October 1, 2017


Dear Prescriber,

As of July 1, 2015, the State of California’s Department of Health Care Services (DHCS) updated the Treatment Policy for the Management of Chronic Hepatitis C to give current guidance for the usage of Hepatitis C treatments. These drugs represent a major leap forward in the successful treatment of HCV.

Due to the extraordinary cost associated with these products, the State developed prior authorization criteria which reference the most recent guidelines and reports published by the American Association of the Study of Liver Diseases (AASLD) for approval of these medications. These guidelines set the treatment considerations and choice of regimen and duration of therapy for patients infected with Hepatitis C virus. Please refer to the AASLD website, www.hcvguidelines.org

DHCS criteria for the identification of treatment candidates follow the AASLD recommendations, where evidence supports treatment for all HCV-infected persons, except those with limited life expectancy (<12 months), and the most immediate benefits of treatment will be realized by populations at highest risk for liver-related complications. The new criteria takes into account resources limiting treatment to those at greatest risk for disease complications and those at risk for transmitting HCV or in whom treatment may reduce transmission risk.

By setting the level of liver fibrosis that would qualify for treatment at Metavir 2 (F2) and for patients with F0-F1 fibrosis with specific co-morbid conditions and considerations, it is most appropriate to treat those at greatest risk of disease complications before treating those with less advanced disease in the absence of mitigating factors. State policy has identified treatment candidates with other special circumstances as follows: Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (vasculitis) or kidney disease (e.g. proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis); HCC with a life expectancy of greater than 12 months; HIV-1 co-infection; Hepatitis B co-infection; other co-existing liver disease (e.g. non-alcoholic steatohepatitis); Insulin resistant type 2 diabetes; Porphryia cutanea tarda; men who have sex with men with high risk practices; active injection drug user; long-term hemodialysis; women of child-bearing age (fertile) who wish to get pregnant; HCV-infected health care worker who performs exposure-prone procedures; debilitating fatigue impacting the quality of life (i.e. secondary to extra-hepatic manifestations and/or liver disease).

1. Do not refer patients for HCV treatment if Metavir score is <2 (F2) in the absence of mitigating factors, as treatment will not be authorized. Treatment approval for Metavir score < 2 (F2) requires:
   a. Severe extrahepatic manifestations -or-
   b. Documentation of one or more special circumstance(s) listed above.
2. Level of fibrosis can be determined by a number of methodologies
   a. Biopsy demonstrating a Metavir score of 2 or greater (fibrosis stage 2)
   b. Biochemical determination – Serum markers of fibrosis should be used in combination with abdominal imaging findings that are consistent with cirrhosis.
      • APRI score > 0.7; [http://www.hepatitisc.uw.edu/page/clinical-calculators/apri](http://www.hepatitisc.uw.edu/page/clinical-calculators/apri)
      • FibroSure testing (costly)/FibroTest >= 0.48
   c. Imaging
      • Fibro elastometry (limited availability) - FibroScan > 7.5 kilopascals
   d. **DO NOT SUBMIT A FIBROMETER TEST – as this does not meet the State of California guideline as a measure of fibrosis.**

3. If there is a high probability of cirrhosis (biopsy, imaging, APRI > 1.5, FIB-4 > 3.25, Fibrosure > .74) please provide a CTP score; [http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/](http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/)

4. Clinical/abdominal findings “suggestive of” cirrhosis will require ALL OF THE FOLLOWING:
   a. Physical exam findings that suggest advanced liver disease (such as palpable left lobe, splenomegaly, palmar erythema)
   b. AND low platelet count (<100,000/mm³)
   c. AND abdominal imaging findings that are consistent with cirrhosis including surface abnormalities, features of portal hypertension and ascites.

5. Genotype 5 and 6 will be considered on a case by case basis following AASLD recommendations.

6. Pre and post liver transplantation treatment will be considered on a case by case basis (transplant specialist referral required).

7. Populations Unlikely to Benefit from HCV Treatment:
   a. Patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment. Little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

8. Note the PHC preferred treatment regimens, which are listed in the new TAR supplemental form for Hepatitis C Treatment.

Checklist to submit with new prescriptions, together with HCV TAR Supplemental information form:
- HCV Genotype
- HCV Viral Load
- Chemistry panel (Platelets, AST, ALT), CBC; if cirrhosis is present, also include INR, CTP score, total bilirubin, and albumin.
- Evidence of Metavir score of F2 or higher (biopsy, US, biochemical profile, evidence of portal HTN)
- If genotype is 1a and requested regimen includes elbasvir (i.e., Zepatier): Hepatitis C Viral RNA Genotype 1 NS5A Drug Resistance assay.
- Request for Epclusa for genotype 3 may require submission of Genotype 3 NS5A Drug Resistance assay (please refer to PHC hepatitis C matrix for details)
• Documentation, as may be required, for: IFN intolerance / ineligible, ascites, esophageal varices, hepatic encephalopathy.
• Letter of clinician experience in the treatment of HCV (once only per clinician)
  o See the attached HCV TAR Supplemental Form for additional submission requirements.

By working together with our hepatitis treating clinicians, patients eligible for HCV treatment can have the elements for authorization for medical treatment ready at the time of consultation- reducing delays in authorization.

Thank you,

Marshall Kubota, MD
Regional Medical Director
Partnership HealthPlan of California
mkubota@partnershiphp.org
PHC Preferred Hepatitis C Treatments:

- Treatments in **DARK BOLD BLUE** are PHC’s exclusively preferred (PHC 1st line) regimens for the indicated genotype/stage. Mavyret is Partnership Health Plan's exclusively preferred Hepatitis C regimen for its indicated genotype/stage.

- Treatments in italics and followed by asterisk(*) indicate that the regimen is not yet approved by the FDA and is considered “Unlabeled” or off-label usage, although usage is supported by AASLD guidelines.

- “Treatment Experienced” is defined as having had a prior null response, rebound or relapse after ETR (End Treatment Response) to HCV treatment. Listing only IFN/RBV experienced; all other regimen experienced will be reviewed on a case-by-case basis.

<p>| H = Harvoni | RBV WB = Ribavirin (wt based) | Lo RBV = Low initial dose of 600mg increase as tolerated |
| Dac = Daclatasvir | RBV LD = Ribavirin (low initial dose of 600mg, increase as tolerated) | Sim = Simeprevir |
| Sof = Sofosbuvir | IFN = Interferon | VL = Viral Load |
| RAVs = Resistance Associated Variants – Applicable to Zepatier | AASLD Alternative Regimens = <em>Italicized</em> (not all alternative regimens are included in the matrix) |</p>
<table>
<thead>
<tr>
<th>Genotype</th>
<th>Stage 0-1</th>
<th>Stage 2-4, unconfirmed cirrhosis</th>
<th>Cirrhosis - definitive (bx, US, FibroSure/Test &gt; 0.75, findings of portal HTN, ascites, varices, encephalopathy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Naïve</td>
<td>IFN/RBV experienced</td>
<td>CTP A (Score 5-6)</td>
</tr>
<tr>
<td></td>
<td>Naïve</td>
<td>IFN/RBV experienced</td>
<td>CTP B (7-9) / C (10-15)</td>
</tr>
<tr>
<td>GT 1a, mixed alb or indeterminate GT 1</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB X 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Harvoni x 8 wks (HCV VL &lt;6 million, non-black, HIV-uninfected)</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa x 12 wks</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Harvoni x 12 wks</td>
<td>Epclusa x 12 wks</td>
</tr>
<tr>
<td></td>
<td>Zepatier (no baseline NS5A RAVs) x 12 wks</td>
<td>Harvoni / RBV LD x 12 wks</td>
<td>Epclusa x 24 wks* if RBV intolerant</td>
</tr>
<tr>
<td></td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Harvoni x 8 wks (HCV VL &lt;6 million, non-black, HIV-uninfected)</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa x 12 wks</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Harvoni x 12 wks</td>
<td>Epclusa x 12 wks</td>
</tr>
<tr>
<td>GT 1b</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td>Treatment eligible only under special circumstances defined by the State of California Medical benefit. Stages 0-1 criteria with special circumstances, the preferred treatment will follow that specified for stages 2-4 at right</td>
<td>Epclusa x 12 wks</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td>GT 2</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks* (RAS testing for Y93H required)</td>
<td>Epclusa x 12 wks</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Mavyret x 12 weeks</td>
<td>Vosevi x 12 weeks*</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Zepatier / Sovaldi x 12 wks*</td>
<td>Dac / Sof / RBV LD x 12 wks</td>
</tr>
<tr>
<td></td>
<td>Mavyret x 12 weeks</td>
<td>Vosevi x 12 wks (when Y93H present)</td>
<td>Mavyret x 16 wks*</td>
</tr>
<tr>
<td></td>
<td>Mavyret x 16 wks</td>
<td>Vosevi x 12 wks (when Y93H present)</td>
<td>Mavyret x 16 wks*</td>
</tr>
<tr>
<td></td>
<td>Mavyret x 16 wks</td>
<td>Mavyret x 16 wks</td>
<td>Epclusa / RBV WB x 12 wks*</td>
</tr>
<tr>
<td>GT 3</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB X 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Zepatier x 12 wks</td>
<td>Zepatier x 12 wks</td>
<td>Epclusa / RBV WB x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Zepatier x 12 wks* (virologic relapse after prior interferon/ribavirin therapy)</td>
<td>Zepatier x 12 wks</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td>GT 4</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB X 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Zepatier x 12 wks</td>
<td>Zepatier x 12 wks</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td></td>
<td>Zepatier x 12 wks* (virologic relapse after prior interferon/ribavirin therapy)</td>
<td>Zepatier x 12 wks</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Epclusa x 12 wks*</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td>GT 5,6</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
<td>Epclusa / RBV WB X 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Epclusa x 12 wks</td>
<td>Epclusa x 12 wks</td>
<td>Epclusa / RBV WB x 24 wks*</td>
</tr>
<tr>
<td></td>
<td>Harvoni x 12 wks</td>
<td>Harvoni x 12 wks</td>
<td>Harvoni / RBV LD x 12 wks</td>
</tr>
</tbody>
</table>

Pre/Post Liver Transplant Case by Case Review, Transplant Specialist Referral Required
II. Patient readiness: Have the following been completed? Yes ______ No ________
- Patients shall be evaluated for readiness to initiate treatment
- Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider
- Caution shall be exercised with patients who have a history of treatment failure with prior hepatitis C treatment due to non-adherence with treatment regimen and appointments.
- Patient shall be educated regarding the potential risks and benefits of hepatitis C virus therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.

III. Requested regimen: ________________________________

For Duration of: ______________________ weeks

IV. Status information; complete the following:

<table>
<thead>
<tr>
<th>Hepatic Information</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HCV genotype</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a 1b 1-indeterminate 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Has the patient been infected for more than 6 months or assumed so- NOT required but resolution of acute cases of HCV without treatment should be considered.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If genotype 1a, 1b, or 1-indeterminant &amp; viral load &lt;6 million IU/mL: Patient is African American</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>• Does the patient have a Metavir score of F2 or greater based on the criteria below - please submit data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Liver biopsy with F2 or greater</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o APRI score of &gt; 0.7 calculator available at --- <a href="http://www.hepatitisc.uw.edu/page/clinical-calculators/apri">http://www.hepatitisc.uw.edu/page/clinical-calculators/apri</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Fibro Sure / Fibro Test &gt; 0.48</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o FibroScan &gt; 7.5 kilopascals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o DO NOT SUBMIT A FIBROMETER TEST, as this does not meet the State of California guideline as a measure of fibrosis.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o If proven cirrhosis provide the numeric CTP score in the appropriate column at right. Calculator available at <a href="http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/">http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/</a> CTP A is score 5-6, CTP B is 7-9 and CTP C is 10-15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A B C
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*TAR Supplemental Form for Hepatitis C Treatment: Effective 10-1-17*

- **In the absence of a Metavir score of F2 or greater, treatment will not be approved, except in the presence of extrahepatic manifestations or other special circumstances** (see next section, page 3).

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**Extrahepatic disease and other special circumstances:** Are there severe extrahepatic manifestations of HCV or other mitigating circumstances as noted below? **Please submit laboratory evidence and clinical notes**

- Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (vasculitis) or kidney disease (e.g. proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis)
- HCC with a life expectancy of greater than 12 months
- HIV – 1 co-infection
- Hepatitis B co-infection
- Other co-existing liver disease (e.g. non-alcoholic steatohepatitis)
- Insulin resistant type 2 diabetes
- Porphyria cutanea tarda
- Men who have sex with men with high risk practices
- Active injection drug user
- Long-term hemodialysis
- Woman of child-bearing age (fertile) who wishes to get pregnant (treatment to be completed prior to pregnancy)
- HCV-infected health care worker who performs exposure-prone procedures
- Debilitating fatigue impacting the quality of life (e.g. secondary to extra-hepatic manifestations and/or liver disease)

**Indicate result of (or absence of) prior HCV treatment (Submit clinic notes and evaluation of nature of failure):**

- Naïve
- Null responder
- Partial responder
- Relapse
- LTFU or Failed to Complete

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<table>
<thead>
<tr>
<th>IFN – Intolerant / Ineligible Criteria – the patient must meet one or more of the following criteria – please send documentation</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Platelet count &lt; 100,000 / mm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Decompensated cirrhosis (CTP Class B or C, CTP score &gt; 7, albumin &lt; 3.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| • Severe mental health conditions (including, but not limited to psychotic disorders, bipolar disorder, major depression, PTSD) that may be exacerbated by IFN or respond poorly to medical therapy  
  o Submit current mental health professional evaluation and ongoing care | | | |
| • Autoimmune diseases that may be exacerbated by IFN-mediated immune modulations | | | |
| • Inability to complete prior treatment course due to documented IFN related adverse effects | | | |
| • A history of preexisting cardiac disease | | | |

**Renal function** – Is the GFR or eGFR ≥ 30 ml/min

**Transplantation**

- Is the patient a transplant recipient (any type)

- Is this  
  1. Pre-liver transplant  
  -or-  
  2. Post liver transplant treatment  (circle one)

**Pregnancy prevention** – if ribavirin is used

- Patient has been counseled on the risks to the fetus if pregnancy occurs during treatment or within 6 months of completion of treatment (**Pregnancy Category X**)  
- Patient is infertile or not sexually active  
- Will the patient (female) use effective contraception during treatment and continue for 6 months afterwards?  
- Male – Will the female partner(s) of treated men use effective contraception during treatment and continue for 6 months afterwards?

**Limited Life Expectancy** – does patient have a limited life expectancy (<12 months) due to non-liver related comorbid condition?

**Clinician Experience and Attestation**

- Is the treating clinician a specialist? **Check one or more:**  
  - Gastroenterologist  
  - Hepatologist  
  - ID  
  - HIV clinician  
  - None of the above (this selection requires submission of a letter detailing the clinician’s experience in the treatment of HCV)

*To the best of my knowledge, the information provided in this form is (1) true, accurate and complete and (2) the requested services are medically indicated and necessary to the health of the patient.*

Signature of the prescriber: ___________________________  Date: ___________________
PARTNERSHIP HEALTHPLAN OF CALIFORNIA
TAR Supplemental Form for Hepatitis C Treatment: Effective 10-1-17

V. Additional required documentation:

Please submit the following data in original form:

- If Genotype is 1a and requested regimen includes elbasvir (i.e. Zepatier): Hepatitis C Viral RNA Genotype 1 NS5A Drug Resistance Assay.
- HCV genotype
- HCV Viral Load (VL)
- Chem panel (AST with reference range, ALT, Plt, total bilirubin, albumin), CBC, - If cirrhosis: INR and CTP score
- Evidence of Metavir score of F2 or higher (biopsy, US, biochemical profile, evidence of portal HTN)
- Documentation, as may be required, for IFN intolerance / ineligible, ascites, esophageal varices, hepatic encephalopathy
- Letter of clinician experience in the treatment of HCV (once only per clinician)
- Request for Eclusa for genotype 3 may require submission of genotype 3 NS5A resistance test result (please refer to matrix)

In-therapy lab requirements:

- All regimens: baseline; start of treatment HCV VL; 12 week SVR VL (to detect relapse vs reinfection)
- All regimens: 4 week HCV VL – if detectable then 6 week VL
- Regimens lasting more than 12 weeks: 12 week HCV VL

VI. Case Management

- Please describe the HCV case management plans for this patient to assure adherence to the treatment protocol and responsibility for medications.
  - Visit frequency should include initiation, and at least monthly until end of treatment. End of treatment visit. 12 week SVR measurement
  - Case management: in lieu of clinical visits, weekly phone call contacts will be required for continued refill of medications – chart documentation will be requested through the Treatment Authorization Request (TAR).

VII. Patient responsibility

- Lost medications might not be replaced and treatment authorization may be revoked
- Evidence of lack of adherence may result in treatment authorization revocation
- Missed appointments and lab data points may result in treatment authorization revocation
- Lack of compliance with case management may result in treatment authorization revocation
VIII. **DHCS Policy: Unlabeled Use of Medication (aka, Off-label use of an FDA approved drug):**

- Authorization for off-label uses of drugs shall not be granted unless the requested use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:
  - Reference to current medical literature
  - Consultation with provider organizations, academic and professional specialists.

IX. **Specialty Pharmacy Requirement:**

- HCV Rx and ALL the required documentation should be submitted to our specialty pharmacy:

  WALGREENS SPECIALTY PHARMACY #15987
  Phone number: 916-738-3300
  Fax number: 916-738-3302