




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

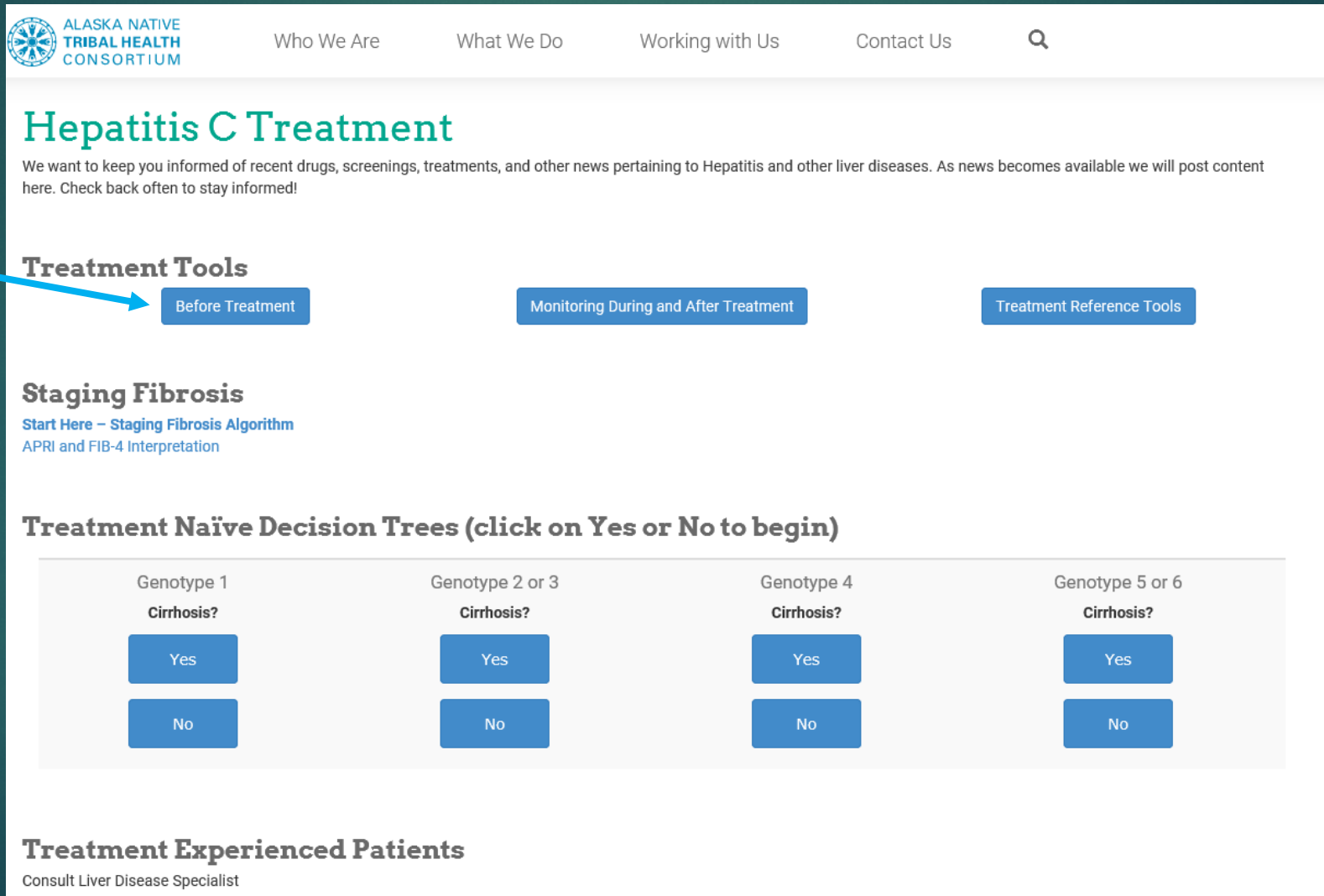
- 1) Humira 40mg sc q 2weeks
- 2) Allopurinol 100mg 2 po qd
- 3) Cetirizine 10mg 1 po qd
- 4) Clobetasol ointment bid
- 5) Clopidogrel 75mg 1 po qd
- 6) Duloxetine 60mg 1 po qd
- 8) Hydrocortisone 1% cream apply tid to face as needed to face
- 9) Metronidazole 1% gel apply to face qhs
- 10) Naproxen 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

- ▶ <https://anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/>



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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)

Genotype 1	Genotype 2 or 3	Genotype 4	Genotype 5 or 6
Cirrhosis?	Cirrhosis?	Cirrhosis?	Cirrhosis?
Yes	Yes	Yes	Yes
No	No	No	No

Treatment Experienced Patients

[Consult Liver Disease Specialist](#)


Hepatitis C Treatment Checklist

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- [Health Summary](#)
- [Insurance Screening](#)
- [Patient Readiness Attestation](#)
- [Hep C Information](#)
- [Pre-Treatment Letter](#)
- [Alcohol Use Disorders Identification Test \(Audit-C\)](#)
- [Patient Health Questionnaire \(PHQ-9\)](#)
- [Child-Turcotte-Pugh \(CTP\) Calculator](#)
- [Hep Drug Interactions](#)

Hepatitis C Treatment Checklist

Hepatitis C Treatment Checklists

Prior to Treatment

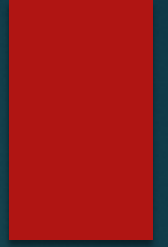
Labs:

- Immediately prior: ☐ Pregnancy test (if applicable)
- ☐ Uric Acid (only with ribavirin)
- Within 1 month: ☐ CBC with differential
- ☐ CMP ¹
- ☐ 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-Pugh² score)
- Once: ☐ Hepatitis B core antibody IgG (HBcAb)
- ☐ NS5A 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

- ▶ CBC-WBC-10.89H, RDW-16.9H, MPV-12.2H, Bands-7H, Lymph-21L, Mono-13H, Eos-4H, otherwise WNL
- ▶ CMP-Creat-1.19H, Est GFR-48L, K-3.2L, Tot Prot-8.2H, Alb-3.6, Alk Phos-150H, AST-68H, ALT-35, Tbili-0.8, otherwise WNL
- ▶ 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 F 4 (**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

- ▶ <https://anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/>

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

Genotype 1
Cirrhosis?

Yes

No

Genotype 2 or 3
Cirrhosis?

Yes

No

Genotype 4
Cirrhosis?

Yes

No

Genotype 5 or 6
Cirrhosis?

Yes

No

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

No

Genotype 4

Cirrhosis?

Yes

No

Genotype 5 or 6

Cirrhosis?

Yes

No

Clinical Calculators

CTP Calculator

APRI Calculator

BMI Calculator

CrCl Calculator

FIB-4 Calculator

Glasgow Coma Scale

GFR Calculator

MELD Calculator

SAAG Calculator

Substance Use Screening Tools

AUDIT-C Questionnaire

CAGE Questionnaire

Child-Turcotte-Pugh (CTP) Calculator

Share

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

Points

Encephalopathy

- ☒ None +1
- ☐ Mild to moderate (grade 1 or 2) +2
- ☐ Severe (grade 3 or 4) +3

Ascites

- ☒ None +1
- ☐ Mild to moderate (diuretic responsive) +2
- ☐ Severe (diuretic refractory) +3

Bilirubin (mg/dL)

- ☒ < 2 +1
- ☐ 2-3 +2
- ☐ > 3 +3

Albumin (g/dL)

- ☒ > 3.5 +1
- ☐ 2.8-3.5 +2
- ☐ < 2.8 +3

International normalized ratio

- ☒ < 1.7 +1
- ☐ 1.7-2.3 +2
- ☐ > 2.3 +3

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 \geq 6

Genotype 2 or 3
Cirrhosis?

Yes

No

Genotype 4
Cirrhosis?

Yes

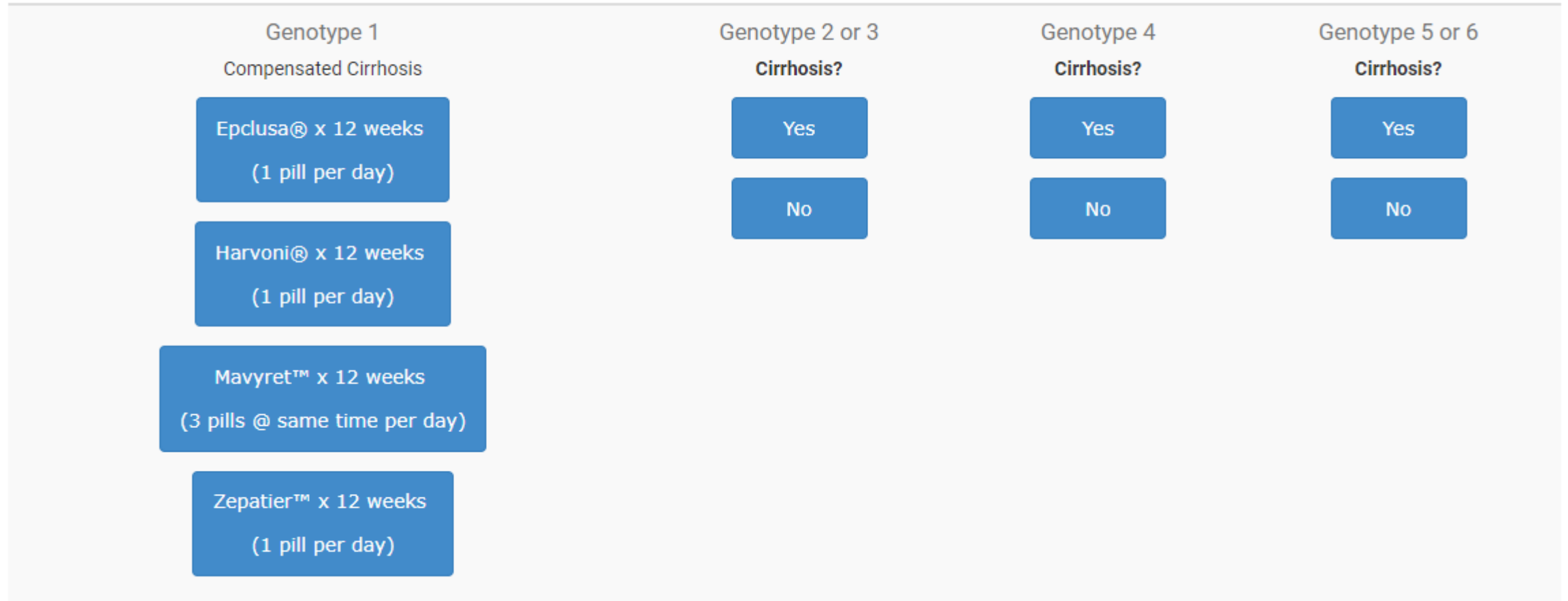
No

Genotype 5 or 6
Cirrhosis?

Yes

No


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



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Treatment Tools

Before Treatment



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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, get 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.

- 
- ▶ 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



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[Hep Drug Interactions](#)

Having trouble viewing the interactions? [Click here for the Interaction Checker Lite.](#)

HEP Drugs	Co-medications	Drug Interactions
<input type="text" value="led"/>	<input type="text" value="clop"/>	<input type="checkbox"/> Check HEP/ HEP drug interactions
<input checked="" type="radio"/> A-Z <input type="radio"/> Class <input type="radio"/> Trade	<input checked="" type="radio"/> A-Z <input type="radio"/> Class	Switch to table view
<input checked="" type="checkbox"/> Ledipasvir/Sofosbuvir	<input checked="" type="checkbox"/> Pantoprazole	Reset Checker
<input checked="" type="checkbox"/> Ledipasvir/Sofosbuvir	<input checked="" type="checkbox"/> Propranolol	<div>Potential Interaction</div> <div>Ledipasvir/Sofosbuvir</div> <div>Pantoprazole</div> <div>More Info</div>
	<input checked="" type="checkbox"/> Clopidogrel	<div>No Interaction Expected</div> <div>Ledipasvir/Sofosbuvir</div> <div>Clopidogrel</div>
	<input type="checkbox"/> Metoclopramide	
	<input type="checkbox"/> Ticlopidine	
	<input type="checkbox"/> Zuclopentixol	

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.

Harvoni Summary of Product Characteristics, Gilead Sciences Ltd, November 2014.

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.

[View all available interactions with Ledipasvir/Sofosbuvir by clicking here.](#)

- 
- ▶ 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

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>

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

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 DNA³

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.

Lab Monitoring

	Week 0 (9/27/17)	Week 4 (11/28/17)	Week 8 (due 12/26/17)	Week 12 (1/23/18)	12 weeks post Tx (due 4/17/18, done 4/30/18)
CBC	WBC-10.89H RBC-4.58 Hgb-12.6 Hct-38.6 Plat-218	WBC-9.41 RBC-4.41 Hgb-11.9 Hct-37.5 Plat-531H	Not Obtained Due to Hospitalization	WBC-10.64H RBC-3.95 Hgb-10.5L Hct-32.7L Plat-545H	WBC-7.89 RBC-4.64 Hgb-11.7 Hct-36.4 Plate-419H
CMP	BUN-13 Creat-1.19H Est GFR-48L Alk Phos-150H ALT-35 AST-68H Tbili-0.8 Alb-3.6	BUN-17 Creat-1.03 Est GFR-57L Alk Phos-135H ALT-21 AST-27 Tbili-0.4 Alb-2.8L	Not Obtained Due to Hospitalization for sepsis	BUN-27H Creat-1.36H Est GFR-41L Alk Phos-79 ALT-29 AST-19 Tbili-0.5 Alb-3.5	BUN-12 Creat-0.92 Est GFR->60 Alk Phos-124 ALT-18 AST-22 Tbili-0.30 Alb-3.8
HCV RNA	HCV RNA Quant - 342,000 IU/ml, 5.53 logIU/ml	HCV RNA Quant <15IU/ml, <1.18 logIU/ml	Not Obtained Due to Hospitalization	HCV RNA Quant <15IU/ml, <1.18 logIU/ml	HCV RNA Quant <15IU/ml, <1.18 logIU/ml

- 
- ▶ 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

TREAT YOUR CHRONIC HEPATITIS C NOW. MAVYRET. ONLY 8 WEEKS...

...FOR ADULTS WITH GENOTYPES 1-6
NOT PREVIOUSLY TREATED AND WITHOUT CIRRHOSIS

Talk to your doctor today and visit MAVYRET.com

DON'T
LOOK
BACK

Individual results may vary.
Your doctor will tell you how long you should take MAVYRET.

Please read a brief summary of important product information below, including the intended use and who should not take MAVYRET.

What is the most important information I should know about MAVYRET?

MAVYRET can cause serious side effects, including:

Hepatitis B virus reactivation. Before starting treatment with MAVYRET, your doctor will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with MAVYRET. Hepatitis B virus becoming active again could lead to liver problems including liver failure and death. Your doctor will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking MAVYRET.

For more information about side effects, see the section "What are the possible side effects of MAVYRET?"

What is MAVYRET?

MAVYRET is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis.

MAVYRET contains the two medicines: glecaprevir and pibrentasvir.

It is not known if MAVYRET is safe and effective in children under 18 years of age.

Do not take MAVYRET if you:

- have certain liver problems;
- also take any of the following medicines:
 - simvastatin (ZOCOR®; SIMVASTATIN®)
 - simvastatin (ZOCOR®; SIMVASTATIN®)

Before taking MAVYRET, tell your doctor about all of your medical conditions, including if you:

- have ever had hepatitis B virus infection;
- have liver problems other than hepatitis C virus infection;
- are pregnant or plan to become pregnant. It is not known if MAVYRET will harm your unborn baby;
- are breastfeeding or plan to breastfeed. It is not known if MAVYRET passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take MAVYRET.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. MAVYRET and other medicines may affect each other. This can cause you to have too much or not enough MAVYRET or other medicines in your body. This may affect the way MAVYRET or your other medicines work, or may cause side effects.

Keep a list of your medicines to show your doctor and pharmacist.

Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take MAVYRET with other medicines.

Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take MAVYRET with other medicines.

How should I take MAVYRET?

- Take MAVYRET exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to.
- Do not stop taking MAVYRET without first talking with your doctor.
- Take 3 MAVYRET tablets at one time each day.
- Take MAVYRET with food.
- It is important that you do not miss or skip doses of MAVYRET during treatment.

• If you miss a dose of MAVYRET and it is:

- Less than 18 hours from the time you usually take MAVYRET, take the missed dose with food as soon as possible. Then take your next dose at your usual time.
- More than 18 hours from the time you usually take MAVYRET, do not take the missed dose. Take your next dose as usual with food.

If you take too much MAVYRET, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of MAVYRET?

MAVYRET can cause serious side effects, including:

• **Hepatitis B virus reactivation.** See "What is the most important information I should know about MAVYRET?"

The most common side effects of MAVYRET include headache and tiredness.

There are not all the possible side effects of MAVYRET.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store MAVYRET?

- Store MAVYRET at or below 80°F (26°C).
- Keep MAVYRET in its original blister package until you are ready to take it.

Keep MAVYRET and all medicines out of the reach of children.

General information about the safe and effective use of MAVYRET

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MAVYRET for a condition for which it was not prescribed. Do not give MAVYRET to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about MAVYRET that is written for health professionals.

What are the ingredients in MAVYRET?

Active ingredients: glecaprevir and pibrentasvir

Inactive ingredients: colloidal silicon dioxide, copovidone type K 298, croscarmellose sodium, hypromellose 2910, iron oxide red, lactose monohydrate, polyethylene glycol 3350, polyethylene glycol monocaprylate type 10, sodium stearoyl fumarate, titanium dioxide, and vitamin E (diphosphoryl polyethylene glycol succinate). The tablets do not contain gluten.

Manufactured by AbbVie Inc., North Chicago, IL 60064.


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For more information go to www.MAVYRET.com or call 1-800-633-9130.

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MAVYRET
glecaprevir/pibrentasvir
100 mg/40 mg tablets

- 
- ▶ 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.