units/kg/week <ul style="list-style-type: none"> If Hgb is 9.0-9.9 g/dl, decrease epoetin alfa to 100 units/kg once weekly and continue RBV at 600 mg/day. If Hgb is 10.0 g/dl or above, epoetin alfa can be discontinued. If the next weekly Hgb remains at 10.0 g/dl or above, increase RBV by 200 mg at two week intervals until the initial RBV dose is reached. Symptomatic anemia: discontinue HCV treatment** † and consider inpatient management and RBC transfusion.
Hgb < 7.5 g/dl or symptomatic anemia	<ul style="list-style-type: none"> Terminate HCV treatment†

* If RBV dose is reduced for anemia:
 • Once Hgb has increased to > 10.0 g/dl, increase the dose by 200 mg/day at two week intervals until the initial dose is reached

** If RBV is temporarily stopped due to anemia:
 • Recheck Hgb within two weeks and at two week intervals until stable
 • If Hgb is > 10.0 g/dl, restart RBV at a dose of 600 mg/day if patient's weight < 75 kg; 800 mg/day if patient's weight ≥ 75 kg
 • If hemoglobin remains > 10.0 g/dl, increase dose by 200 mg/day at two week intervals until the initial dose is reached

§ If the patient is taking protease or polymerase inhibitor, urgent consultation with the CCHCS HCV warmline is *strongly* recommended prior to stopping PEG or RBV as resistance can develop rapidly. CPHCSHCVquestions@cdcr.ca.gov.

† If genotype 1, and treatment is discontinued, submit CDCR form 7413-4, End of Treatment Evaluation to CPHCSHCVquestions@cdcr.ca.gov

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SELF MANAGEMENT
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MANAGEMENT OF SIDE EFFECTS OF HEP C TREATMENT (CONT'D)

THROMBOCYTOPENIA -	
<i>CONSIDER CONSULTATION WITH HCV WARMLINE AT CCHCSHCVQUESTIONS@CDCR.CA.GOV</i>	
PLATELET COUNT	ACTION
< 50,000 /μl	<ul style="list-style-type: none"> • Decrease PEG to 135 mcg/week
< 25,000 /μl	<ul style="list-style-type: none"> • Discontinue PEG^{§†}

LEUKOPENIA/NEUTROPENIA -	
<i>CONSIDER CONSULTATION WITH HCV WARMLINE AT CCHCSHCVQUESTIONS@CDCR.CA.GOV</i>	
COUNT	ACTION
WBC < 1000 cells/μl	<ul style="list-style-type: none"> • Discontinue PEG^{§†}
ANC < 750 cells /μl	<ul style="list-style-type: none"> • Decrease PEG to 135 mcg/week
ANC < 500 cells/μl	<ul style="list-style-type: none"> • Consider filgrastim [granulocyte colony stimulating factor-GCSF](see dosing, page 13) if asymptomatic and: <ul style="list-style-type: none"> ◦ ANC < 500 cells/μl and <ul style="list-style-type: none"> > HIV positive > cirrhotic > age > 55 ◦ ANC < 400 cells/μl and <ul style="list-style-type: none"> > HIV negative > not cirrhotic > age < 55 • Monitor patient weekly to assess for signs of infection, provide education regarding warning signs of acute illness or fever and weekly WBCs. • Stop HCV treatment if: <ul style="list-style-type: none"> ◦ Patient presents with a neutropenic fever, acute illness or infection. Emergent evaluation recommended. ◦ ANC drops to < 250 cells/μl ◦ ANC declines from prefilgrastim nadir after two or more weekly doses of filgrastim • If ANC rises to over 750 cells/μl, reduce weekly dose of filgrastim by 50% <ul style="list-style-type: none"> ◦ If subsequent weekly ANC is > 750 cells/μl, discontinue filgrastim ◦ If subsequent weekly ANC is < 750 cells/μl, increase filgrastim to original dose • If ANC increases to > 2000 cells/μl, discontinue filgrastim

[§] If the patient is taking protease or polymerase inhibitor , urgent consultation with the CCHCS HCV warmline is *strongly* recommended prior to stopping PEG or RBV as resistance can develop rapidly. CPHCSHCVquestions@cdcr.ca.gov.

[†] If treatment is discontinued, submit CDCR form 7413-4, End of Treatment Evaluation to CPHCSHCVquestions@cdcr.ca.gov

SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

Summary of “FDA Drug Safety Communication: Erythropoiesis-Stimulating Agents (ESAs): Epogen® and Aranesp®” as it pertains to the use of Epogen® (epoetin alfa) for Hepatitis C patients who have become anemic from HCV treatment.

Safety Announcement

The FDA said in a safety announcement dated 02/16/2010, that it is requiring all Erythropoiesis-Stimulating Agents (ESAs) to be prescribed and used under a risk management program to ensure the safe use of these drugs. Epogen®, which we may prescribe to our hepatitis C patients who have become anemic due to their use of ribavirin or interferon, is an ESA.

According to the safety announcement, studies have shown that ESAs can increase the risk of heart attack, heart failure, stroke, and blood clots in patients who use these drugs for conditions other than cancer.

This announcement was primarily focused on cancer patients and oncologists.

The announcement said that **health care professionals** who prescribe ESAs to patients who have anemia from causes other than cancer chemotherapy **are**:

- Required to provide a copy of the *Medication Guide* to each patient or his/her representative when an ESA is dispensed
- Not required to enroll in the ESA APPRISE Oncology program.

The announcement added that **patients** with chronic kidney failure, including those on dialysis and those not on dialysis, who are using ESAs **should**:

- Know that the use of ESAs can increase the risk for stroke, heart attack, heart failure, blood clots, and death.
- Read the *Medication Guide* to understand the benefits and risks of using an ESA (which can be found at <http://www.fda.gov/downloads/Drugs/Drugsafety/ucm088988.pdf>)
- Get blood tests while using ESAs. The test results help guide the course of therapy and lower the risks of using these drugs. A patient’s health care professional should make them aware of how often to have blood tests.
- Talk with their health care professional about any questions they have about the risks and benefits of using ESAs.

DRUG-DRUG INTERACTIONS

Multiple drug-drug interactions exist between the direct acting HCV medications and other medication classes, including, but not limited to, certain antimicrobials, analgesics, antiarrhythmics, oral contraceptives, anxiolytics, lipid lowering agents, acid lowering agents, antiretrovirals, herbal preparations, corticosteroids, and anticonvulsants and specific medications such as rifampin, salmeterol, and warfarin.

For more information on drug-drug interactions:

- ▶ **Contact the HCV warmline at CPHCSHCVquestions@cdcr.ca.gov**
- ▶ **<http://www.hep-druginteractions.org>**

PATIENT EDUCATION/Self MANAGEMENT



WHAT YOU SHOULD KNOW: HEPATITIS C

WHAT IS HEPATITIS C (HEP C)?

- Hep C is a virus that causes swelling and irritation of the liver.
- The liver helps with digestion and filters waste products out of the blood. Hep C can cause serious damage to the liver.
- There is no vaccination for Hep C, but you can be vaccinated for Hepatitis A and B to prevent more damage to your liver.

HOW DO YOU GET HEP C?

You can get Hep C from:

- Dirty needles (tattoos or piercing).
- Snorting drugs with infected equipment.
- Sharing needles to inject drugs.
- Unprotected sex (rarely).
- A blood transfusion if you got one in the United States before 1992. (All blood is now tested for Hep C before it is used for transfusion.)



HOW DO YOU KNOW IF YOU HAVE HEP C?

- Most people who have Hep C look and feel fine.
- You can have Hep C for a long time and not know it.
- Usually Hep C is found by doing blood tests.
- If Hep C damages the liver, it can cause scarring. This is called cirrhosis (sir-oh-sis). Your health care provider may order more tests to see how much liver damage you have.
- Some people with Hep C can have:
 - Fatigue
 - Stomach pain
 - Joint pain
 - Night sweats
 - Loss of appetite or nausea



WHAT CAN YOU DO TO TAKE CARE OF YOURSELF?

- Get vaccinated for Hepatitis A and B. Get yearly vaccinations for pneumonia and the flu.
- Do not drink alcohol or use illegal drugs - these will damage your liver more.
- Do not take a lot of medications like acetaminophen (Tylenol®) and Motrin®. Talk to your health care provider about all medications, including over-the-counter medications, vitamins, and herbs to be sure they will not damage your liver. Ask your health care provider before you take any pain medicine.
- Do not get tattoos in prison to avoid blood borne infections.
- Do not share your toothbrush, razor, or other personal items.
- Try to lose weight if you are overweight.
- Eat a healthy diet.
- Drink plenty of water.
- Get plenty of rest and regular exercise.
- Quit smoking cigarettes.
- Follow your health care provider's instructions about medications for Hep C treatment.
- See your health care provider regularly.



DOES EVERYONE WITH HEPATITIS C NEED TREATMENT?

- Most people with Hep C do not need treatment.
- A few people may develop severe liver damage and can die from problems with Hep C.
- Who needs treatment depends on many things and these are different for each person. You should discuss your case with your health care provider.