Viekira Pak™ (Ombitasvir/Paritaprevir/Ritonavir; Dasabuvir) or Viekira XR ™ (Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir) Treatment Agreement

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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™) for the treatment of hepatitis C genotype 1b, including those with HCV/HIV co-infection.

Treatment with Viekira Pak™ requires 6 scheduled visits over 6 months for a treatment course of 12 weeks.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Viekira Pak™ or Viekira XR™ will harm an unborn or breastfeeding baby, so it is recommended that women do not get pregnant or breastfeed while taking this medicine.

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™. Progestin only contraceptives (e.g. mini pill, Depo shot, Nexplanon™) are safe to use during treatment with Viekira Pak™ or Viekira XR™.

HOW THE TREATMENT PROCESS WORKS

You will have blood and urine tests.

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

Liver Clinic Provider, choose appropriate treatment regimen:

Viekira Pak™ or Viekira XR™ will be given for 12 weeks if:

____ You have genotype 1b and do not have cirrhosis.

____ You have genotype 1b and have mild cirrhosis. (Contraindicated in persons with moderate to severe cirrhosis)

Your first visit will be at the start of treatment (week 0) and then visits will be once each month until you stop taking the medications.

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

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

TREATMENT MEDICATIONS AND SIDE EFFECTS

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 250mg 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™)
- Rifampin (Rifadin™, Rifamate™, Rifater™, Rimactane™)
- Ranolazine (Ranexa®)
- 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 <u>not recommended with Viekira Pak™ or Viekira XR™</u>:

- 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 <u>dosage adjustments or monitoring may be recommended</u>:

- 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
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®); tacrolimus (Astagraf XL®, Envarsus XR™, FK506 (common name), Hecoria™, Prograf®)
- Buprenorphine/naloxone (Suboxone®)
- Omeprazole (Prilosec®, Prilosec OTC®)
- Alprazolam (Xanax®)
- Quetiapine (Seroquel®)
- Rosuvastatin (Crestor®); pravastatin (Pravachol®)

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Viekira Pak™ or Viekira XR™ prior to starting any new medications. You must let Liver Clinic 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 1b, without cirrhosis who were treatment-naïve (never treated before) or treatment-experienced (prior treatment failed), given Viekira Pak™ (the components of Viekira XR™) for 12 weeks had a 100% response (cure) rate. Those with compensated (Child Pugh A) cirrhosis who were either treatment naïve or had prior treatment experience had a 100% response rate.

WHOM TO CALL

If you have any questions about your treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or 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 taking Viekira Pak™ or Viekira XR™, 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**