

Zepatier™ (Elbasvir/Grazoprevir) 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 January 2016 the FDA approved elbasvir combined with grazoprevir in one tablet (Zepatier™) for the treatment of hepatitis C genotype 1 and 4.

Treatment with Zepatier™ requires 5 scheduled visits over 6 months for a treatment course of 12 weeks.

PREGNANCY & BREASTFEEDING WARNING

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

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, select the appropriate treatment regimen and reason:

_____ Zepatier™ will be given for 12 weeks if:

- You have genotype 1a and do not have baseline NS5A polymorphisms (mutations in the hepatitis C virus that can decrease response to treatment).
- You have genotype 1b.
- You have genotype 4 without or with compensated (mild) cirrhosis.

- You have genotype 4 without or with compensated (mild) cirrhosis and relapsed after treatment with pegylated interferon and ribavirin.

Your first visit will be at the start of treatment. After that, the visits will be once each month until you stop taking the medications.

You may need to come into 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 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

Zepatier™ is a fixed-dose combination tablet containing elbasvir 50mg and grazoprevir 100mg. You will take Zepatier™ once daily by mouth with or without food. Store the medication at room temperature. If you miss a dose, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of Zepatier™ in a day. Take your next dose at your regular time the next day.

- The most common side effects are ALT (a liver enzyme) elevation, tiredness, nausea, and headache.

Tell your healthcare provider if you are taking any of the following medicines, as they are contraindicated with Zepatier™ (this list is not all inclusive; medications that are OATP1B1/3 inhibitors or strong CYP3A inducers are contraindicated):

- Phenytoin (Dilantin®), (Phenytek®)
- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol® XR)
- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort
- Efavirenz (ATRIPLA®, Sustiva®); Tipranavir (Aptivus®); Atazanavir (Reyataz®, Evotaz™); Darunavir (Prezista®, PrezcoBix®); Lopinavir (Kaletra®); Saquinavir (Invirase®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Zepatier™ (this list is not all inclusive; medications that are moderate CYP3A inducers are not recommended):

- Nafcillin
- Ketoconazole
- Bosentan (Tracleer®)
- Modafinil (Provigil®)
- Cobicistat containing regimens: elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate or alafenamide (Stribild®, Genvoya®)
- Etravirine (Intelence®)

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

- Tacrolimus (Astagraf XL®, Envarsus XR™, FK506 (common name), Hecoria™, Prograf®)
- Cholesterol lowering medications: atorvastatin (Lipitor®), rosuvastatin (Crestor®), fluvastatin (Lescol®), lovastatin (Mevacor®, Altoprev®), simvastatin (Zocor®)

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Zepatier™ 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/Studies:

Persons with genotype 1a who did not have pretreatment NS5A polymorphisms and those with genotype 1b who were treated with Zepatier™ for 12 weeks had a 98% response (cure) rate. Response rates in persons with mild cirrhosis were similar to those without cirrhosis.

Persons with severe renal disease treated with Zepatier™ for 12 weeks had an overall 94% response rate. Those with compensated (mild) cirrhosis had an 86% response rate.

Persons with genotype 4 who took Zepatier™ for 12 weeks had a 97% response rate.

Persons with genotype 4 who relapsed after pegylated interferon and ribavirin treatment were treated with Zepatier for 12 weeks and had a 100% (2/2) response.

WHOM TO CALL

If you have any questions about 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 Zepatier™ 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