HCV Treatment in Primary Care - Case Presentation

SCOTT MILLER PA-C, CHIEF ANDREW ISAAC HEALTH CENTER
50 y/o female seen on 9/12/17 to discuss Tx options for Hepatitis C. She has a Hx of Hepatitis C, genotype 1a, Dx’d in ’03. US 2/24/17 revealed mildly enlarged and mildly fatty replaced liver. She has not had prior Tx and has not had a liver Bx. She has a Hx of EtOH dependence. She last drank 2 shots of Vodka on 7/30/17. Denies illicit drug use. She is eager to began Tx and is now devoted to sobriety. She promised her late husband that she would complete Tx. Up until now, she was not ready for Tx because she was grieving her husband’s death, since he had been murdered by her son on 5/5/17.
Past Medical History

1) Chronic Hepatitis C - Genotype 1a with Cirrhosis
2) Essential hypertension
3) Recurrent TIAs, s/p PFO Closure 12-21-11
4) Generalized psoriasis
5) Rosacea
6) Depressive disorder - Husband was Murdered by Son on 5-5-17
7) Anxiety disorder
8) Alcohol dependence
9) Tobacco Use Disorder
10) Remote Hx of IV Drug Use
11) Prediabetes
12) Cervical disc disease-Posterolateral Disc Extrusion C5-C6 w/ Foraminal Stenosis
13) Allergic rhinitis
14) Gout
15) Obesity
Medications

1) Humira 40mg sc q 2weeks
2) Allopurinol 100mg 2 po qd
3) Cetirizine 10mg 1 po qd
4) Clobetasol ointment bid
5) Clopidogrel 75mg 1 po qd
6) Duloxetine 60mg 1 po qd
8) Hydrocortisone 1% cream apply tid to face as needed to face
9) Metronidazole 1% gel apply to face qhs
10) Naproxen 500mg 1 po bid
11) Pantoprazole 40mg 1 po qd
12) Propranolol 10mg 1 po bid
13) Triamterene/HCTZ 37.5/25mg 1 po qd
What next??

- Pre-treatment Screening...
- Pre-treatment labs...
- Recommended Treatment...
- Medication Interactions...
- What will be covered by insurance, Medicaid, Medicare, VA?
- What if there is no insurance? How does one enroll into Patient Assistance Programs?
- Monitoring labs...
ANTHC Hepatitis C Treatment


Hepatitis C Treatment

We want to keep you informed of recent drugs, screenings, treatments, and other news pertaining to Hepatitis and other liver diseases. As news becomes available we will post content here. Check back often to stay informed!

Treatment Tools

- Before Treatment
- Monitoring During and After Treatment
- Treatment Reference Tools

Staging Fibrosis

Start Here - Staging Fibrosis Algorithm
APRI and FIB-4 Interpretation

Treatment Naïve Decision Trees (click on Yes or No to begin)

<table>
<thead>
<tr>
<th></th>
<th>Genotype 1</th>
<th>Genotype 2 or 3</th>
<th>Genotype 4</th>
<th>Genotype 5 or 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cirrhosis?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Treatment Experienced Patients

Consult Liver Disease Specialist
Hepatitis C Treatment Checklist

Hepatitis C Treatment
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- Hep Drug Interactions
Hepatitis C Treatment Checklist

Prior to Treatment

Labs:
- Immediately prior: ___ Pregnancy test (if applicable)
- ___ Uric Acid (only with ribavirin)
- Within 1 month: ___ CBC with differential
- ___ CMP
- ___ PT/INR
- ___ HCV RNA
- Within 3 months: ___ Genotype confirmation
- ___ HBV DNA (if HBV cAb or sAg +)
- Within 6 months: ___ AFP
- Within 1 year: ___ HIV screening
  - ___ FibroSure [LabCorp], FibroTest [Quest], FibroSpect [Prometheus], or FibroScan (If any result suggests cirrhosis, calculate Child-Pugh’s score)
- Once:
  - ___ Hepatitis B core antibody IgG (HbcAb)
  - ___ NSSA RAS (Genotype 3 if failed prior treatment or cirrhotic & treating with Epclusa)

Miscellaneous:
- ___ Hepatitis A vaccine status (If unknown: draw HAV antibody total IgG)
- ___ Hepatitis B vaccine status (If unknown: draw HBsAg & HBsAb)
- ___ Review drug-drug interactions
- ___ PHQ-9 baseline
- ___ AUDIT-C
- ___ Counsel about pregnancy prevention
- ___ Review & sign Treatment Readiness Attestation
- ___ Review Information Packet at Treatment Start
Pretreatment Screening Labs

9/27/17

- HCV Genotype 1a
- HCV RNA Quant - 342,000 IU/ml (HCV RNA Log IU - 5.53)
- Hep B virus DNA <20 IU/ml (not detected) (Hep B virus Log <1.30)
- Fibrosure - F1-F2 (Minimal Fibrosis)
- AFP-4.0
- Vitamin D -23L
- PT-10.4, INR-1.0
Imaging

- Fibroscan 10/10/17
  - 35.5 kPa consistent with cirrhosis. Fibroscan interpretation - 35.3 kPa with an interquartile range of 7% indicating this is a reliable test equivalent to Metavir F4 (cirrhosis). CAP score 261 with an interquartile range of 39 (with 70% of scores falling within the S2 to S3 range) so it is likely there is at least a moderate (S2-S3) steatosis.

- US ABDOMEN LIMITED 2/24/17
  Impression:
  1. SPLENECTOMY. A WELL DEFINED ROUNDED STRUCTURE IN THE REGION MOST LIKELY REPRESENTS A SPLENIC LOBULE.
  2. MILDLY ENLARGED AND MILDLY FATTY REPLACED LIVER. NO FOCAL LESIONS.
  3. NORMAL HEPATOPEDAL FLOW IN THE MAIN PORTAL VEIN.
Review

- Hepatitis C, genotype 1a, Dx'd in '03.
- Treatment naïve
- Fibroscan on 10/10/17 - 35.3 kPa equivalent to Metavir F 4 (cirrhosis).
- AUDIT -C
  - Score of 6 (positive for identifying hazardous drinking or active alcohol use disorders)
- PHQ 9
  - Score of 11 (moderate depression)
Back to website

# Child-Turcotte-Pugh (CTP) Calculator

Use the Child-Turcotte-Pugh Classification for Severity of Cirrhosis calculator to estimate the cirrhosis severity. Select the applicable Clinical and Lab Criteria, then check the classification at the bottom.

### Clinical and Lab Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Encephalopathy</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>+1</td>
</tr>
<tr>
<td>Mild to moderate (grade 1 or 2)</td>
<td>+2</td>
</tr>
<tr>
<td>Severe (grade 3 or 4)</td>
<td>+3</td>
</tr>
<tr>
<td><strong>Ascites</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>+1</td>
</tr>
<tr>
<td>Mild to moderate (diuretic responsive)</td>
<td>+2</td>
</tr>
<tr>
<td>Severe (diuretic refractory)</td>
<td>+3</td>
</tr>
<tr>
<td><strong>Bilirubin (mg/dL)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; 2</td>
<td>+1</td>
</tr>
<tr>
<td>2-3</td>
<td>+2</td>
</tr>
<tr>
<td>&gt; 3</td>
<td>+3</td>
</tr>
<tr>
<td><strong>Albumin (g/dL)</strong></td>
<td></td>
</tr>
<tr>
<td>&gt; 3.5</td>
<td>+1</td>
</tr>
<tr>
<td>2.8-3.5</td>
<td>+2</td>
</tr>
<tr>
<td>&lt; 2.8</td>
<td>+3</td>
</tr>
<tr>
<td><strong>International normalized ratio</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; 1.7</td>
<td>+1</td>
</tr>
<tr>
<td>1.7-2.3</td>
<td>+2</td>
</tr>
<tr>
<td>&gt; 2.3</td>
<td>+3</td>
</tr>
</tbody>
</table>

**Child-Turcotte-Pugh Class obtained by adding score for each parameter (total points)**

- **Class A. Least severe liver disease**: 5 points
Treatment Naïve Decision Trees (click on Yes or No to begin)

**Genotype 1**
Yes Cirrhosis
Click for CTP Calculator

- CTP Score < 6
- CTP Score >= 6

**Genotype 2 or 3**
Cirrhosis?

- Yes

**Genotype 4**
Cirrhosis?

- Yes

**Genotype 5 or 6**
Cirrhosis?

- Yes

- No
# Treatment Naïve Decision Trees (click on Yes or No to begin)

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<th>Genotype 4</th>
<th>Genotype 5 or 6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compensated Cirrhosis</strong></td>
<td><strong>Cirrhosis?</strong></td>
<td><strong>Cirrhosis?</strong></td>
<td><strong>Cirrhosis?</strong></td>
</tr>
<tr>
<td>Epclusa® x 12 weeks (1 pill per day)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Harvoni® x 12 weeks (1 pill per day)</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Mavyret™ x 12 weeks (3 pills @ same time per day)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zepatier™ x 12 weeks (1 pill per day)</td>
<td></td>
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</tbody>
</table>

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Hepatitis C Pre-Treatment Insurance Screen

DOB_______ MRN___________

Name____________________ Phone Number____________________

Do you currently have:

1. Private Health Insurance for yourself or through your spouse?
   No ____       Yes ____   [If yes, got copy of insurance card]

2. Medicaid OR Denali Kid Care? (circle which one)
   No ____       Yes ____

3. Medicare
   a. Medicare Part A/B only? No ____       Yes ____
   b. Medicare Part D? No ____       Yes ____
   c. Medicare with Medicaid? No ____       Yes ____
   [If Medicaid & Medicare without Part D, submit through Medicare pharmacy program]

4. VA Benefits
   No ____       Yes ____ currently eligible & registered for benefits? Yes/No

5. TriCare?
   No ____       Yes ____

Screening done by: ____________________________  Date: _____ / _____ / _____

Next Steps:

For "yes" to 1, 2, 3b, 3c: begin prior authorization process.

For "yes" to 3a or "no" to everything: begin patient assistance program process.
See Treatment Reference Tools: Patient Assistance Programs

For VA/TriCare, coordinate with local VA for coverage and treatment.

ANTHC Liver Disease & Hepatitis Program 09/2018
Based on recommendations and insurance coverage, it was decided to proceed with Harvoni (ledipasvir/sofosbuvir) 90mg/400mg 1 po qd x 12 weeks
Medications Interactions

Hepatitis C Treatment

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<table>
<thead>
<tr>
<th>HEP Drugs</th>
<th>Co-medications</th>
<th>Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ledipasvir/Sofosbuvir</td>
<td>clop</td>
<td>Potential Interaction</td>
</tr>
<tr>
<td>Propranolol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metoclopramide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ticlopidine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zuclopentixol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ledipasvir/Sofosbuvir</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pantoprazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
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</tbody>
</table>

Having trouble viewing the interactions? Click here for the Interaction Checker Lite.
Common Medical Interaction

Potential Interaction

Ledipasvir/Sofosbuvir

Pantoprazole

Summary:
Coadministration has not been studied, but data with omeprazole show only a small decrease in ledipasvir exposure. Proton pump inhibitor doses comparable to omeprazole 20 mg can be administered simultaneously with ledipasvir/sofosbuvir. Proton pump inhibitors should not be taken before ledipasvir/sofosbuvir.

Description:
Proton pump inhibitor doses comparable to omeprazole 20 mg can be administered simultaneously with ledipasvir/sofosbuvir. Proton pump inhibitors should not be taken before ledipasvir/sofosbuvir.

Proton-pump inhibitor doses comparable to omeprazole 20 mg or lower can be administered simultaneously with ledipasvir/sofosbuvir under fasted conditions.
Harvoni US Prescribing Information, Gilead Sciences, October 2014.
Based on this information, her Pantoprazole was reduced to 20mg qd which is to be taken at the same time of her Harvoni.

Patient ultimately began Tx with Harvoni on 10/31/17 and presented to clinic with medication in hand.

Follow up appointments and lab monitoring was discussed extensively and arranged that day.

Patient also had close followed with Behavioral Health Consultant to avoid EtOH relapse and to provide additional support due to depression.
## Monitoring During Treatment

**Week 2 (only with ribavirin)**
- ___ CBC
- ___ CMP¹

**Week 4**
- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test
- ___ HBV DNA³

**Weeks 8, 12, 16, 20, & 24**
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test
- ___ HBV DNA³
- ___ HCV RNA (only at end of treatment)

---

**Monthly follow-up in clinic or by phone:**
- ___ Managing side effects
- ___ Medication adherence discussion
- ___ Alcohol intake
- ___ Birth control reminder
- ___ Refill reminder

---

1. **Sofosbuvir-based regimen** - If GFR <30, no safe recommendation.  
   **With ribavirin** - If GFR <50, decrease dose (refer to package insert).
2. Child-Pugh Calculator: [https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp](https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp)  
   Child-Pugh B or C - Do not treat with Mavyret™, Zepatier™, or Vosevi®
3. **HBV DNA**: If cAb+ & HBV DNA (+) pre-treatment **OR** if Hep B carrier **OR** seroconverted carrier, check HBV DNA monthly during treatment & 12 weeks after treatment. **If** HBV DNA (-) pre-treatment & not a carrier, check again only at end of treatment.
Monitoring After Treatment:

12 weeks after last dose:
- CBC
- LFTs
- HCV RNA (to test for cure)
- AFP (if more than 6 months since last result)
- HBV DNA

6 months post-treatment:
- If Advanced Fibrosis or Cirrhosis prior to treatment continue AFP & RUQ q 6 months to screen for hepatocellular carcinoma (HCC)

1 year post-treatment for 5 years:
- Zero to minimal scarring (F0-F2): yearly CBC & LFTs
- Advanced Fibrosis (F3): RUQ US & AFP q 6 months; yearly CBC, LFTs, & AFP
  - Liver Field Clinic appointment every 2-3 years
- Cirrhosis (F4): RUQ US & AFP q 6 months; yearly CBC, CMP, AFP, PT/INR
  - Yearly Liver Field Clinic appointment
Complicating Factors

- Pt was hospitalized at Providence 1/18 for neck cellulitis likely odontogenic vs pharyngeal source with resulting acute respiratory failure requiring intubation, severe sepsis/septic shock.
- During this time she lost her Harvoni therefore did not complete the last 2 weeks of her 12 week Tx regimen.
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</tr>
</thead>
<tbody>
<tr>
<td>CBC</td>
<td>WBC-10.89H RBC-4.58 Hgb-12.6 Hct-38.6 Plat-218</td>
<td>WBC-9.41 RBC-4.41 Hgb-11.9 Hct-37.5 Plat-531H</td>
<td>Not Obtained Due to Hospitalization</td>
<td>WBC-10.64H RBC-3.95 Hgb-10.5L Hct-32.7L Plat-545H</td>
<td>WBC-7.89 RBC-4.64 Hgb-11.7 Hct-36.4 Plat-419H</td>
</tr>
<tr>
<td>CMP</td>
<td>BUN-13 Creat-1.19H Est GFR-48L Alk Phos-150H ALT-35 AST-68H Tbili-0.8 Alb-3.6</td>
<td>BUN-17 Creat-1.03 Est GFR-57L Alk Phos-135H ALT-21 AST-27 Tbili-0.4 Alb-2.8L</td>
<td>Not Obtained Due to Hospitalization for sepsis</td>
<td>BUN-27H Creat-1.36H Est GFR-41L Alk Phos-79 ALT-29 AST-19 Tbili-0.5 Alb-3.5</td>
<td>BUN-12 Creat-0.92 Est GFR-&gt;60 Alk Phos-124 ALT-18 AST-22 Tbili-0.30 Alb-3.8</td>
</tr>
<tr>
<td>HCV RNA</td>
<td>HCV RNA Quant - 342,000 IU/ml, 5.53 logIU/ml</td>
<td>HCV RNA Quant &lt;15IU/ml, &lt;1.18 logIU/ml</td>
<td>Not Obtained Due to Hospitalization</td>
<td>HCV RNA Quant &lt;15IU/ml, &lt;1.18 logIU/ml</td>
<td>HCV RNA Quant &lt;15IU/ml, &lt;1.18 logIU/ml</td>
</tr>
</tbody>
</table>
Pt is doing well to this day and was ecstatic to accomplish this goal.

I did obtain one last viral load on 9/5/18 to assure SVR since she had the lapse in Tx for 2 weeks.

She will continue to have cirrhosis monitoring:
- CMP, AFP, and Liver US q 6 mos
- CBC, PT/INR q 12mos
- f/u with ANMC Liver Clinic q 12 mos
En route to Fenway Park for Game 2 of American League Championship Series – Red Sox vs. Astros
TREAT YOUR
CHRONIC HEPATITIS C NOW.
MAVRET. ONLY 8 WEEKS...

...FOR ADULTS WITH GENOTYPES 1-4
NOT PREVIOUSLY TREATED AND WITHOUT CIRRHOsis

Talk to your doctor today and visit MAYRET.com

Please read a brief summary of important product information before you use MAYRET. For more information, visit www.MAYRET.com.

What is the most important information you should know about MAYRET?

MAYRET has caused serious side effects, including death.

What are the possible side effects of MAYRET?

Serious side effects may include:

- Death
- Liver problems, which can cause serious liver injury or death
- Blood clots in the lung, which can cause death
- Extraordinary bleeding in the brain or elsewhere in the body
- Pregnancy and breastfeeding

What is MAYRET?

MAYRET contains daclatasvir and sofosbuvir. DAACLATASVIR and SOFOSBUVIR are medicines that treat chronic (long-term) hepatitis C virus (HCV) infection. HCV is a virus that can cause liver disease. DAACLATASVIR is a medicine that stops the production of viral enzymes. SOFOSBUVIR is a medicine that stops the production of viral RNA. HCV is a virus that can cause liver disease. HCV is a virus that can cause liver disease.

How do I take MAYRET?

MAYRET is a daily oral tablet. It should be taken with or without food. It is recommended to take MAYRET with food. You should take the tablet with a full glass of water. It is important to take all doses of MAYRET as directed. If you miss a dose of MAYRET, take it as soon as you remember. Do not take double doses to make up for a missed dose.

What are the possible side effects of MAYRET?

MAYRET can cause side effects, including:

- Nausea
- Diarrhea
- Fatigue
- Headache
- Constipation
- Muscle pain
- Blood clotting

What should I do if I take too much MAYRET?

If you take too much MAYRET, contact your doctor or poison control center.

What should I avoid while taking MAYRET?

Avoid taking other medications that can affect your liver, such as alcohol.

What should I do if I am pregnant or breastfeeding?

If you are pregnant or breastfeeding, you should not take MAYRET.

What should I do if I am allergic to MAYRET?

Do not use MAYRET if you are allergic to any of the active ingredients or to any component of MAYRET.

What should I do if I experience a serious side effect?

If you experience a serious side effect, stop taking MAYRET and contact your doctor.

What should I do if I experience a side effect that is not listed?

If you experience any side effect, contact your doctor.

What should I do if I miss a dose of MAYRET?

If you miss a dose of MAYRET, take it as soon as you remember. Do not take double doses to make up for a missed dose.

What should I do if I overdose on MAYRET?

If you overdose on MAYRET, contact your doctor or poison control center.

What should I do if I am taking other medications?

Tell your doctor about all the medications you are taking, including prescription and non-prescription medications, vitamins, and herbal supplements. Your doctor or pharmacist may tell you to stop taking one of your medications before starting MAYRET.

What should I do if I have a medical condition that might interact with MAYRET?

Tell your doctor about any medical condition that might interact with MAYRET, including:

- Blood clotting disorders
- Liver problems
- Congenital (born with) or acquired (developed later) heart valve problems
- Heart problems

What should I do if I am planning to have a medical procedure or surgery?

Tell your doctor about any medical procedure or surgery you plan to have.

What should I do if I am taking other medications that might interact with MAYRET?

Tell your doctor about any medications you are taking, including:

- Blood thinners
- Other medication that might interact with MAYRET

What should I do if I am allergic to any component of MAYRET?

Do not use MAYRET if you are allergic to any component of MAYRET.

What should I do if I am planning to breastfeed?

Tell your doctor if you plan to breastfeed.

What should I do if I am planning to get pregnant?

Tell your doctor if you plan to get pregnant.

What should I do if I am planning to have surgery?

Tell your doctor if you plan to have surgery.

What should I do if I am planning to get breastfed?

Tell your doctor if you plan to get breastfed.

What should I do if I am planning to get pregnant?

Tell your doctor if you plan to get pregnant.

What should I do if I am planning to have surgery?

Tell your doctor if you plan to have surgery.

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What should I do if I am planning to have surgery?

Tell your doctor if you plan to have surgery.

What should I do if I am planning to get breastfed?

Tell your doctor if you plan to get breastfed.

What should I do if I am planning to get pregnant?
If the typical “subway go-er” is being empowered to seek out Tx for Hepatitis C then the typical provider should also feel empowered to Tx. The Tx is available, easy, effective, and support is out there, if needed.