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).

Zepatier™ (Elbasvir/Grazoprevir) & Ribavirin 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.

In January 2016 the FDA approved elbasvir combined with grazoprevir in one tablet (Zepatier™) for the treatment of hepatitis C genotypes 1 and 4. In some circumstances, it has been found that the treatment works better when given with ribavirin.

Treatment with Zepatier™ and ribavirin requires 6 scheduled visits over a 6 month period for a 12-week treatment course. If you undergo a 16-week treatment course, there are 7 scheduled visits over 7 months.

PREGNANCY & BREASTFEEDING WARNING

Ribavirin can harm an unborn child or breastfeeding infant. A woman must not get pregnant and a man must not father a child while taking ribavirin or for 6 months after treatment. You must **use 2 forms of birth control** when you take ribavirin and for 6 months after your last dose.

Acceptable Birth Control Methods (must use 2):

- Birth control pills or other hormone containing birth control
- Male or female condom
- Spermicides (creams, films, foams, gels, and/or suppositories)
- Diaphragm or cervical cap
- Intrauterine device (IUD), Today® vaginal sponge

Unacceptable Birth Control Methods:

- Rhythm method or withdrawal

HOW THE TREATMENT PROCESS WORKS

You will have blood and urine tests.

- These tests will include a pregnancy test for female patients of childbearing age. Urine pregnancy tests will be done monthly during clinic visits. If you are a woman and your treatment includes ribavirin it is recommended that you continue monthly home pregnancy testing for 6 months after treatment and notify your healthcare provider if you become pregnant. Female partners of males whose treatment includes ribavirin should do a monthly home pregnancy test during treatment and for 6 months after treatment completion and notify their health care provider if they become pregnant.
- 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.

Provider, select the appropriate treatment regimen:

_____ Zepatier™ & ribavirin will be given for 12 weeks if you have genotype 1a or 1b and have had previous treatment peginterferon, ribavirin and a protease inhibitor (boceprevir, simeprevir, or telaprevir).

_____ Zepatier™ & ribavirin will be given for 16 weeks if you have genotype 1a with baseline NS5A polymorphisms (mutations in the hepatitis C virus that can decrease response to treatment) or genotype 4 and past treatment with peginterferon and ribavirin that failed.

Your first three visits will be at the start of treatment (week 0) and weeks 2 and 4 after you begin taking the medications. 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 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

Zepatier™ is a fixed-dose combination tablet containing elbasvir 50mg and grazoprevir 100mg. You will take Zepatier™ 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 Zepatier™ in a day. Take your next dose at your regular time the next day.

- The most common side effects are ALT (a liver enzyme) elevation, tiredness, nausea, and headache.

Tell your healthcare provider if you are taking any of the following medicines, as they are contraindicated with Zepatier™ (this list is not all inclusive; medications that are OATP1B1/3 inhibitors or strong CYP3A inducers are contraindicated):

- Phenytoin (Dilantin®, Phenytek®)
- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol® XR)
- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort
- Efavirenz (ATRIPLA®, Sustiva®); Tipranavir (Aptivus®); Atazanavir (Reyataz®, Evotaz™); Darunavir (Prezista®, Prezcobix®); Lopinavir/ritonavir (Kaletra®); Saquinavir (Invirase®); Etravirine (Intelence®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Zepatier™ (this list is not all inclusive; medications that are moderate CYP3A inducers are not recommended):

- Nafcillin
- Ketoconazole
- Bosentan (Tracleer®)
- Modafinil (Provigil®)
- Cobicistat containing regimens: elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate or alafenamide (Stribild®, Genvoya®)

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

- Tacrolimus (Astagraf XL®, Envarsus XR™, FK506 (common name), Hecoria™, Prograf®)

- Cholesterol lowering medications: atorvastatin (Lipitor®), rosuvastatin (Crestor®), fluvastatin (Lescol®), lovastatin (Mevacor®, Altoprev®), simvastatin (Zocor®)

Ribavirin is a 200mg capsule or tablet. You will take ribavirin pills twice daily by mouth with food (dose is based on your weight). Ribavirin dose may be adjusted based on your tolerance of this medication. You should not miss/skip taking any pills. A common side effect is anemia. Anemia is a condition where the blood has a decreased number of red blood cells. This occurs more often in older persons taking ribavirin. Anemia can be serious in patients who have kidney problems. In patients who have coronary artery disease (narrowing of the blood vessels in the heart), anemia may make the problem worse, leading to chest pain or heart attack. If your provider believes you may have coronary artery disease, you will be tested for this and excluded from treatment if it is serious.

- Other common side effects include: headache, trouble sleeping, nausea, vomiting, weakness or lack of energy, shortness of breath, loss of appetite, itching, cough, muscle pain, swelling and pain in your joints (gout), depression, nervousness, and dizziness.
- Studies in animals have shown when ribavirin is given to pregnant females, death of the developing embryo or birth of deformed baby animals may result. It is expected that similar results as seen in the animal studies could occur in humans.

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Zepatier™ & ribavirin 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 should 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 had 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 Studies:

Six persons with genotype 1a with baseline NS5A polymorphisms (mutations in the hepatitis C virus that can decrease response to treatment) treated with Zepatier™ and ribavirin for 16 weeks had a 100% response (cure) rate.

Persons who had genotype 1a or 1b previously treated with Peg-interferon, ribavirin and a protease inhibitor (boceprevir, simeprevir, or telaprevir) and took Zepatier™ and ribavirin for 12 weeks had an overall 96% response (cure) rate.

Five persons with genotype 4 whose previous treatment with peginterferon and ribavirin failed, took Zepatier™ and ribavirin for 16 weeks and had a 100% response (cure) rate.

WHOM TO CALL

If you have any questions about your 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 to evaluate my health and well-being during treatment and the effectiveness of treatment.

_____ I will use 2 acceptable methods of birth control during treatment and for 6 months after I stop treatment (see lists, page 1).

_____ As a female, I understand that I cannot be pregnant or breastfeeding during the treatment and for 6 months after treatment. I understand that my treatment will be stopped if I become pregnant. ____ Not applicable, I am surgically sterile or post-menopausal.

_____ As a male taking ribavirin I understand that I should not father a child during treatment and for 6 months after treatment.

_____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**

Zepatier™ (Elbasvir/Grazoprevir) & Ribavirin Treatment Medications

You will be taking the following medications:

1. **Zepatier™ (elbasvir 50mg/grazoprevir 100mg)**
   Take ONE tablet by mouth daily, with or without food.
   The generic name for Zepatier™ is elbasvir 50mg/grazoprevir 100mg
   - Do not take supplements or tea containing St. John's wort while taking Zepatier™.

2. **Ribavirin 200mg capsules**
   Take ___ capsules in the morning **with food** and ___ capsules in the evening **with food**.
   The earlier in the evening you take ribavirin, the less likely you will have sleep problems.

You get Zepatier™ from _____.
You get ribavirin from _____.

Pick up refills on: _____
_____

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

***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"

Zepatier™ (Elbasvir & Grazoprevir) & Ribavirin 12 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: _____

AFP: ____ Vit D 25OH: _____

PT/INR: _____ GFR*:_____

A1C/Glucose: _____ Uric Acid:_____

Medication Regimen

1- Zepatier ™ (Elbasvir 50mg/Grazoprevir 100mg)
1 tablet PO daily. Do not change dose.

2- Ribavirin: _____ mg/day PO divided into 2 doses. Take with breakfast & dinner.
<66kg= 800mg/day | 66-80kg= 1000mg/day
81-105kg=1200mg/day | 105kg=1400mg/day

**Dose Reduction/Date: _____/_____

**Additional Dose Change/Date: _____/_____

**Consult ANTHC Liver Disease & Hepatitis Specialists for further guidance about dose changes.

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													
Week 2													
optional													
Week 4											HCV RNA		
optional													
optional													
Week 8													
optional													
optional													
Week 12											HCV RNA		
optional													
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.

Please note the following critical values. These may require modification of dosage or discontinuation of causative med. Contact ANTHC Liver Disease Specialists with any questions.

GFR <50 If GFR is <50, decrease ribavirin dose (refer to ribavirin package insert) and consult ANTHC Liver Disease Specialists.

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