Daklinza™ (Daclatasvir) & 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.

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.

Liver Clinic 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 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

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®, Epitol®, 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 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 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 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 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**