Hepatitis C Health Summary

Name: _____

DOB: _____
Phone #: _____
Alternate Contact: _____

Medications[2]:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Allergies:

_____

_____

Labs Prior to Treatment:

Immediately prior: □ Pregnancy test
□ Uric Acid (ribavirin only)
Within 1 month: □ CBC with differential
□ CMP (If GFR <30, do not start tx [1])
□ PT/INR
□ HCV RNA
Within 3 months: □ Genotype confirmation
□ HBV DNA (if HBV cAb or sAg +)
Within 6 months: □ AFP
□ TSH
□ A1C or Fasting Glucose
□ Vitamin D 25OH
Within 1 year: □ HIV screening
□ NS5A RAV (genotype 3 only)
Once: □ IL-28b (if considering 8 weeks)

Pertinent Medical History:

Previous hepatitis C treatment[1] □ Yes □ No
Specify: _____
Cirrhosis[1] □ Yes □ No
Child-Pugh Score: _____
Other Liver Disease[1] □ Yes □ No
Specify: _____
Pulmonary Disorders[1] □ Yes □ No
Specify: _____
Cardiac Disease[2] □ Yes □ No
Specify: _____
DVT or PE[1] □ Yes □ No
Specify: _____
PPI/H2 blocker/Antacid use[2] □ Yes □ No
Specify: _____
Autoimmune Disorders[2] □ Yes □ No
Specify: _____
Cancer □ Yes □ No
Specify: _____
Current infection[1] □ Yes □ No
Specify: _____
High Blood Pressure □ Yes □ No
High Cholesterol □ Yes □ No
Kidney Disease[2] □ Yes □ No
Anemia[1, 2] □ Yes □ No
Current TB Treatment[2] □ Yes □ No
Diabetes Specify Type 1 or 2 □ Yes □ No
HIV or AIDS[1] □ Yes □ No
Seizure Disorder[2] □ Yes □ No
Depression/Anxiety □ Yes □ No
Other Psychiatric Conditions □ Yes □ No
Specify: _____

Screen & Review: AUDIT-C ___ PHQ-9 ___

Vaccine Status (give if needed):
Hepatitis A ___ (If unknown, check hep A total IgG)
Hepatitis B ___ (If unknown, check HBsAg & HBsAb)
Other vaccines as appropriate:
□ Flu (annually)
□ PCV-13 (≥ age 65 or immunosuppressed)
□ PPSV-23 (≥ age 50 AN/AI in AK or high risk)
□ Td (once every 10 years) **OR** Tdap (once)
□ Zoster (≥ age 60)
□ ECG (over age 65 or h/o cardiac disease)

Birth Control: Birth Control Methods: _____
Females: LMP: _____ Pregnant □ Yes □ No
Males: Is your partner pregnant? □ Yes □ No
□ Counsel about pregnancy prevention (see Treatment Agreement)
□ Hepatitis C Treatment Agreement reviewed and signed

1- Further evaluation as indicated; consult Liver Disease Specialist prior to treatment.
2- Check drug interactions to treatment drugs. Further evaluation as indicated.

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Liver Disease & Hepatitis Program
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Phone: 907-729-1560 Fax: 907-729-1570
http://www.anthc.org/hep
Follow us on Twitter:
Liver Program @ANTHCLiver

We are glad to hear you are interested in treatment for hepatitis C!

Here are some things to think about (and do) before you make your final decision about treatment:

Why do treatment now? New medicines have increased the chance of cure and have fewer side effects.

Some people have worse liver disease than others. If you have more severe liver disease (a lot of scarring in the liver or cirrhosis) you should consider getting treatment sooner.

What will happen during treatment?

There are 6 FDA approved treatment options for **genotype 1**:

- Option 1 is Harvoni® (ledipasvir/sofosbuvir), 1 tablet taken once a day for 8-24 weeks. The most common side effects are feeling tired and headache. In clinical studies, treatment response rates to Harvoni® were 94-100%.
- Option 2 is Epclusa® (sofosbuvir/velpatasvir), 1 tablet taken once a day for 12 weeks. The most common side effects are headache and feeling tired. In clinical studies, treatment response rates to Epclusa® were 94-98% for genotype 1.
- Option 3 is Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) co-packaged as 3 tablets in the morning and 1 tablet in the evening with food for 12-24 weeks. The major side effects are nausea, itching, and insomnia. In clinical studies, response rates to Viekira Pak™ treatments were 86-100%.
- Option 4 is Zepatier™ (elbasvir/grazoprevir), 1 tablet taken once a day for 12-16 weeks. The most common side effects are feeling tired, nausea, and headache. In clinical studies, treatment response rates to Zepatier™ were 95-100%.
- Option 5 is Olysio® (simeprevir) plus Sovaldi® (sofosbuvir) 1 tablet of each taken once daily for 12 weeks. The most common side effects are feeling tired, headache, and nausea. In clinical studies, treatment response rates to Olysio® and Sovaldi® were 86-100%.
- Option 6 is Daklinza™ (daclatasvir) plus Sovaldi® (sofosbuvir) 1 tablet of each taken once daily for 12 weeks. The most common side effects are headache and feeling tired. In clinical studies, treatment response rates to Daklinza™ and Sovaldi® were 50-100%.

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

There are 2 FDA-approved treatment options for **genotype 3**:

- Option 1 is Epclusa® (sofosbuvir/velpatasvir), 1 tablet taken once a day for 12 weeks. The most common side effects are headache and feeling tired. In clinical studies, treatment response rates to Epclusa® were 85-98% for genotype 3.
- Option 2 is Daklinza™ (daclatasvir) and Sovaldi® (sofosbuvir) 1 tablet of each taken once daily for 12 weeks. The most common side effects are headache and feeling tired. In clinical studies, treatment response rates for Daklinza™ and Sovaldi® were 58-98%.

Some treatments will require ribavirin which is 5-6 additional tablets 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. There are no studies on Harvoni®, Epclusa®, Sovaldi®, Viekira Pak™, Zepatier™, or Daklinza™ in pregnant women or nursing mothers. Safety/risk during pregnancy or breastfeeding has not been established.

Are you ready for treatment?

To ensure that you will be successful in completing hepatitis C treatment we ask that the following items be done before starting treatment. We will review them together.

- You must be alcohol and drug-free. If you have recent drug/alcohol abuse, you need to be in an approved drug treatment program.
- You need to discuss hepatitis C treatment with your primary care provider and get his or her "OK" to start treatment.
- You should have a relative/close friend who is willing to help support you during treatment.
- You need to be committed to making every treatment appointment and getting **FREQUENT** blood draws (every 1-4 weeks). We will want to follow you very closely during treatment.

Additional Requirements If Checked:

____ If you have cirrhosis, you may need an EGD (when a doctor looks into your esophagus and stomach for swollen veins that can bleed).

____ If you have cirrhosis, you need to have an ultrasound of the liver (done in the past 6 months). This ultrasound checks your liver for cancer.

Once everything you need to do on the list has been done, call your primary care provider to make an appointment to plan for hepatitis C treatment. At this appointment, treatment and side effects will be discussed in detail.

If you are coming to Anchorage and want a Fibroscan, call the Liver Clinic ahead of your visit to schedule. 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.

Congratulations on completing all the pre-treatment requirements!

Hepatitis C Treatment Checklists

Prior to Treatment

Labs

Immediately prior: ___ Pregnancy test (if applicable)
___ Uric Acid (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
___ TSH
___ A1C or Fasting Glucose
___ Vitamin D 25OH (treat if deficient)

Within 1 year:
___ HIV screening
___ NS5A RAV (genotype 3 only)

Once:
___ IL-28b (if considering 8 weeks)

Miscellaneous:
___ Hepatitis A (If vaccine status is unknown, draw HAV total)
___ Hepatitis B (If vaccine status is unknown, draw HBsAg & HBsAb)
___ PHQ-9 baseline
___ AUDIT-C
___ Counsel about pregnancy prevention
___ Review & sign Treatment Agreement

8 week

Week 4
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

Week 8
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

12 week

Week 2 (with ribavirin)
___ CBC
___ CMP[1]

Week 4
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

Week 8
___ CBC
___ CMP[1]
___ Pregnancy test

Week 12
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

16 week

Week 2 (with ribavirin)
___ CBC
___ CMP[1]

Week 4
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

Weeks 8 & 12
___ CBC
___ CMP[1]
___ Pregnancy test

Week 16
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

24 week

Week 2 (with ribavirin)
___ CBC
___ CMP[1]

Week 4
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

Weeks 8, 12, 16, & 20
___ CBC
___ CMP[1]
___ Pregnancy test

Week 24
___ HCV RNA
___ CBC
___ CMP[1]
___ Pregnancy test

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

3 months post treatment
___ CBC
___ Liver Function Tests
___ HCV RNA
___ AUDIT-C

6 months post treatment
___ HCV RNA
___ AFP
___ RUQ US (if advanced fibrosis)
___ AUDIT-C

1- Sofosbuvir- or daclatasvir-based regimen - If GFR <30, no safe recommendation.
With ribavirin - If GFR <50, decrease dose (refer to package insert).

Harvoni® (Ledipasvir/Sofosbuvir) Treatment Agreement

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 sign the form.

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

Treatment with Harvoni® requires 4 scheduled visits over a 5-month period if your treatment course is 8 weeks, 5 scheduled visits over 6 months if your treatment course is 12 weeks, and 9 scheduled visits over 9 months if your treatment course is 6 months.

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.

HOW THE TREATMENT PROCESS WORKS

You will have blood and urine tests.

- These tests will include a pregnancy test for female patients. A urine pregnancy test will be done monthly during a clinic visit.
- Random drug and alcohol tests may be requested.
- At each visit, about 2-3 tubes of blood will be collected. Other examinations and tests may be done during the treatment if your provider feels there is a need.

Liver Clinic Provider, select the appropriate treatment regimen and reason:

____ Harvoni® will be given for 12 weeks if:

□ You do not have cirrhosis and have never been treated before.

□ You have compensated (mild) cirrhosis and have never been treated before.

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

□ You have compensated (mild) cirrhosis, and prior treatment failed, and you have genotype 4, 5, or 6 hepatitis C.

____ 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 24 weeks if you have genotype 1 with cirrhosis and prior peginterferon alfa, ribavirin treatment failed, including prior protease inhibitor treatment or

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

Your first three visits will be at the start of treatment (week 0) and weeks 2 and 4 after you begin taking the medication. Week 2 visit will be at the discretion of your provider. After that, the visits will be once each month until you stop taking the medications.

You may need to see your primary care provider more frequently if you are having side effects or problems related to the treatment.

You will have a liver clinic visit 3 months after treatment completion and then yearly (corresponding to your end of treatment date) for 5 years. If you have cirrhosis you should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months and regular clinic visits.

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 and headache.

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

- Digoxin (Lanoxin®)
- Efavirenz/emtricitabine/tenofovir disoproxil fumarate (ATRIPLA®)
- Regimens containing tenofovir disproxil fumarate (DF) (VIREAD®, TRUVADA®) without a HIV protease inhibitor/ritonavir (Norvir®) or cobicistat (Tybost®)
- Regimens containing tenofovir disproxil fumarate (VIREAD®, TRUVADA®) with an HIV protease inhibitor/ritonavir or cobicistat (consider alternative HCV or antiviral therapy)
    - atazanavir (Reyataz®) /ritonavir (Norvir®) or cobicistat (Tybost®) + emtricitabine/tenofovir DF (TRUVADA®)
    - darunavir (Prezista®) /ritonavir (Norvir®) or cobicistat (Tybost®) + emtricitabine/tenofovir DF (TRUVADA®)
    - lopinavir/ritonavir (Kaletra®) + emtricitabine/tenofovir DF (TRUVADA®)

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 your providers know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

***Hepatitis C treatment does not cause pain that requires narcotic pain medication.

BENEFITS OF TREATMENT

In most cases, hepatitis C will respond to treatment as determined by a blood test that measures the presence and amount of hepatitis C in the blood. If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, this is called a "sustained virologic response" and means you no longer have hepatitis C. Your chance of achieving a sustained virologic response depends on the hepatitis C genotype, how much hepatitis C virus you have in your blood at the beginning of treatment, any past treatment response, and how much liver damage you have prior to treatment.

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. You may choose to stop treatment at any time.

In 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 99% response (cure) rate. In persons with a baseline viral load of less than 6 million who did not have cirrhosis, the response rate was 97% with 8-week treatment and 96% with 12-week treatment.

Persons with cirrhosis who were treatment-naïve had a 94% response rate.

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 95% and for those who received 24 weeks the response was 99%.

Persons with cirrhosis in whom prior treatment with peginterferon, ribavirin, and/or a protease inhibitor failed had an 86% response to 12 weeks and 100% response rate to 24 weeks of Harvoni®.

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 the response was 71%.

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 who were genotype 4 or 5 had a 93% or better treatment response (cure) rate. Those who were genotype 6 had a 96% response rate.

WHOM TO CALL

If you have any questions about treatment, contact your primary care provider.

TREATMENT AGREEMENT

To receive treatment, please review the following statements and initial beside the responses:

_____ I agree not to drink alcohol or use recreational drugs during the treatment.

_____ I will tell my provider if I have any serious medical conditions (such as heart disease, high blood pressure, diabetes, high cholesterol, rheumatoid arthritis, or drug addiction), or psychiatric conditions (depression, history of suicide attempts, bipolar disorder, or psychosis).

_____ I am willing to visit the clinic and see a provider on a regular schedule for the entire length of the treatment. If I am unable to attend an appointment, I will let my provider know this ahead of time and I will reschedule my appointment.

_____ I understand that my treatment will be stopped if I cannot attend appointments as required for evaluation of my health and well-being during treatment and the effectiveness of treatment.

_____As a female taking Harvoni®, I will not get pregnant or breastfeed while on treatment. I understand that my treatment will be stopped if I become pregnant.

___ Not applicable, I am surgically sterile or post-menopausal.

_____If I have any problems with the medications or side effects that bother me, I will let my provider or nurse know right away.

_____ I understand that my hepatitis C may not respond to treatment.

_____ I understand that my provider can stop my treatment if the provider feels that stopping it is in the best interest of my health and welfare.

_____ I will do my best to take my medications as prescribed by my provider. If I am unable to do so, I will contact my provider.

_____ I will protect myself and others from hepatitis C by not sharing needles, toothbrushes, razors or nail clippers and covering cuts to prevent blood exposure.

My signature below means that I have read this treatment agreement and/or the meaning of the information has been explained to me. I agree to treatment.

_____

Patient's Name (PLEASE PRINT) **Patient's Signature** **Date**

_____

Provider's Name (PLEASE PRINT) **Provider's Signature** **Date**

Harvoni® (Ledipasvir/Sofosbuvir) Treatment Medication

You will take **Harvoni®**.
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®.

You get _____ from _____.

Pick up refills on: _____
_____

***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: http://www.anthctoday.org/community/hep/patients/index.html
Click on "Patient Guide- Managing HepC Treatment"

Harvoni® 24 week Lab Tracking Form

General Patient Information

Name: _____

DOB: _____/_____/_____

MRN: _____

Phone #: _____

Treatment Start Date: _____

Pre-Treatment Lab Results

HCV RNA: _____ PHQ-9: ____

Genotype: _____ HIV: ____ TSH: ____

Vit D 25OH: _____ AFP: _____ GFR*: _____

PT/INR: _____ A1C/Glucose: _____

Medication Regimen

Harvoni® (Ledipasvir 90mg/Sofosbuvir 400mg)
1 tablet PO daily.
Do not change dose.

Completed Treatment Week	Lab Date	Hgb	Hct	WBC	PLT	ALT	AST	Alk Phos	Total Bili	Creat/ GFR	HCV RNA (Specified weeks)	Weight (kg)	Pregnancy Test
Pre-Treatment													
Treatment Start Week 0											HCV RNA		
optional													
optional													
optional													
Week 4											HCV RNA		
optional													
optional													
Week 8													
optional													
optional													
Week 12											HCV RNA		
optional													
Week 16													
optional													
Week 20													
optional													
Week 24											HCV RNA		
3 months post treatment											HCV RNA		

Labs recommended for each follow up visit: CBC, CMP, pregnancy test (females of childbearing age), and HCV RNA as specified.

***GFR <30** If GFR is <30, do not start treatment; consult with Liver Disease Specialist.

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.

http://anthctoday.org/community/hep/providers/treatment/index.html