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.
Hepatitis C Treatment Checklists

Prior to Treatment

Labs:
Immediately prior: ___ Pregnancy test (if applicable)
___ Uric Acid (only if ribavirin to be given)
Within 3 months: ___ CBC (without diff)
___ CMP
___ PT/INR
___ HCV RNA
___ Genotype confirmation
___ HBV DNA (if HBcAb or HBsAg +)¹
Within 6 months: ___ AFP
Within 1 year: ___ HIV screening
___ FibroSure [LabCorp], FibroTest [Quest], FibroSpect [Prometheus], or FibroScan (If any result suggests F3 or F4/cirrhosis, calculate Child-Pugh² score)
Once: ___ Hepatitis B core antibody IgG (HBcAb)
___ NS5A RAS (if failed prior DAA treatment or if cirrhotic genotype 3 & 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 (ethinyl estradiol not recommended with Mavyret)
___ Review & sign Treatment Readiness Attestation
___ Review medication-specific Information Packet at Treatment Start

Monitoring During Treatment
If taking ribavirin, see footnote³ below.

Week 4
___ HCV RNA
___ LFTs
___ Creatinine and eGFR
___ Pregnancy test
___ HBV DNA¹

Weeks 8, 12, 16, 20, & 24 (as clinically indicated)
___ LFTs
___ Creatinine and eGFR
___ Pregnancy test
___ HBV DNA¹

End of Treatment
___ HCV RNA

¹- HBV DNA: If HBcAb+ & 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.
²- Child-Pugh Calculator: https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp
   If score >6 (Child-Pugh B or C), do not treat with Mavyret™, Zepatier™, or Vosevi® and consult Liver Disease Specialist.
³- If treatment includes ribavirin, additional monitoring of CBC, CMP is recommended at weeks 2, 4 and monthly throughout treatment and adjustment to ribavirin dose if GFR <50. Consult Liver Disease specialist if patient is prescribed ribavirin.
Hepatitis C Treatment Checklists

**Monitoring After Treatment:**

12 weeks after last dose:
- HCV RNA (to test for cure)
- AFP (if advanced fibrosis or cirrhosis and 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:
- Zero to minimal scarring (F0-F2): yearly CBC & LFTs as clinically indicated
- Advanced Fibrosis (F3): RUQ US & AFP q 6 months; yearly CBC, LFTs, & AFP
  - Liver Field Clinic appointment every 2 years
- Cirrhosis (F4): RUQ US & AFP q 6 months; yearly CBC, CMP, AFP, PT/INR
  - Yearly Liver Field Clinic appointment

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1- HBV DNA: If HBcAb+ & 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.

2- Child-Pugh Calculator: [https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp](https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp)
   If score >6 (Child-Pugh B or C), do not treat with Mavyret™, Zepatier™, or Vosevi® and consult Liver Disease Specialist.

3- If treatment includes ribavirin, additional monitoring of CBC, CMP is recommended at weeks 2, 4 and monthly throughout treatment and adjustment to ribavirin dose if GFR <50. Consult Liver Disease specialist if patient is prescribed ribavirin.
We are glad to hear you are interested in treatment for HCV! Here are some things to think about (and do) before you make your decision about treatment:

**Why be treated?** Current medications have high cure rates and less side effects. Getting rid of HCV reduces your risk of developing complications and improves your quality of life.

**What FDA-approved treatments are available?**

These are commonly used treatments for **Genotype 1**:

- Option 1 is Mavyret™ (glecaprevir/pibrentasvir), 3 tablets taken once daily with food for 8-12 weeks. The most common side effects are headache (18%) and fatigue (15%). In clinical studies, the treatment response rate to Mavyret™ was 99% for genotype 1.

- Option 2 is Harvoni® (ledipasvir/sofosbuvir), 1 tablet taken once a day for 8-12 weeks. The most common side effects are feeling tired (16%) and headache (14%). In clinical studies, treatment response rates to Harvoni® were 94-100%.

- Option 3 is Epclusa® (sofosbuvir/velpatasvir), 1 tablet taken once a day for 12 weeks. The most common side effects are headache (22%) and feeling tired (15%). In clinical studies, treatment response rates to Epclusa® were 94-98% for genotype 1.

These are commonly used treatment options for **Genotype 2**:

- Option 1 is Mavyret™ (glecaprevir/pibrentasvir), 3 tablets taken once daily with food for 8-12 weeks. The most common side effects are headache (18%) and fatigue (15%). In clinical studies, treatment response rates to Mavyret™ were 98-100% for genotype 2.

- Option 2 is Epclusa® (sofosbuvir/velpatasvir), 1 tablet taken once a day for 12 weeks. The most common side effects are headache (22%) and feeling tired (15%). In clinical studies, the treatment response rate to Epclusa® was 99% for genotype 2.

These are commonly used treatment options for **Genotype 3**:

- Option 1 is Mavyret™ (glecaprevir/pibrentasvir), 3 tablets taken once daily with food for 8-12 weeks. The most common side effects are headache (18%) and fatigue (15%). In clinical studies, treatment response rates to Mavyret™ were 95-98% for genotype 3.

- Option 2 is Epclusa® (sofosbuvir/velpatasvir), 1 tablet taken once a day for 12 weeks. The most common side effects are headache (22%) and feeling tired (15%). In clinical studies, treatment response rates to Epclusa® were 85-98% for genotype 3.
There are no data on the new HCV drugs in pregnant women or nursing mothers. Safety/risk during pregnancy or breastfeeding has not been established.

Some treatments will require ribavirin which is 5-6 more tablets per day divided between morning and evening with food. The major side effects are feeling tired, nausea, itching and skin rash, trouble sleeping, irritability and weakness. A common side effect of ribavirin is anemia. PLEASE NOTE: Ribavirin cannot be given to a pregnant or breastfeeding female or to a female who plans to become pregnant or a male who plans to father a child during or for 6 months after treatment because it can cause birth defects.

Are you ready for treatment?
To ensure your success in completing HCV treatment, please consider the following:

• Drinking alcohol or misusing opioids or other drugs can hurt the liver. If you have recent drug/alcohol abuse, it is recommended that you attend an approved drug treatment program for support.

• Have you discussed HCV treatment with your primary care provider?

• It’s helpful to have a relative/close friend to support you during treatment.

• Are you committed to making every treatment appointment and getting monthly blood draws? We will want to monitor your progress during treatment.

• Can you return for an appointment 12 weeks after completing medication to be tested for cure?

Additional Requirements If Checked:
If you have cirrhosis, you may need an:

_____ EGD (A tube put into the esophagus and stomach to look for swollen veins that can bleed).

_____ Ultrasound of the liver (done in the past 6 months). This non-invasive test checks your liver for cancer.

If you are coming to Anchorage and want a FibroScan, call the Liver Clinic ahead of your visit to schedule an appointment. FibroScan is a test using ultrasound waves to check liver stiffness or scarring/fibrosis in your liver. FibroScan testing is done in the Internal Medicine Clinic. Do not eat or drink for 3 hours before the test. Call us at 907-729-1560 or 1-800-655-4837.
AUDIT-C Questionnaire

Patient Name ______________________________ Date of Visit ______________________

1. Within the past year, how often did you have a drink of alcohol?
   □ a. Never
   □ b. Monthly (e.g. Special occasions/Rare)
   □ c. 2-4 times a month (e.g. 1x on weekend - “Fridays only” or “every other Thursday”)
   □ d. 2-3 times a week (e.g. weekends – Friday-Saturday or Saturday-Sunday)
   □ e. 4 or more times a week (e.g. daily or most days/week)

2. Within the past year, how many standard drinks containing alcohol did you have on a typical day?
   □ a. 1 or 2
   □ b. 3 or 4
   □ c. 5 or 6
   □ d. 7 to 9
   □ e. 10 or more

3. Within the past year, how often did you have six or more drinks on one occasion?
   □ a. Never
   □ b. Less than monthly
   □ c. Monthly
   □ d. Weekly
   □ e. Daily or almost daily

AUDIT-C is available for use in the public domain.
AUDIT-C - Overview

The AUDIT-C is a 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of the 10 question AUDIT instrument.

Clinical Utility

The AUDIT-C is a brief alcohol screen that reliably identifies patients who are hazardous drinkers or have active alcohol use disorders.

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are:
- a = 0 points, b = 1 point, c = 2 points, d = 3 points, e = 4 points
- **In men**, a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- **In women**, a score of 3 or more is considered positive (same as above).
- However, when the points are all from Question #1 alone (#2 & #3 are zero), it can be assumed that the patient is drinking below recommended limits and it is suggested that the provider review the patient’s alcohol intake over the past few months to confirm accuracy.¹
- Generally, the higher the score, the more likely it is that the patient’s drinking is affecting his or her safety.

Psychometric Properties

For identifying patients with heavy/hazardous drinking and/or Active-DSM alcohol abuse or dependence

<table>
<thead>
<tr>
<th></th>
<th>Men¹</th>
<th></th>
<th>Women²</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥3</td>
<td>Sens: 0.95 / Spec. 0.60</td>
<td>Sens: 0.66 / Spec. 0.94</td>
<td></td>
</tr>
<tr>
<td>≥4</td>
<td>Sens: 0.86 / Spec. 0.72</td>
<td>Sens: 0.48 / Spec. 0.99</td>
<td></td>
</tr>
</tbody>
</table>

For identifying patients with active alcohol abuse or dependence

<table>
<thead>
<tr>
<th></th>
<th>Men¹</th>
<th></th>
<th>Women²</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 3</td>
<td>Sens: 0.90 / Spec. 0.45</td>
<td>Sens: 0.80 / Spec. 0.87</td>
<td></td>
</tr>
<tr>
<td>≥ 4</td>
<td>Sens: 0.79 / Spec. 0.56</td>
<td>Sens: 0.67 / Spec. 0.94</td>
<td></td>
</tr>
</tbody>
</table>

³. Frequently Asked Questions guide to using the AUDIT-C can be found via the website: www.ogp.med.va.gov/portal/uploads/FAQ%20AUDIT-C
# PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

**NAME:**

**DATE:**

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Over the last 2 weeks, how often have you been bothered by any of the following problems? (use "✓" to indicate your answer)

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead, or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

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**add columns:**

**TOTAL:**

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10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

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PHQ-9 is adapted from PRIME MD TODAY, developed by Drs Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr Spitzer at rls8@columbia.edu. Use of the PHQ-9 may only be made in accordance with the Terms of Use available at [http://www.pfizer.com](http://www.pfizer.com). Copyright ©1999 Pfizer Inc. All rights reserved. PRIME MD TODAY is a trademark of Pfizer Inc.
**PHQ-9 QUICK DEPRESSION ASSESSMENT**

**For initial diagnosis:**

1. Patient completes PHQ-9 Quick Depression Assessment on accompanying tear-off pad.
2. If there are at least 4 ✓s in the blue highlighted section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

3. **Consider Major Depressive Disorder**
   — if there are at least 5 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)

   **Consider Other Depressive Disorder**
   — if there are 2 to 4 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)

**Note:** Since the questionnaire relies on patient self-report, all responses should be verified by the clinician and a definitive diagnosis made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

**To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:**

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✓s by column. For every ✓: Several days = 1; More than half the days = 2; Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying PHQ-9 Scoring Card to interpret the TOTAL score.
5. Results may be included in patients’ files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

**PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION**

**Scoring—add up all checked boxes on PHQ-9**

For every ✓: Not at all = 0; Several days = 1; More than half the days = 2; Nearly every day = 3

**Interpretation of Total Score**

<table>
<thead>
<tr>
<th>Total Score</th>
<th>Depression Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>Minimal depression</td>
</tr>
<tr>
<td>5-9</td>
<td>Mild depression</td>
</tr>
<tr>
<td>10-14</td>
<td>Moderate depression</td>
</tr>
<tr>
<td>15-19</td>
<td>Moderately severe depression</td>
</tr>
<tr>
<td>20-27</td>
<td>Severe depression</td>
</tr>
</tbody>
</table>
Harvoni® (Ledipasvir/Sofosbuvir) Information Packet

Liver Disease & Hepatitis Program Providers:  
Brian McMahon, MD; Youssef Barbour, MD; Lisa Townshend-Bulson, APRN, FNP-C;  
Annette Hewitt, APRN, FNP-C; Leah Besh, PA-C; Stephen Livingston, MD

Family Medicine Provider: _____________________________________________

If you are considering hepatitis C treatment, please read this treatment agreement carefully and be sure to ask any questions you may have before you begin treatment.

The FDA approved ledipasvir combined with sofosbuvir in one tablet (Harvoni®) for the treatment of hepatitis C genotypes 1, 4, 5, and 6.

PREGNANCY & BREASTFEEDING WARNING  
It is not known if Harvoni® will harm an unborn or breastfeeding baby, so it is recommended that women do not get pregnant or breastfeed while taking this medicine.

PLEASE NOTE  
You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Harvoni® prior to starting any new medications. You must let Liver Clinic providers know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

If you have ever had hepatitis B infection, the virus could become active again during or after taking Harvoni®. You will have blood tests to check for hepatitis B infection before starting treatment (HBsAg, HBCAb). If you have hepatitis B or are HBCAb or HBsAg positive you will have HBV DNA levels checked before and while on treatment.

HOW THE TREATMENT PROCESS WORKS  
You will have an appointment monthly while you are taking the medication.

- At each visit blood will be collected.
- A monthly pregnancy test will be done for female patients of childbearing potential.
- Random drug and alcohol tests may be requested.
- Other tests may be done during the treatment if your provider feels there is a need.

Three months after completing treatment you will have an appointment to test for cure of hepatitis C. You will then be seen yearly (corresponding to your end of treatment date) for the next 5 years. You may need to see your primary care provider during treatment if you have any other health concerns.

IF YOU HAVE ADVANCED FIBROSIS OR CIRRHOSIS  
- You should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months.
• You will have an additional appointment in Liver Clinic 6 months after completing treatment.
Liver Clinic Provider, select the appropriate treatment regimen and reason:

____ Harvoni® will be given for 8 weeks if you have genotype 1, do not have cirrhosis, have never been treated before, have a viral load <6 million IU/mL, are non-black, and HIV-uninfected.

____ Harvoni® will be given for 12 weeks if:

□ You have genotype 1 or 4, do not have cirrhosis or have compensated (mild) cirrhosis and have never been treated before.

□ You have genotype 1, do not have cirrhosis and prior treatment with peginterferon alfa, ribavirin ± a protease inhibitor (telaprevir, boceprevir, or simeprevir) failed.

□ You have genotype 4, do not have cirrhosis and prior treatment with peginterferon alfa and ribavirin failed.

____ Harvoni® will be given for 24 weeks if you have genotype 1 or 4 hepatitis C with decompensated cirrhosis and are ribavirin ineligible.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Harvoni® is a fixed-dose combination tablet containing ledipasvir 90mg and sofosbuvir 400mg. You will take Harvoni® once daily by mouth with or without food. Store the medication at room temperature. If you miss a dose, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of Harvoni® in a day. Take your next dose at your regular time the next day.

- The most common side effects are tiredness (~16%) and headache (~14%).

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Harvoni® (this list is not all inclusive, medicines that are P-gp inducers are not recommended):

- Amiodarone (Cordarone®, Nexterone®, Pacerone®) [Provider note: If there is no alternative treatment option refer to full prescribing information and counsel patients about risk of symptomatic bradycardia (near-fainting, fainting, dizziness or lightheadedness, extreme tiredness, weakness, excessive tiredness, shortness of breath, chest pain, confusion, or memory problems)].

- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)

- Oxcarbazepine (Trileptal®, Oxtellar XR®, Phenytoin (Dilantin®, Phenytek®); Phenobarbital (Luminal®); Primidone (Mysoline®)

- Rifabutin (Mycobutin®); Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®); Rifapentine (Priftin®)

- Rosuvastatin (Crestor®)

- Simeprevir (Olysio®)

- St. John’s wort (Hypericum perforatum) or a product that contains St. John’s wort
• Tipranavir (Aptivus®) used in combination with ritonavir (Norvir®)
• Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate (STRIBILD®)

Tell your healthcare provider if you are taking any of the following medicines, as they require dose adjustment and/or monitoring:

• An antacid that contains aluminum or magnesium hydroxide (such as Rolaids®, Maalox® and Mylanta®) must be taken 4 hours before or 4 hours after you take Harvoni®.
• Twice daily medicine for indigestion, heartburn, or stomach ulcers must be taken at the same time or 12 hours apart from Harvoni®. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®), cimetidine (Tagamet®), and ranitidine (Zantac®) have not been studied with Harvoni®.
• Once daily medications for indigestion, heartburn, or stomach ulcers must be taken at the same time as Harvoni®. Omeprazole (Prilosec®) no more than 20 mg daily is okay. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Harvoni®.
• Atorvastatin (Lipitor®) Monitor for myopathy and rhabdomyolysis.
• Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.
• Digoxin (Lanoxin®)
• Efavirenz/emtricitabine/tenofovir disoproxil fumarate (ATRIPLA®)
• Regimens containing tenofovir disoproxil fumarate (DF) (VIREAD®, TRUVADA®) without a HIV protease inhibitor/ritonavir (Norvir®) or cobicistat (Tybost®)
• Regimens containing tenofovir disoproxil fumarate (VIREAD®, TRUVADA®) with an HIV protease inhibitor/ritonavir or cobicistat (consider alternative HCV or antiviral therapy)
  o atazanavir (Reyataz®)/ritonavir (Norvir®) or cobicistat (Tybost®) + emtricitabine/tenofovir DF (TRUVADA®)
  o darunavir (Prezista®)/ritonavir (Norvir®) or cobicistat (Tybost®) + emtricitabine/tenofovir DF (TRUVADA®)
  o lopinavir/ritonavir (Kaletra®) + emtricitabine/tenofovir DF (TRUVADA®)

**BENEFITS OF TREATMENT**

If you have no hepatitis C in your blood 12 weeks after the end of treatment, you are cured. Your chance of cure depends on the hepatitis C genotype, how much virus you have in your blood at the beginning of treatment, any past treatment response, how much liver damage you have had prior to treatment, and taking the medication every day.

It is possible that you may develop some serious side effects, which will require you to stop the treatment. You may still benefit from treatment even if it does not get rid of your hepatitis C, as it may slow down the disease.

Harvoni® (Ledipasvir/Sofosbuvir) 03/2019
In Studies and Clinical Trials:
Persons with genotype 1 who were treatment-naïve (never treated before), did not have cirrhosis, and were treated with Harvoni® for 12 weeks had a 98% response (cure) rate (ION-1). In persons with cirrhosis who were treatment-naïve the response rate was 97% (ION-1).

Persons with genotype 1 with a baseline viral load of less than 6 million, who were treatment naive, and did not have cirrhosis, the response rate was 97% (119/123) with an 8-week treatment and 96% (126/131) with 12-week treatment (ION-3).

Persons without cirrhosis in whom prior treatment with peginterferon, ribavirin and/or a protease inhibitor failed were treated for 12 and 24 weeks with Harvoni®. The response in those who took 12 weeks was 94% (33/35) (ION-2).

There are no data available on the use of Harvoni® for 24 weeks in decompensated cirrhosis. However, in one study of this regimen in persons with genotype 1 with compensated cirrhosis, who failed previous therapy with peginterferon, ribavirin, and/or a protease inhibitor, the response was 97% (Bourliere, 2015).

In persons with genotypes 4, 5 or 6 regardless of prior treatment experience or the presence or absence of compensated cirrhosis took Harvoni® for 12 weeks.
- Persons with genotype 4 had a response rate of 95%. Of these persons, 40% were treatment experienced and 43% had advanced fibrosis (Synergy Trial).
- Those with genotype 5 had a 93% (38/41) response (Study 1119).
- Those with genotype 6 had a 96% (24/25) response rate (ELECTRON-2).

To take care of your liver and prevent the spread of hepatitis C
- Do not share needles or other drug works, toothbrushes, razors, or nail clippers.
- Cover cuts to prevent blood exposure.
- Only get a tattoo if the equipment and ink used is sterile (such as at a commercial, regulated tattoo studio).
- Practice safe sex.
- Do not drink alcohol or use drugs because these hurt the liver.

WHOM TO CALL
If you have any questions about treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.
**Harvoni® Treatment Medication**

You will take **Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg)**.

Take ONE tablet by mouth daily, with or without food.

The generic name for Harvoni® is **ledipasvir 90mg/sofosbuvir 400mg**

- An antacid that contains aluminum or magnesium hydroxide (such as Rolaids®, Maalox® and Mylanta®) must be taken 4 hours before or 4 hours after you take Harvoni®.

- Twice daily medicine for indigestion, heartburn, or stomach ulcers **must be taken at the same time or 12 hours apart from Harvoni®**. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®), cimetidine (Tagamet®), and ranitidine (Zantac®) have not been studied with Harvoni®.

- Once daily medications for indigestion, heartburn, or stomach ulcers **must be taken at the same time as Harvoni®**. Omeprazole (Prilosec®) no more than 20 mg daily is okay. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Harvoni®.

- Do not take supplements or tea containing St. John’s wort while taking Harvoni®.

Pick up refills for **Harvoni®** after monthly appointments.

For Specialty Pharmacy refills, call: ______________________

On these dates: ________________________

Call ____________________ to schedule your family medicine treatment appointments, or if you have any other health concerns.

Call Liver Clinic (907-729-1560) if you feel you are having any significant side effects while taking these medications, or have any other questions about treatment.

***For any emergencies after normal business hours, please go to the Emergency Room. Make sure any healthcare provider you see knows you are on treatment. Carry a list of your medicines with you.

For more information on managing side effects visit our website at [http://anthc.org/hep](http://anthc.org/hep)
Please Remember

Give the End of Treatment Letter to the patient at the completion of treatment.

End of Treatment Letter is found in Treatment Monitoring section on webpage.

12 weeks after treatment completion obtain an HCV RNA to check for a sustained virologic response (SVR). SVR is considered a virologic cure of hepatitis C.

SVR12 Cure Letter is found in Treatment Monitoring section on webpage.

If person had advanced fibrosis or cirrhosis prior to treatment, continue to obtain AFP & RUQ US every 6 months.

For more information visit our website at http://anthc.org/hep
You have completed your treatment for HCV, here’s what will happen next:

In 3 months you will need blood work, including an HCV RNA which is a test that will look for hepatitis C virus. If there is no HCV virus in your blood you are cured! Due: ______________.

Your follow up plan after cure:

___ If you had zero to minimal scarring in your liver there is no need for you to continue being seen in Liver Clinic.

___ If you had advanced scarring of the liver you should have a CBC and LFTs annually and an AFP drawn and RUQ US every 6 months. Due: ______/______.

    You should be seen in Liver Clinic every 2 years. Due: ____________.

___ If you had cirrhosis of the liver you should have a CBC, CMP, & PT/INR annually and an AFP drawn and RUQ US every 6 months. Due: ______/______.

    You should be seen in Liver Clinic every year. Due: ____________.

If you are coming to Anchorage, and want a FibroScan, call the Liver Clinic ahead of your visit to schedule. ***Remember not to eat or drink for 3 hours before the FibroScan***
**Tips to Keep Your Liver Healthy:**

**You are not immune to HCV.** It is possible to become re-infected. To prevent re-infection, avoid all blood – this includes not sharing needles, razors, toothbrushes, or nail clippers. Remember to practice safe sex.

**The HCV antibody test will remain positive after you are cured.** This is your immune system remembering that you had the virus. The test to see if you have HCV is the **HCV RNA** test which will look for virus in your blood.

**Eat a balanced, healthy diet** that includes lots of vegetables, fruit, fish, whole grains, and low fat foods. Drink plenty of water; avoid soda and sweetened juices.

**Drink coffee.** Up to 3 cups per day of black, decaf or regular, coffee has been associated with less liver scarring.

**Do not drink alcohol or use drugs** because these hurt the liver.

**Exercise daily.** Aim for 30-60 minutes a day.

**Decrease stress in your life.** Talk to people who are supportive.

**Stop smoking.** Ask for help if you need it. The Alaska Tobacco Quitline number is 1-800-QUIT-NOW (1-800-784-8669).