Hepatitis C Health Summary

Name:		Pertinent Medical History:				
DOB:		Previous hepatitis C treatment				
Phone #:		Specify: Cirrhosis ¹				
Alternate Contact	:			⊔ NO		
Medications ² :		Child-Pugh Score: Other Liver Disease ¹		- No		
ivieuications .						
		Specify: Pulmonary Disorders ¹				
				⊔ NO		
		Specify: Cardiac Disease ²	□ Yes			
		Specify: DVT or PE ¹				
		Specify: PPI/H2 blocker/Antacid use ²	□ Yes			
			⊔ res	⊔ NO		
		Specify: Autoimmune Disorders ²	□ Yes			
		Specify:				
		Cancer	□ Yes			
		Specify: Current infection ¹				
		Specify:				
		High Blood Pressure	□ Yes			
		High Cholesterol	□ Yes	□ No		
		Kidney Disease ²	□ Yes	□ No		
		Anemia ^{1, 2}	□ Yes	□ No		
		Current TB Treatment ²		□ No		
		Diabetes Specify Type 1 or 2		□ No		
Allergies:		HIV or AIDS ¹	□ Yes	□ No		
		Seizure Disorder ²	□ Yes			
		Depression/Anxiety				
		Other Psychiatric Conditions				
Labs Prior to Trea	tment:	Specify:		.		
	: □ Pregnancy test	Screen & Review: AUDIT-C	PHO-	-9		
miniculately prior	☐ Uric Acid (ribavirin only)	Vaccine Status (give if needed):				
Within 1 month:	□ CBC with differential	Hepatitis A (If unknown, che	eck hep A	total IgG)		
Within I month.	☐ CMP (If GFR <30, do not start tx ¹)	Hepatitis B (If unknown, che	•			
	□ PT/INR	Other vaccines as appropr	iate:			
	□ HCV RNA	Flu (annually)				
Within 3 months:	☐ Genotype confirmation	□ PCV-13 (≥ age 65 or ir	nmunosup	pressed)		
	☐ HBV DNA (if HBV cAb or sAg +)	□ PPSV-23 (≥ age 50 AN				
Within 6 months:		□ Td (once every 10 ye	ears) or T	dap (once)		
	□ TSH	□ Zoster (≥ age 60)		,		
	☐ A1C or Fasting Glucose	☐ ECG (over age 65 or h/o cardi	ac diseas	e)		
	□ Vitamin D 250H	Birth Control: Birth Control Methods:				
Within 1 year:	□ HIV screening	Females: LMP: Pregr		s 🗆 No		
, 22	□ NS5A RAV (genotype 3 only)	Males: Is your partner pregnan	t? □ Ye	es 🗆 No		
Once:	☐ IL-28b (if considering 8 weeks)	□ Counsel about pregnancy pr	evention	(see		
	(2 2 2 2 3 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Treatment Agreement)				
		□ Hepatitis C Treatment Agree	ment rev	viewed 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.



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:

<u>Why do treatment now?</u> 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 <u>or</u> 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:

months). This ultrasound checks your liver for cancer.

If yo	ou have cirrhosi	is, you may	y need an	EGD	(when	a docto	or loo	ks into	your	esop	hagu	JS
and stomac	h for swollen ve	eins that ca	ın bleed).									
If yo	ou have cirrhos	is, you nee	ed to have	e an	ultrasou	nd of	the liv	ver (do	ne in	the	past	6

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

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Prior to Treatment			
Labs			
Immediately prior:	Pregnancy test (if applicable) Uric Acid (with ribavirin)	Miscellaneous Henatitis	: A (If vaccine status is
Within 1 month:	CBC with differential	 '	wn, draw HAV total)
Within I month.	CMP ¹		B (If vaccine status is
			-
	PT/INR		wn, draw HBsAg & HBsAb)
	HCV RNA	PHQ-9 bas	seline
Within 3 months:	Genotype confirmation	AUDIT-C	
	HBV DNA (if HBV cAb or sAg +)		bout pregnancy prevention
Within 6 months:	AFP	Review &	sign Treatment Agreement
	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)		
Office.	IL-28b (II considering 8 weeks)		
8 week	12 week	16 week	24 week
Week 4	Week 2 (with ribavirin)	Week 2 (with ribavirin)	Week 2 (with ribavirin)
HCV RNA	CBC	CBC	CBC
CBC ₁	$\underline{\hspace{1cm}}$ CMP ¹	CMP ¹	CMP ¹
CMP ¹			
Pregnancy test	Week 4	Week 4	Week 4
Week 8	HCV RNA	HCV RNA	HCV RNA
HCV RNA	CBC CMP ¹	CBC CMP ¹	CBC CMP ¹
CBC	CiviP Pregnancy test	Pregnancy test	Pregnancy test
CMP ¹	regnancy test	regrandy test	regnutey test
Pregnancy test	Week 8	Weeks 8 & 12	Weeks 8, 12, 16, & 20
	CBC	CBC	CBC
	CMP ¹	CMP ¹	CMP ¹
	Pregnancy test	Pregnancy test	Pregnancy test
	Week 12	Week 16	Week 24
	HCV RNA	HCV RNA	HCV RNA
	CBC	CBC	CBC
	CMP ¹	CMP ¹	CMP ¹
	Pregnancy test	Pregnancy test	Pregnancy test
Nurse follow-up in clinic	or by phone:		
Managing side effects			
Medication adherence			
Alcohol intake			
Birth control reminde	er		
Refill reminder	3 months post tre	atment 6 months	post treatment
	CBC		HCV RNA
	Liver Funct		AFP
	HCV RNA		RUQ US (if advanced fibrosis)
	AUDIT-C		AUDIT-C
	I AUDII-C	<i>F</i>	10DII-C

^{1- &}lt;u>Sofosbuvir- or daclatasvir-based regimen</u> - If GFR <30, no safe recommendation. <u>With ribavirin</u> - If GFR <50, decrease dose (refer to package insert).

Daklinza™	(Daclatasvir)) & Sovaldi® (Sofosbuvir) Treatment	Agreement
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amily 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:

Daclat	casvir 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.
Daclat	tasvir 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

<u>Daclatasvir</u> 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[®], Epitol[®], Equetro[®],
 Tegretol[®])

Tell your healthcare provider if you are taking any of the following medicines, as they are <u>not</u> 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®)
- Saguinavir 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®)

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

- 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 <u>not</u> 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

Provider's Name (PLEA	SE PRINT)	Provider's Signature	 Date
Patient's Name (PLEAS	E PRINT)	Patient's Signature	Date
_		ead this treatment agreement ne. I agree to treatment.	t and/or the meaning of
razors or nail clippers a	nd covering cuts to	o prevent blood exposure.	
I will protect my	self and others fro	m hepatitis C by not sharing no	eedles, toothbrushes,
do so, I will contact my	provider.		
I will do my best	t to take my medio	ations as prescribed by my pr	ovider. If I am unable to
it is in the best interest	of my health and	welfare.	
I understand tha	at my provider car	stop my treatment if the pro	vider feels that stopping
I understand tha	nt my hepatitis C m	ay not respond to treatment.	
provider or nurse know	right away.		
If I have any pro	blems with the m	edications or side effects that	bother me, I will let my
Not applica	able, I am surgicall	y sterile or post-menopausal.	
my treatment will be st	topped if I become	pregnant.	
As a female, I wil	l not get pregnant	or breastfeed while on treatm	ent. I understand that
treatment.			
required to evaluate m	y health and well-l	peing during treatment and the	e effectiveness of
I understand tha	it my treatment wi	II be stopped if I cannot attend	d appointments as
this ahead of time and	I will reschedule m	ny appointment.	
length of the treatment	t. If I am unable to	attend an appointment, I will	let my provider know
I am willing to vi	sit the clinic and se	ee a provider on a regular sche	edule for the entire
conditions (depression,	, history of suicide	attempts, bipolar disorder, or	psychosis).
blood pressure, diabet	es, high cholester	ol, rheumatoid arthritis, or dru	ug addiction), or psychiatri
I will tell my pro	ovider if I have an	y serious medical conditions (such as heart disease, high
•	ink alcohol or use	recreational drugs during the t	reatment.
responses:			

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) 24 week Lab Tracking Form

General Patient Information	Pre-Treatment Lab Results	Medication Regimen				
Name:	HCV RNA: PHQ-9: Genotype: HIV: TSH: AFP: Vit D 25OH: GFR*:	1- Daclatasvir 60mg daily 1 tablet daily. Consult Liver Disease Specialist prior to dose change.				
Phone #:	PT/INR: A1C/Glucose:	2- Sofosbuvir 400mg daily. 1 tablet daily. Do not change dose				
Treatment Start Date:						

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													
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.

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 <30 If GFR is <30, do not start treatment; consult with 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 <u>HCV RNA</u> 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