

## **HEPATITIS C TREATMENT AGREEMENT**

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**Primary Care 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 combination of peginterferon and ribavirin is approved by the U.S. Food and Drug Administration for the treatment of hepatitis C, all genotypes. The U.S. Food and Drug Administration recently approved (2011) boceprevir and telaprevir, in combination with peginterferon and ribavirin for the treatment of hepatitis C, genotype 1 only.

The entire treatment may require up to 19 scheduled visits over an 18-month period if you have genotype 1. If you have genotype 2 or 3, there are approximately 13 scheduled visits over 12 months.

### **PREGNANCY WARNING**

This treatment can harm an unborn child or breastfeeding infant.

#### **Acceptable Birth Control Methods during Treatment**

Use 2 of the following methods:

- Male or female condom with spermicidal jelly
- Diaphragm with spermicidal jelly
- Cervical cap with spermicidal jelly
- An intrauterine device (IUD)

#### **Unacceptable Birth Control**

Birth control pills are not considered reliable during treatment and up to two weeks after boceprevir or telaprevir treatment is completed. You may continue to use them but you should use 2 other methods.

### **HOW THE TREATMENT WORKS**

You will be asked to give a medical history and have a complete medical examination; including but not limited to an eye examination, an ECG (a tracing by machine that shows how well your heart is working) if you are a man over the age of 40 or a woman over the age of 50, and/or a cardiac stress test, if the provider thinks they are needed.

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You will have blood and urine tests. These tests will include a pregnancy test for female patients - a urine pregnancy test will be done at each clinic visit. Random drug and alcohol tests may be requested.

You will be given information about the role of liver biopsy in hepatitis C. If you have genotype 1 hepatitis C, a liver biopsy is recommended prior to treatment.

If you have a history of depression or other psychiatric conditions, you should see a mental health provider before hepatitis C treatment consideration.

You will receive peginterferon and ribavirin for 24 weeks if you have genotype 2 or 3. You will take peginterferon, ribavirin and either boceprevir or telaprevir if you have genotype 1. The length of time for treatment of genotype 1 will be determined by a liver clinic provider based on how much scarring your liver has, whether you have had previous hepatitis C treatment, and your response to treatment. You will have follow-up 6 months and 1 year after treatment. Peginterferon will be given once a week by injection (a shot). You or a family member will be taught how to give the shots. You must take ribavirin by mouth two times each day with food. You must take telaprevir or boceprevir three times each day with food (genotype 1 only).

The first four visits will be at the start of treatment and at 1, 2, and 4 weeks after you begin to take the medicines. After that, the visits will be once each month until you stop taking the medicines. **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.**

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.

## **TREATMENT MEDICATIONS AND SIDE EFFECTS**

**Peginterferon** is given with a short needle just under the skin of the abdomen. You may have pain and redness where the needle goes into the skin.

- Most common side effects are flu-like symptoms - fever, feeling tired, chills, nausea, headache and poor appetite. These happen in almost all persons with the first 1 to 3 doses of peginterferon. After that they may go away or lessen; but sometimes these symptoms continue throughout the treatment course. Your white blood count and/or blood platelet count may go down while you are taking peginterferon (white blood cells help protect the body from infections and platelets help your blood clot). You may also get a skin rash.
- Less common side effects are diarrhea, vomiting, temporary hair loss, nervousness, dizziness, confusion and depression. Severe depression and, more rarely, suicide have been reported in patients treated with peginterferon. Some people have had lung problems, pneumonia and liver problems; some people have died from these illnesses. Other side effects that can occur are numbness or tingling in your hands and feet, bleeding in parts of your eye, and irregular heart beat. A rarely reported side effect from peginterferon is visual loss.

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- If at any time during treatment you have a change/loss of vision, stop treatment immediately and call your primary care provider.
- It is not known whether peginterferon can cause harm to a pregnant woman and/or the unborn child, or whether it can affect the ability of a woman to become pregnant or a man to father a child.
- A small percentage of patients treated with peginterferon have developed thyroid problems (either an overactive or underactive thyroid) which have required treatment. These types of thyroid problems can be controlled with medicines but treatment may have to be lifelong.

**Ribavirin** – Comes in a 200mg capsule. You must take 2 to 4 ribavirin capsules (based on your weight) twice daily with food. You should not miss any pills. The most common side effect is anemia. Anemia is a condition where the blood has a decreased number of red blood cells. This is seen more often in older persons taking ribavirin. The 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), this anemia may make the problem worse, leading to chest pain or, rarely, heart attack. If your doctor believes you may have coronary artery disease, you will be tested for this and excluded from treatment if it is serious.

- Other side effects that are common in people taking ribavirin include:
  - itching
  - cough
  - muscle pain
  - swelling and pain in your joints (gout)
- Effects on the nervous system may include:
  - depression (may be severe)
  - nervousness
  - difficulty sleeping
  - dizziness
- Studies in animals have clearly shown that 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.

**Telaprevir** – Comes in a 325mg tablet. You must take 2 telaprevir tablets three times each day. The pills should be taken 7 to 9 hours apart with fatty food (approximately 20 grams of fat each time; we will give you examples of this). You should not miss any pills. Telaprevir is taken for 12 weeks. The most common side effects of telaprevir are rash (56%), and fatigue (56%). Other common side effects that occur in over 20% of patients include: itching (47%), nausea (39%), anemia (36%), and diarrhea (26%).

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There is a risk of severe skin reactions in persons taking telaprevir along with peginterferon and ribavirin. The presenting signs of a severe reaction include: rash, fever, facial swelling, blistering and loss of skin, and kidney and liver problems. If a severe reaction occurs, all treatment must be discontinued immediately.

**Boceprevir** – Comes in a 200mg capsule. You must take 4 boceprevir capsules three times each day with food, 7 to 9 hours apart. You should not miss any pills. Boceprevir will not be started until you have had 4 weeks of peginterferon and ribavirin. You will take boceprevir for 24 to 44 weeks total, depending on your response to treatment and the amount of scarring there is in your liver.

The most common side effects of boceprevir are fatigue (58%), anemia (50%), nausea (46%), and a bad taste in your mouth (35%). Other common side effects that occur in over 20% of patients include: chills (34%), difficulty sleeping (34%), hair loss (27%), diarrhea (25%), low white blood cell count (25%), decreased appetite (25%), irritability (22%) and vomiting (20%).

### **PLEASE NOTE:**

Telaprevir and boceprevir have many interactions with other medications, including statins (for cholesterol), rifampin (for infections), anti-seizure medications, birth control pills, ergots (for headaches), St. John's wort (for mood/depression), and certain heart medications, as well as many others. You must let your medical, mental health and dental providers and pharmacist(s) know that you are on treatment medications 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. If you have pain and feel that you need narcotic pain medications, you will need to see your primary care provider. Prescribing of narcotic pain medications will be left up to your primary care provider's discretion.

### **BENEFITS OF TREATMENT**

Your hepatitis C may respond well to treatment, as determined by a blood test which measures the presence and amount of hepatitis C in the blood. If you have no hepatitis C in your blood 24 weeks **after** the end of treatment, this is considered a "sustained virologic response" and, in 99% of persons is a cure. Your chance of achieving a sustained virologic response depends on genotype, how much hepatitis C virus you have in your blood at the beginning of treatment, and how much liver damage you have had prior to treatment.

Persons with genotype 1 who are treated with either boceprevir or telaprevir and peginterferon/ribavirin have a 67-72% chance of achieving a sustained virologic response. Persons with genotype 1 who are treated with peginterferon/ribavirin alone have only a 40-50% chance of sustained virologic response. Persons with genotypes 2 and 3 have a 70-80% chance of achieving a sustained virologic response from peginterferon/ribavirin. The response rates are much lower in persons with cirrhosis and those who did not respond previously to treatment.

## **HEPATITIS C TREATMENT AGREEMENT**

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.

### **WHOM TO CALL**

If you have any questions about your treatment, contact the Liver Disease & Hepatitis Program @ 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 during the treatment.

\_\_\_\_\_ I have not abused alcohol or other substances (intravenous drugs, cocaine, prescription pain medications) within the last 6 months.

\_\_\_\_\_ 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). Failure to tell my provider about my medical and psychiatric conditions can have life-threatening consequences during this treatment.

\_\_\_\_\_ I am willing to visit the clinic and see a provider on a regular schedule for the whole time of the treatment. If I am unable to attend an appointment, I will let the Liver Clinic 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 effective methods of birth control (see list below) during treatment. I will continue birth control during the whole time I am being treated and for 6 months after I stop treatment.

\_\_\_\_\_ 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, I understand that I should not father a child during treatment and for 6 months after treatment. I understand that I need to use 2 methods of birth control (see list below) because this treatment can cause harm to a baby that I father during treatment and up to 6 months after treatment.

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\_\_\_\_\_ 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 will need to stop my treatment if the hepatitis C virus level (HCV RNA) does not drop adequately to meet the criteria for continuing treatment as identified in the medication guidelines.

\_\_\_\_\_ 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.

**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 pursue the treatment.**

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**Patient's Name (PLEASE PRINT)**

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**Patient's Signature**

**Date**

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**Provider's Signature/Title**

**Date**