

Hepatitis C Health Summary

Name: _____

DOB: _____

Phone #: _____

Alternate Contact: _____

Medications²:

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 treatment¹ Yes No
Specify: _____
- Cirrhosis¹ Yes No
Child-Pugh Score: _____
- Other Liver Disease¹ Yes No
Specify: _____
- Pulmonary Disorders¹ Yes No
Specify: _____
- Cardiac Disease² Yes No
Specify: _____
- DVT or PE¹ Yes No
Specify: _____
- PPI/H2 blocker/Antacid use² Yes No
Specify: _____
- Autoimmune Disorders² Yes No
Specify: _____
- Cancer Yes No
Specify: _____
- Current infection¹ Yes No
Specify: _____
- High Blood Pressure Yes No
- High Cholesterol Yes No
- Kidney Disease² Yes No
- Anemia^{1,2} Yes No
- Current TB Treatment² Yes No
- Diabetes Specify Type 1 or 2 Yes No
- HIV or AIDS¹ Yes No
- Seizure Disorder² 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

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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

- | | |
|--|---|
| <p>Immediately prior: ___ Pregnancy test (if applicable)</p> <p style="padding-left: 20px;">___ Uric Acid (with ribavirin)</p> <p>Within 1 month: ___ CBC with differential</p> <p style="padding-left: 20px;">___ CMP¹</p> <p style="padding-left: 20px;">___ PT/INR</p> <p style="padding-left: 20px;">___ HCV RNA</p> <p>Within 3 months: ___ Genotype confirmation</p> <p style="padding-left: 20px;">___ HBV DNA (if HBV cAb or sAg +)</p> <p>Within 6 months: ___ AFP</p> <p style="padding-left: 20px;">___ TSH</p> <p style="padding-left: 20px;">___ A1C or Fasting Glucose</p> <p style="padding-left: 20px;">___ Vitamin D 25OH (treat if deficient)</p> <p>Within 1 year: ___ HIV screening</p> <p style="padding-left: 20px;">___ NS5A RAV (genotype 3 only)</p> <p>Once: ___ IL-28b (if considering 8 weeks)</p> | <p>Miscellaneous:</p> <p>___ Hepatitis A (If vaccine status is unknown, draw HAV total)</p> <p>___ Hepatitis B (If vaccine status is unknown, draw HBsAg & HBsAb)</p> <p>___ PHQ-9 baseline</p> <p>___ AUDIT-C</p> <p>___ Counsel about pregnancy prevention</p> <p>___ Review & sign Treatment Agreement</p> |
|--|---|

8 week

Week 4

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Week 8

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

12 week

Week 2 (with ribavirin)

- ___ CBC
- ___ CMP¹

Week 4

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Week 8

- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Week 12

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

16 week

Week 2 (with ribavirin)

- ___ CBC
- ___ CMP¹

Week 4

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Weeks 8 & 12

- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Week 16

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

24 week

Week 2 (with ribavirin)

- ___ CBC
- ___ CMP¹

Week 4

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Weeks 8, 12, 16, & 20

- ___ CBC
- ___ CMP¹
- ___ Pregnancy test

Week 24

- ___ HCV RNA
- ___ CBC
- ___ CMP¹
- ___ 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).

Daklinza™ (Daclatasvir) & Sovaldi® (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.

In July 2015 the FDA approved daclatasvir (Daklinza™) in combination with sofosbuvir (Sovaldi®) for the treatment of hepatitis C genotypes 1 and 3.

Treatment with daclatasvir and sofosbuvir requires 6 scheduled visits over a 6 month period if you undergo a 12-week treatment course. If you undergo a 24-week treatment course, there are approximately 9 scheduled visits over 9 months.

PREGNANCY & BREASTFEEDING WARNING

It is not known if daclatasvir or sofosbuvir will harm an unborn or breastfeeding baby, so it is recommended that women do not get pregnant or breastfeed while taking these medications.

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.
- 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:

____ Daclatasvir plus sofosbuvir will be given for 12 weeks if:

- You do not have cirrhosis;
- You have genotype 3 without cirrhosis and prior treatment with pegylated interferon and ribavirin failed.

____ Daclatasvir plus sofosbuvir will be given for 24 weeks if you have decompensated cirrhosis and cannot tolerate ribavirin.

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

Daclatasvir is a 60 mg tablet. You will take daclatasvir once daily by mouth with or without food. Store daclatasvir at room temperature. If you miss a dose of daclatasvir, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of daclatasvir in a day. Take your next dose of daclatasvir at your regular time the next day.

- The most common side effects are headache and tiredness.

Tell your healthcare provider if you are taking any of the following medicines, as they are contraindicated with daclatasvir:

- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- St. John's wort (hypericum perforatum)

- Phenytoin (Dilantin[®], Phenytek[®]), carbamazepine (Carbatrol[®], Eptol[®], Equetro[®], Tegretol[®])

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with daclatasvir:

- Amiodarone (Cordarone[®], Nexterone[®], Pacerone[®])
- Dabigatran etexilate mesylate (Pradaxa[®]); in renal impairment, refer to prescribing information.

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

Drugs that require daclatasvir dose reduction to 30mg:

- Atazanavir/ritonavir (Reyataz[®])
- Indinavir (Crixivan[®])
- Nelfinavir mesylate (Viracept[®])
- Saquinavir mesylate (Invirase[®])
- Cobicistat-containing antiretroviral regimens (except darunavir/cobicistat)
- Clarithromycin (Biaxin[®])
- Telithromycin (Ketek[®])
- Itraconazole (Onmel[®], Sporanox[®])
- Ketoconazole
- Posaconazole (Noxafil[®])
- Voriconazole (Vfend[®])
- Nefazodone (Serzone[®])

Drugs that require daclatasvir dose increase to 90mg:

- Efavirenz (Sustiva[®]); Etravirine (Intelence[®])
- Nevirapine (Viramune[®])
- Nafcillin
- Bosentan (Tracleer[®])
- Dexamethasone (Decadron[®])
- Modafinil (Provigil[®])
- Rifapentine (Priftin[®])

Drugs that are moderate CYP3A inhibitors and require monitoring for side effects or drug level*:

- Digoxin (Lanoxicaps[®], Lanoxin[®]) – *Dose reduction recommended and monitor digoxin level while on treatment
- Buprenorphine (Buprenex[®], Butrans[®], Belbuca[™], Subutex[®])
- Buprenorphine/Naloxone (Zubsolv[®], Bunavail[®], Suboxone[®])

HMG-CoA Reductase Inhibitors require monitoring for side effects such as myopathy:

- Atorvastatin (Lipitor[®]); Fluvastatin (Lescol[®]); Pitavastatin (Livalo[®])
- Pravastatin (Pravachol[®]); Rosuvastatin (Crestor[®]); Simvastatin (Zocor[®])

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

- Most common side effects are feeling tired, headache.

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

- Amiodarone (Cordarone[®], Nexterone[®], Pacerone[®])
- 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[®])
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort
- Tipranavir (Aptivus[®])

PLEASE NOTE

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking daclatasvir and sofosbuvir 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:

Persons with genotype 1 who did not have cirrhosis were treated with daclatasvir and sofosbuvir for 12 weeks and had a 96% response (cure) rate. Those with cirrhosis had a 91% response.

Persons with genotype 3 without cirrhosis had a 96% response rate after taking daclatasvir and sofosbuvir for 12 weeks. Those with cirrhosis had a 63% response rate after taking daclatasvir and sofosbuvir for 12 weeks.

The European compassionate use program reported an 86% sustained virologic response rate (cure) in persons with genotype 3 with cirrhosis who were treated for 24 weeks. Those with severe cirrhosis (Childs Pugh B or C) had a 70.6% response.

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.

_____ As a female, 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

Daklinza™ (Daclatasvir) and Sovaldi® (Sofosbuvir) Treatment Medications

You will be taking the following medications:

1. Daklinza™ 60mg tablet

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

The generic name for Daklinza™ is Daclatasvir 60mg. (Also available in 30mg and 90mg tablets).

2. Sovaldi® 400mg tablet

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

The generic name for Sovaldi® is Sofosbuvir.

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

You get _____ from _____.

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”

Daklinza™ (Daclatasvir) & Sovaldi® (Sofosbuvir) 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: ____
 Vit D 25OH: _____ AFP: _____ GFR*: _____
 PT/INR: _____ A1C/Glucose: _____

Medication Regimen

1- Daklinza™ (Daclatasvir) 60mg
 1 tablet PO daily. Consult Liver Disease providers prior to dose change.

2- Sovaldi® (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		
<i>optional</i>													
<i>optional</i>													
<i>optional</i>													
Week 4											HCV RNA		
<i>optional</i>													
<i>optional</i>													
Week 8													
<i>optional</i>													
<i>optional</i>													
Week 12											HCV RNA		
<i>optional</i>													
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>