Olysio® (Simeprevir) & Sovaldi® (Sofosbuvir) 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 has approved simeprevir (Olysio®) plus sofosbuvir (Sovaldi®) for the treatment of hepatitis C genotype 1 without HIV co-infection.

Treatment with simeprevir plus sofosbuvir requires approximately 5 scheduled visits over 6 months.

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.

Liver Clinic Provider, select the appropriate rationale for treatment course of simeprevir plus sofosbuvir for 12 weeks:

___ You have genotype 1 hepatitis C without cirrhosis and have never been treated before.

___ You have genotype 1 hepatitis C without cirrhosis and previous treatment with pegylated interferon and ribavirin failed.

Your first visit will be at the start of treatment (week 0) and then 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

Simeprevir is a 150mg capsule. You will take simeprevir once daily by mouth with food. Store at room temperature. If you miss a dose and it is more than 12 hours until your next dose, take the missed dose as soon as possible with food. If you miss a dose of simeprevir and it is less than 12 hours until your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses of simeprevir to make up for a missed dose.

- Most common side effects are feeling tired, headache, and nausea.

Tell your healthcare provider if you take any of the following medicines, as they are not recommended to be used with simeprevir (this list is not all inclusive, medicines that are moderate or strong inducers or inhibitors of CYP3A are not recommended):

- Amiodarone (Cordarone®, Nexterone®, Pacerone®)
- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®); Oxycarbazepine (Oxtellar XR®, Trileptal®); Phenobarbital (Luminal®); Primidone (Mysoline®); Phenytoin (Dilantin®, Phenytek®)
- Cisapride (Propulsid®, Propulsid Quicksolv®)
- Cobicistat-containing medicines (Stribild®, Evotaz™, Prezcobix®, Genvoya®, Tybost®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)
- Atazanavir (Reyataz®); Darunavir (Prezista®); Indinavir (Crixivan®); Lopinavir/ritonavir (Kaletra®); Nelfinavir (Viracept®); Ritonavir (Norvir®); Saquinavir mesylate (Invirase®); Tipranavir (Aptivus®)

- Delavirdine mesylate (Rescriptor®); Efavirenz (Sustiva®, Atripla®); Etravirine (Intelence®); Nevirapine (Viramune®, Viramune XR®)
- Fosamprenavir (Lexiva®)
- Milk thistle (Silybum marianum) or products containing milk thistle
- Rifabutin (Mycobutin®); Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®); Rifapentine (Priftin®)
- St. John's wort (Hypericum perforatum) or products containing St. John's wort

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

- Digoxin (Lanoxin®)
- Rosuvastatin (Crestor®); Atorvastatin (Lipitor®, Caduet®); Simvastatin (Zocor®, Vytorin®, Simcor®); Pitavastatin (Livalo®); Pravastatin (Pravachol®); Lovastatin (Advicor®, Altoprev®, Mevacor®)
- Sirolimus (Rapamune®)
- Sildenafil (Revatio®, Viagra®); Tadalafil (Adcirca®, Cialis®); Vardenafil (Levitra®)

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

- Dexamethasone (Ozurdex®, Baycadron™)
- Clarithromycin (Biaxin®, Prevpac®); Telithromycin (Ketek®)
- Erythromycin (E.E.S. ®, Eryc®, Ery-Tab®, Erythrocin®, Erythrocin Stearate®)
- Itraconazole (Sporanox®, Onmel®); Ketoconazole; Posaconazole (Noxafil®); Fluconazole (Diflucan®); Voriconazole (Vfend®)

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

- Disopyramide (Norpace®); Flecainide (Tambocor®); Mexiletine; Propafenone (Rythmol SR®); Quinidine (Nuedexta®, Duraquin®, Quinaglute®)

- Amlodipine (Norvasc®); Diltiazem (Cardizem®), Dilacor XR®, Tiazac®); Felodipine (Plendil®); Nicardipine (Cardene®); Nifedipine (Adalat CC®, Afeditab CR®, Procardia®); Nisoldipine (Sular®); Verapamil (Calan®, Covera-HS®, Isoptin®, Tarka®)
- Midazolam
- Triazolam (Halcion®)

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, nausea, trouble sleeping, and itching.

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®); Oxycarbazepine (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 sofosbuvir and ribavirin 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 Studies:

Persons with genotype 1 without cirrhosis who were treated with simeprevir and sofosbuvir for 12 weeks had a 95% response rate. Those who were previously treated with pegylated interferon and ribavirin were treated with simeprevir and sofosbuvir for 12 weeks and had a 95% 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, I understand that I cannot be pregnant or breastfeeding during the 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**