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

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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).

Viekira Pak™ (Ombitasvir/Paritaprevir/Ritonavir; Dasabuvir) or Viekira XR ™ (Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir) & 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.

The FDA approved ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets co-packaged (Viekira Pak™) and dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets (Viekira XR™) to be given with ribavirin for the treatment of hepatitis C genotype 1a without cirrhosis or with compensated cirrhosis (Child-Pugh Class A), including those with HCV/HIV co-infection, as well as genotype 1 liver transplant recipients with normal hepatic function and mild fibrosis.

Treatment with Viekira Pak™ or Viekira XR™ requires 6 scheduled visits over 6 months if your treatment course is 12 weeks and 9 scheduled visits over 9 months if your treatment course is 24 weeks.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Viekira Pak™ or Viekira XR™ will harm an unborn or breastfeeding baby. However, 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 are taking ribavirin and for 6 months after your last dose.

You must stop using ethinyl estradiol-containing medicines before you start treatment with Viekira Pak™ or Viekira XR™. If you use these medicines as a method of birth control you must use another method of birth control during treatment with Viekira Pak™ or Viekira XR™, and for about 2 weeks after finishing treatment with Viekira Pak™ or Viekira XR™.

<u>Acceptable</u> Birth Control Methods (must use 2):

Progestin only contraceptives (e.g. mini pill, Depo shot, Nexplanon™)

Male or female condom

Spermicides (creams, films, foams, gels, and/or suppositories)

Diaphragm or cervical cap

Intrauterine device (IUD), Today™ vaginal sponge

<u>Unacceptable</u> 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:

___ Viekira Pak™ or Viekira XR™ & ribavirin for 12 weeks for genotype 1a without cirrhosis

___ Viekira Pak™ or Viekira XR™ & ribavirin for 24 weeks for genotype 1a with compensated cirrhosis

Ribavirin dose is based on weight (1000 mg for persons less than or equal to 75 kg (165 lb.) and 1200 mg/day for those greater than 75 kg, divided and taken twice daily with food) except for those post liver transplant, see below.

Note: Viekira Pak™ and Viekira XR™ are contraindicated in persons with moderate to severe cirrhosis (Child-Pugh Class B or C).

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

Viekira Pak™ contains ombitasvir, paritaprevir, and ritonavir tablets and dasabuvir tablets co-packaged for oral use. Two pink tablets contain ombitasvir 12.5mg, paritaprevir 75mg and ritonavir 50mg and are taken at the same time daily (in the morning) with a meal. Two beige tablets contain dasabuvir 250 mg and one of them is taken twice daily (in the morning and evening) with a meal. Store the medication at room temperature.

If you miss a dose of the pink tablets, and it is less than 12 hours from the time you usually take your dose, take the missed dose with a meal as soon as possible. Take your next dose at your regular time the next day with a meal. If you miss a dose of the pink tablets more than 12 hours from the time you usually take your dose, do not take the missed dose. Take your next dose at your regular time the next day with a meal.

If you miss a dose of the beige tablet and it is less than 6 hours from the time you usually take your dose, take the dose with a meal as soon as possible. Then take your next dose at your regular time with a meal. If it is more than 6 hours since you missed your dose, do not take the missed dose. Instead, take your next dose at your regular time with a meal.

Viekira XR™ contains dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets, for oral use. Three pale yellow-colored tablets contain dasabuvir 200mg, ombitasvir 8.33mg, paritaprevir 50mg, and ritonavir 33.33mg and are taken at the same time daily with a

meal. Taking the tablets in a fasting state could result in reduced cure and the development of resistance. Swallow the tablets whole and do not consume alcohol within 4 hours of taking Viekira XR. Do not skip or miss doses. Store the medication at or below 86°F.

Do not take more than the prescribed dose of Viekira Pak™ or Viekira XR™ (no doubling up).

Do not take Viekira Pak™ or Viekira XR™ if you have had a severe skin rash after taking ritonavir (Norvir®).

The most common side effects of Viekira Pak™ or Viekira XR™ are nausea, itching and sleep problems.

Tell your healthcare provider if you are taking any of the following medicines; as they are contraindicated with Viekira Pak™ or Viekira XR™:

- Alfuzosin hydrochloride (Uroxatral™)
- Colchicine (COLCRYS, Mitigare®)
- Carbamazepine (Carbatrol™, Epitol™, Equetro™, Tegretol™); Phenytoin (Dilantin™, Phenytek™); Phenobarbital (Luminal™); Primidone (Mysoline®)
- Dronedarone (Multaq®); Lurasidone (Latuda®)
- Efavirenz (Atripla™, Sustiva™)
- Ergot containing medicines including: ergotamine tartrate (Cafergot™, Ergomar™, Ergostat™, Medihaler™); dihydroergotamine mesylate (D.H.E. 45™, Migranal™); methylergonovine (Methergine®); ergonovine (Ergotrate®)
- Ethinyl estradiol-containing medications; combination birth control pills or patches, such as Lo Loestrin™ FE, Norinyl™, Ortho Tri-Cyclen Lo™, Ortho Evra™; hormonal vaginal rings such as NuvaRing®; hormonal replacement therapy medicine Fem HRT™.
- Gemfibrozil (Lopid™); Lovastatin (Advicor™, Altoprev™, Mevacor™); Simvastatin (Simcor™, Vytorin™, Zocor™)
- Midazolam, when taken by mouth; Triazolam (Halcion™)
- Pimozide (Orap™)
- Ranolazine (Ranexa®)
- Rifabutin (Mycobutin®); Rifampin (Rifadin™, Rifamate™, Rifater™, Rimactane™)

- Sildenafil citrate (Revatio™) when taken for pulmonary artery hypertension
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort

Tell your healthcare provider if you are taking any of the following medicines; as they are not recommended with Viekira Pak™ Viekira XR™:

- Darunavir (Prezista®) / ritonavir; lopinavir/ ritonavir (Kaletra®); rilpivirine (Edurant®, Complera®, Odefsey®)
- Salmeterol (Serevent, Advair®)

Tell your healthcare provider if you are taking any of the following medicines; as dosage adjustments or monitoring may be recommended:

- Amiodarone (Cordarone®, Nexterone®, Pacerone®); bepridil; disopyramide (Norpace®, Norpace CR®); flecainide (Tambocor™); systemic lidocaine (Xylocaine®); mexiletine; propafenone (Rythmol, Rythmol SR); quinidine (Nuedexta®)
- Valsartan (Diovan®, Exforge®, Entresto™); losartan (Cozaar®, Hyzaar®); candesartan (Atacand®)
- Amlodipine (Norvasc®); Nifedipine (Procardia®, Adalat®); Diltiazem (Cardizem®, Tiazac®); Verapamil (Covera-HS®, Calan®, Verelan®)
- Furosemide (Lasix®)
- Ketoconazole; Voriconazole (Vfend®)
- Fluticasone (Inhaled- Arnuity™ Ellipta®, Breo Ellipta®, Flovent®, Advair®; Nasal – Flonase®, Veramyst, Dymista®)
- Atazanavir (Reyataz®)/ ritonavir (when co-administered with Viekira Pak, atazanavir 300mg without ritonavir should only be given in the morning)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®); tacrolimus (Astagraf XL®, Envarsus XR™, FK506 (common name), Hecoria™, Prograf®)
- Buprenorphine/naloxone (Suboxone®)
- Omeprazole (Prilosec®, Prilosec OTC®) (avoid use of > 40mg daily)
- Alprazolam (Xanax®)
- Quetiapine (Seroquel®)

- Rosuvastatin (Crestor®) dose not to exceed 10mg daily; pravastatin (Pravachol®) dose not to exceed 40mg daily

Ribavirin is a 200mg capsule or tablet. You will take ribavirin pills twice daily by mouth with food (dose is based on your weight, except for those who have had a liver transplant). 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.

The most common side effects of Viekira Pak™ or Viekira XR™ when given with ribavirin are tiredness, nausea, itching, skin reactions such as redness or rash, sleep problems, and feeling weak.

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Viekira Pak™ or Viekira XR™ & 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 Clinical Trials:

Persons with genotype 1a who did not have cirrhosis were treated with Viekira Pak™ (the components of Viekira XR™) and ribavirin for 12 weeks and had a 94% or better response (cure) rate.

Those with genotype 1a with compensated cirrhosis treated with Viekira Pak™ and ribavirin for 24 weeks had a 95% response rate.

Liver transplant recipients who were 12 months or longer after transplant and had normal liver function and mild fibrosis were given Viekira Pak™ (the components of Viekira XR™) and ribavirin for 24 weeks. Of 34 subjects, 97% (28/29) of those who were genotype 1a and 100% (5/5) of those who were genotype 1b responded.

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 2).

_____ 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**

Viekira Pak™ (Ombitasvir/Paritaprevir/Ritonavir & Dasabuvir) & Ribavirin or Viekira XR™ (Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir) & Ribavirin Treatment Medications

You will be taking the following medications:

1. _____ You will take **Viekira Pak™**
   Take 2 pink tablets and 1 beige tablet in the morning with a meal. Take 1 beige tablet in the evening with a meal.
   The generic name for Viekira Pak™ is ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets, co-packaged for oral use.
   Two pink tablets contain ombitasvir 12.5 mg, paritaprevir 75 mg, and ritonavir 50 mg. The two pink tablets are taken at the same time daily (in the morning) with a meal.
   The beige tablets contain dasabuvir 250 mg. Take one beige tablet twice daily (in the morning and evening) with a meal.
   _____ You will take **Viekira XR™**.
   Take 3 pale yellow-colored tablets each morning with a meal.
   The generic name for Viekira XR™ is dasabuvir, ombitasvir, paritaprevir, and ritonavir extended release tablets for oral use.
   These tablets contain dasabuvir 200mg, ombitasvir 8.33mg, paritaprevir 50mg, and ritonavir 33.33mg.

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 _____ from _____.
You get _____ from _____.

Pick up refills on: _____
_____

Call _____ to schedule your family medicine 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"

Viekira Pak™ or Viekira XR™ & Ribavirin 12 week Lab Tracking Form

General Patient Information

Name: _____

DOB: _____/_____/_____

MRN: _____

Phone #: _____

Treatment Start Date: _____

Pre-Treatment Lab Results

HCV RNA: _____

Genotype: _____ HIV: ____ TSH: ____

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

PT/INR: _____ A1C/Glucose: _____

Uric Acid:_____

Medication Regimen

1 -Viekira Pak™ Do not change dose.

2 pink tablets of ombitasvir, paritaprevir, ritonavir with breakfast.

1 beige tablet of dasabuvir with breakfast and 1 with dinner.

-Viekira XR™ Do not change dose.

3 yellow tablets of dasabuvir, ombitasvir, paritaprevir, ritonavir with a meal.

2- Ribavirin: _____ mg/day PO divided into 2 doses. Take with breakfast & dinner.

≥75kg = 1200mg/day <75kg = 1000mg/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	PHQ-9 (Specified weeks)	HCV RNA (Specified weeks)	Weight (kg)	Pregnancy Test
Pre-Treatment														
Treatment Start Week 0											PHQ-9	HCV RNA		
optional														
Week 2														
optional														
Week 4												HCV RNA		
optional														
optional														
Week 8														
optional														
optional														
Week 12											PHQ-9	HCV RNA		
optional														
3 months post treatment											PHQ-9	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.

Hgb <10.0 gm/dL If hemoglobin drops below 10, reduce ribavirin dose to 600mg (refer to ribavirin package insert). **If hemoglobin <8.5, hold ribavirin & consult ANTHC Liver Disease Specialists.**

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

PLTs <50 K/uL If platelet count drops below 50, 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