

Liver Disease & Hepatitis Program 4315 Diplomacy Drive, Anchorage, AK 99508 Phone: 907-729-1560 Fax: 907-729-1570

Website: http://www.anthctoday.org/community/hep/index.html

We are glad to hear you are interested in treatment for hepatitis C!

Here are some things to think about (and do) before you make your final decision about treatment:

<u>Why do treatment now?</u> New medicines have increased the chance of cure and have fewer side effects.

<u>Why would I wait?</u> Within 1-2 years additional new medicines will be available. They may work even better, shorten treatment time, cost less, and have fewer side effects.

Some people have worse liver disease than others. If you have more severe liver disease (a lot of scarring in the liver or cirrhosis) you should consider getting treatment sooner.

What will happen during treatment?

There are 2 medication options for genotype 1:

- Option 1 is Harvoni[®] (ledipasvir/sofosbuvir), 1 tablet taken once a day by mouth. Treatment length is 12 weeks for most patients. 24 weeks of treatment is required for some persons with decompensated (significant) cirrhosis AND persons with cirrhosis who had previous treatment that failed. The major side effects (experienced in ≥ 10% of clinical trial subjects) include feeling tired and headache. In clinical studies, treatment response rates for Harvoni[®] were 94-100%.
- Option 2 is Viekira Pak® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) co-packaged as 3 tablets in the morning and 1 tablet in the evening with food. Most treatments with Viekira Pak® also require ribavirin, which is 5-6 additional tablets divided between morning and evening with food. Treatment length is 12 to 24 weeks depending on genotype subtype and cirrhosis status. The major side effects include feeling tired, nausea, itching and skin rash, trouble sleeping and weakness. A common side effect of ribavirin is anemia. In clinical studies, treatment response rates for Viekira Pak® and Viekira Pak®/ribavirin were 86-100%.

Genotype 2 and 3 treatment is Sovaldi® (sofosbuvir), which is 1 tablet once a day and 5-6 ribavirin capsules divided between morning and evening with food. Treatment length is 12 weeks for genotype 2 and 24 weeks for genotype 3. The major side effects include feeling tired, headache, nausea, insomnia, weakness, itching, diarrhea, and irritability. A common side effect of ribavirin is anemia. In clinical studies, treatment response rates for Sovaldi®/ribavirin were 82-100% in genotype 2 and 60% -93% in genotype 3.

 Another Genotype 3 treatment option for those who can take peginterferon, is 12 weeks of Sovaldi® (sofosbuvir) plus ribavirin (6-7 pills/day), and a weekly peginterferon injection can be given. In addition to the side effects occurring with Sovaldi®/ribavirin treatment additional side effects include flu-like symptoms, depression and body aches, and side effects that may show up only in blood tests. In a clinical study, this treatment resulted in a treatment response rate of 83%.

PLEASE NOTE: No treatments containing ribavirin can be given to a pregnant or breastfeeding female or to a female who plans to become pregnant or a male who plans to father a child during treatment and for 6 months after treatment because this treatment can cause birth defects. There are no studies on ledipasvir or sofosbuvir (Harvoni® or Sovaldi®) in pregnant women or nursing mothers. Safety/risk during pregnancy or breastfeeding has not been established.

Are you ready for treatment?

There are several requirements for hepatitis C treatment. These requirements are to ensure that you are going to be successful in completing treatment, and to protect your physical and mental health. The following items must be done before you can start treatment. We will review them together.

- You must be alcohol and drug-free for at least 6 months before you can start treatment.
- You need to discuss hepatitis C treatment with your primary care provider and get his or her "OK" to start treatment. Your family medicine provider can help you with non-liver related health problems during and after treatment.
- You should have a relative or close friend who is willing to help support you during treatment. The person you choose should come with you to the pre-treatment appointment.
- You need to be committed to making every treatment appointment and getting FREQUENT blood draws (every 1-4 weeks). We will want to follow you very closely during treatment.

Additional Requirements If Checked:

| If you have cirrhosis, you may need an EGD (when a doctor looks into your esophagus |
|---|
| and stomach for swollen veins that can bleed). This requires sedation and is done as a Day |
| Surgery procedure. Your primary care provider will make this referral if needed. |
| If you have cirrhosis, you need to have an ultrasound of the liver (done in the past 6 months). This ultrasound checks your liver for cancer. |
| Other: |
| Other: |
| Once everything you need to do on the list has been done, call your primary care provider to |

once everything you need to do on the list has been done, call your primary care provider to make an appointment to plan for hepatitis C treatment. At this appointment, treatment and side effects will be discussed in detail.

Please bring your support person with you to this appointment.

Congratulations on completing all the pre-treatment requirements!

Hepatitis C Health Summary

| | | Pertinent Medical History: | | | | | |
|----------------------------|---------------------------------------|---|------------|-----------------|--|--|--|
| Name: | | Previous hepatitis C treatment | ¹ □ Yes | □ No | | | |
| DOB: | | Specify: | | | | | |
| | | Cirrhosis ¹ | □ Yes | □ No | | | |
| Phone #: | | Child-Pugh Score: | | | | | |
| | :: | Other Liver Disease ¹ | □ Yes | □ No | | | |
| Alternate Contact | | Specify: | | | | | |
| Medications ² : | | Pulmonary Disorders ¹ | □ Yes | □ No | | | |
| Wicalcations . | | Specify: | | | | | |
| | | Cardiac Disease ² | □ Yes | □ No | | | |
| | | Specify: | | | | | |
| | | DVT or PE ¹ | □ Yes | | | | |
| | | Specify: | | | | | |
| | | Thyroid disease ² | □ Yes | | | | |
| | | , Specify: | | | | | |
| | | Autoimmune Disorders ² | □ Yes | | | | |
| | | Specify: | | | | | |
| | | Cancer | □ Yes | □ No | | | |
| | | Specify: | | | | | |
| | | Visual Impairment ³ | □ Yes | | | | |
| | | Specify: | | | | | |
| | | Current infection ¹ | □ Yes | | | | |
| | | Specify: | ⊔ res | | | | |
| | | High Blood Pressure ³ | □ Yes | | | | |
| | | High Cholesterol ³ | □ Yes | | | | |
| | | Kidney Disease ² | | | | | |
| | | Anemia ^{1, 2} | □ Yes | _ | | | |
| | | | □ Yes | □ No | | | |
| | | Current TB Treatment ² | □ Yes | □ No | | | |
| | | Diabetes ³ Specify Type 1 or 2 | | | | | |
| | | HIV or AIDS ¹ | □ Yes | □ No | | | |
| | | Seizure Disorder ² | □ Yes | | | | |
| Allergies: | | Depression/Anxiety ⁴ | □ Yes | | | | |
| | | Other Psychiatric Conditions ⁴ | □ Yes | □ No | | | |
| | | Specify: | | | | | |
| | | Screen & Review: AUDIT-C | | | | | |
| Labs Prior to Trea | tmont: | Vaccine Status: Hepatitis A | | itis B | | | |
| | | Other vaccines as appropri | ate: | | | | |
| illillediately prior | : Pregnancy test | □ Flu (annually) | | | | | |
| \\/;+h:n 1 magneth. | ☐ Uric Acid (ribavirin only) | □ PCV-13 (≥ age 65 or im | - | - | | | |
| Within 1 month: | ☐ CBC with differential | □ PPSV-23 (≥ age 50 AN/AI in AK or high risk) | | | | | |
| | ☐ CMP (If GFR <30, do not start tx ¹) | = 10 (0.000 0.00) = 7 | | | | | |
| | □ PT/INR | □ Zoster (≥ age 60) | _ | | | | |
| Within 3 months: | | □ ECG (over age 65 or h/o cardia | | - | | | |
| | ☐ Genotype confirmation | ☐ Stress Test (h/o cardiac disease, p | rior to *P | EG or ribavirin | | | |
| Within 6 months: | | Birth Control: | | | | | |
| | □ TSH | Females: LMP: Pregn | ant □ Ye | s □ No | | | |
| | ☐ A1C or Fasting Glucose | Birth Control Methods: | | | | | |
| | □ Vitamin D 250H | Males: Is your partner pregnant | | | | | |
| Within 1 year: | ☐ HIV screening | Birth Control Methods: | | | | | |

- 1- Consult Liver Disease Specialist
- 2- Check contraindications to treatment drugs. Further evaluation as indicated.
- 3- If treatment includes peginterferon complete dilated retinal exam if patient has HTN, HLD, DM, or h/o retinal disease.
- 4- If treatment includes peginterferon complete Mental Health Evaluation & Clearance if h/o depression or other psychiatric conditions.

Hepatitis C Pre-Treatment Checklist

Before Treatment Starts:

| • Labs: | |
|---------------------------------------|--|
| Immediately prior: | □ Pregnancy test |
| | ☐ Uric Acid (with ribavirin) |
| Within 1 month: | ☐ Complete Blood Count with differential |
| | □ Comprehensive Metabolic Panel |
| | (If GFR <30, do not start treatment; consult Liver Disease Specialist) |
| | □ PT/INR |
| Within 3 months: | □ HCV RNA |
| M | □ Genotype confirmation |
| Within 6 months: | □ AFP |
| | □ TSH |
| | □ A1C or Fasting Glucose |
| MCILC. A | Ultramin D 250H |
| Within 1 year: | ☐ HIV screening |
| • Screen & Review: AUD | |
| = | & Alcohol Screen (at discretion of provider) |
| Vaccine Status/Screening | _ |
| • | nations are recommended for all persons with HCV |
| - | (If vaccine status is unknown, check hep A total IgG) |
| • | (If vaccine status is unknown, check HBsAg & HBsAb) |
| Other vaccines as app | • |
| □ Flu (annuall | • • |
| | cal-13 (≥ age 65 or high risk/immunosuppressed) |
| | cal-23 (≥ age 50 AN/AI living in Alaska or high risk) |
| · | ery 10 years) OR Tdap (once) |
| □ Zoster (≥ ag | e 60) |
| Pre-Treatment Clinical Evalu | ation: |
| | luding liver disease history and past hepatitis C treatment |
| - | on/Diabetes controlled |
| □ Counsel abo | out smoking cessation |
| | out pregnancy prevention (see Treatment Agreement) |
| | ons; check for drug interactions with treatment meds |
| □ Physical Exam | |
| ☐ Hepatitis C Treatme | ent Agreement reviewed and signed |
| ☐ ECG (If treatment inc | cludes ribavirin or peginterferon, over age 65 or h/o cardiac |
| disease) | |
| If treatment includes peg | interferon complete the following: |
| □ Mental Health Eval | uation if h/o depression or other psychiatric condition |
| | diac disease, prior to peginterferon or ribavirin) |
| - | thalmology exam (peginterferon candidates only who have |
| · · · · · · · · · · · · · · · · · · · | I, or h/o retinal disease or blindness) |

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 current FDA approved treatment for genotypes 2 and 3 is Sovaldi® (Sofosbuvir) in combination with ribavirin.

PREGNANCY & BREASTFEEDING WARNING

Ribavirin can harm an unborn child or breastfeeding infant. A woman must not get pregnant and a man must not father a child while taking ribavirin or for 6 months after treatment. You must **use 2 forms of birth control** when you take ribavirin and for 6 months after your last dose.

Acceptable Birth Control Methods:

Birth control pills or other hormone containing birth control Male or female condom
Spermicides (creams, films, foams, gels, and/or suppositories)
Diaphragm or cervical cap
Intrauterine device (IUD), Today® vaginal sponge

Unacceptable Birth Control Methods:

Rhythm method or withdrawal

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. If you are a woman and your treatment includes ribavirin it is recommended that you continue monthly home pregnancy testing for 6 months after treatment and notify your healthcare provider if you become pregnant. Female partners of males whose treatment includes ribavirin should do a monthly home pregnancy test during treatment and for 6 months after treatment completion and notify their health care provider if they become pregnant.
- 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.

Provider, select the appropriate treatment regimen:

| Sofosbuvir plus ribavirin will be given for 12 weeks for genotype 2. |
|---|
| Sofosbuvir plus ribavirin will be given for 16 weeks for genotype 2 with cirrhosis or previous treatment experience (have been treated before). |
| Sofosbuvir plus ribavirin will be given for 24 weeks for genotype 3. |
| |

Treatment with sofosbuvir and ribavirin requires 6 scheduled visits over a 6 month period if you undergo a 12-week treatment course. There will be 7 scheduled visits over 7 months if you do a 16 week treatment course. If you undergo a 24-week treatment course, there are approximately 9 scheduled visits over 9 months.

Your first three visits will be at the start of treatment (week 0) and weeks 2 and 4 after you begin taking the medications. After that, the visits will be once each month until you stop taking the medications. You may need to see your primary care provider more frequently if you are having side effects or problems related to the treatment.

You will have follow-up 3 months after treatment completion. If you have cirrhosis you should continue to have a liver ultrasound every six months and regular clinic visits.

TREATMENT MEDICATIONS AND SIDE EFFECTS

<u>Sofosbuvir</u> is a 400mg tablet. You will take sofosbuvir by mouth once daily 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:

- Amiodarone (Cordarone®, Nexterone®, Pacerone®)
- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
- Oxycarbazepine (Trileptal[®], Oxtellar XR™)
- Phenytoin (Dilantin®, Phenytek®)
- Phenobarbitol (Luminal®)
- 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®)/Ritonavir

<u>Ribavirin</u> is a 200mg capsule or tablet. You will take ribavirin pills twice daily by mouth with food (dose is based on your weight). You should not miss/skip taking any pills. A common side effect is anemia. Anemia is a condition where the blood has a decreased number of red blood cells. This occurs more often in older persons taking ribavirin. 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), anemia may make the problem worse, leading to chest pain or heart attack. If your provider believes you may have coronary artery disease, you will be tested for this and excluded from treatment if it is serious.

- Other common side effects include: headache, trouble sleeping, nausea, vomiting, weakness or lack of energy, shortness of breath, loss of appetite, itching, cough, muscle pain, swelling and pain in your joints (gout), depression, nervousness, and dizziness.
- Studies in animals have shown 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.

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 your healthcare provider 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

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 12 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 hepatitis C genotype, how much hepatitis C virus you have in your blood at the beginning of treatment, 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 2 who were treatment-naïve (never treated before) had a \geq 95% chance of achieving a sustained virologic response after taking sofosbuvir and ribavirin for 12 weeks. Those with cirrhosis had a response rate of 83%.

Two studies, Fusion and Boson, have looked at extending sofosbuvir and ribavirin treatment. Persons with genotype 2 who were treatment-experienced (previously treated) with cirrhosis and took sofosbuvir with ribavirin for 16 weeks had a response rate of 87% (13 of 15 subjects) in the Boson study and 78% (7 of 9 subjects) in the Fusion study. Those who were treatment-experienced and did not have cirrhosis had a response rate of 92% (24 of 26 subjects) in the Fusion study.

Persons with genotype 3 who were treatment-naïve, regardless of cirrhosis status had a \geq 92% response rate after taking sofosbuvir and ribavirin for 24 weeks. For those who were treatment-experienced, the response rate was 77%. For those who were treatment-experienced with cirrhosis, the response rate was 60%.

WHOM TO CALL

If you have any questions about treatment, contact your primary care provider at . .

| TREATMENT AGREEMENT | | |
|--|------------------------------|--------------------------------|
| To receive treatment, please review the | ne following statements | and initial beside the |
| responses: | | |
| I agree <u>not</u> to drink alcohol or use red | | |
| I have not abused alcohol or other su | bstances (intravenous drug | gs, cocaine, prescription |
| pain medications) within the last 6 months. | | |
| I will tell my provider if I have any s | | - |
| blood pressure, diabetes, high choleste | _ | |
| (depression, history of suicide attempts, bip | olar disorder, or psychosis |). Failure to tell my provider |
| about my medical and psychiatric condition | ns can have life-threatenir | ng consequences during this |
| treatment. | | |
| I am willing to visit the clinic and see | a provider on a regular sch | edule for the entire |
| length of the treatment. If I am unable to at | ttend an appointment, I wi | ll let my provider know |
| this ahead of time and I will reschedule my a | appointment. | |
| I understand that my treatment will be | be stopped if I cannot atter | nd appointments as |
| required to evaluate my health and well-bei | | |
| treatment. | | |
| I will use 2 acceptable methods of bir | th control during treatmer | nt and for 6 months after I |
| stop treatment (see lists, page 1). | 5 | |
| As a female, I understand that I cannot | ot be pregnant or breastfe | eding during the |
| treatment and for 6 months after treatment | · | |
| I become pregnant Not applicable, I a | • | • • |
| As a male taking ribavirin I understan | | |
| and for 6 months after treatment. | a that i should not lather a | terma daring treatment |
| If I have any problems with the med | ications or side effects tha | at hother me I will let my |
| provider or nurse know right away. | ications of side effects the | it bother me, I will let my |
| I understand that my hepatitis C may | not respond to treatment | |
| I understand that my provider can st | | |
| | | ovider reers that stopping |
| it is in the best interest of my health and we | | rovidor If I am unable to |
| I will do my best to take my medicati | ions as prescribed by my p | rovider. If Fam unable to |
| do so, I will contact my provider. | haratita Charataha dar | and the startists of the |
| I will protect myself and others from | | needles, toothbrushes, |
| razors or nail clippers and covering cuts to p | revent blood exposure. | |
| My signature below means that I have read | d this treatment agreeme | nt and/or the meaning of |
| the information has been explained to me. | I agree to the treatment. | |
| | | |
| | | |
| Dationt's Name (DIEASE DRINT) | Patient's Signature | Date |
| Patient's Name (PLEASE PRINT) | ratient s signature | Date |
| D 11 / 11 O T11 / 11 T1 A T11 T1 | | |
| Provider's Name & Title (PLEASE PRINT) | Provider's Signature | Date |

HCV Treatment Symptoms Inventory (Complete at Weeks 0, 2, 4, and monthly after that)

Are you experiencing any of the following symptoms? Check here if Yes

| Feeling excessively tired/fatigued/exhausted | |
|--|-------|
| Trouble Sleeping | |
| Headache | |
| Muscle Aches/Pains | |
| Joint Aches/Pains | |
| Back pain | |
| Weakness | |
| Flu-Like Illness | |
| Chills | |
| Fever | |
| Diarrhea | |
| Decreased Appetite | |
| Nausea | |
| Vomiting | |
| Weight loss | |
| Heartburn or upset/sour stomach | |
| Itching | |
| Rash/Skin Reactions Describe: | |
| Irritability | |
| Depression / Anxiety | |
| Changes in mood/Mood swings | |
| Feeling forgetful, problems concentrating | |
| Decreased or blurred vision | |
| Shortness of breath | |
| Cough | |
| Dizziness | |
| Dry Mouth | |
| Hair Loss | |
| Other, specify: | |
| Nurse or Provider to check if yes this week: | |
| Anemia (Hgb below 10 g/dL) | |
| Neutropenia (ANC ≤ 0.5 x 10 ⁹ /L) | |
| Thrombocytopenia (Plt < 50 x 10 ⁹ /L) | |
| Hypothyroidism/Hyperthyroidism (Specify which) | |
| Name: Char | rt #: |
| # Weeks of Treatment Completed: Date: | |

Sovaldi® (Sofosbuvir) & Ribavirin 12 week Treatment Checklist

| Prior to Treatment | | |
|-------------------------------|----------------------------------|---|
| Labs | | |
| Immediately prior: | Pregnancy test (if applicable) | |
| | Uric Acid | |
| Within 1 month: | CBC with differential | |
| | CMP (If GFR <30, do not start to | reatment; consult Liver Disease Specialist) |
| | PT/INR | |
| Within 3 months: | HCV RNA | |
| | Genotype confirmation | |
| Within 6 months: | AFP | |
| | TSH | |
| | A1C or Fasting Glucose | |
| | Vitamin D 25OH (treat if deficie | ent) |
| Within 1 year: | HIV screening | |
| Miscellaneous | | |
| Hepatitis A | status/screening if not done | |
| | status/screening if not done | |
| PHQ-9 base | | |
| AUDIT-C | | |
| | Inventory baseline | |
| / ! | , | |
| Week 2 CBC CMP¹ Symptoms I | Inventory | 3 months post treatment CBC Liver Function Tests HCV RNA |
| HCV RNA | | PHQ-9 |
| CBC | | Nurse follow-up in clinic or by phone: |
| CMP ¹ | | |
| Symptoms I | Inventory | Symptoms Inventory Managing side effects |
| Pregnancy t | test (if applicable) | Medication adherence discussion |
| | | Alcohol intake |
| Week 8 | | Birth control reminder |
| CBC | | Refill reminder |
| $___CMP^1$ | | <u> </u> |
| Symptoms I | • | |
| Pregnancy t | test (if applicable) | |
| Mack 12 | | |
| Week 12 | | |
| HCV RNA CBC | | |
| CMP ¹ | | |
| | Inventory | |
| Symptoms I | • | |
| Pregnancy t | test (if applicable) | |

1- If GFR <30, consult Liver Disease Specialist.

Sovaldi® (Sofosbuvir) & Ribavirin 12 week Lab Tracking Form

General Patient Information

Pre-Treatment Lab Results

Medication Regimen

| | 1- Sofosbuvir 400mg 1 tablet PO daily. Do not change dose. |
|------------------------|---|
| | 2- Ribavirin: mg/day PO divided into 2 doses. Take with breakfast & dinner. ≥75kg = 1200mg/day <75kg = 1000mg/day |
| Genotype: HIV: ISH: | **Dose Reduction/Date:/ |
| Vit D 250H: AFP: GFR*: | **Additional Dose Change/Date:/ |
| PT/INR: A1C/Glucose: | **Consult ANTHC Liver Disease & Hepatitis Specialists for further guidance about dose changes. |
| | |

| Completed | | | | | | | | | | | PHQ-9 | | | |
|---------------------------|----------|------|------|------|------|------|-----|-----------|------------|-----------|------------|-------------------|--------|-----------|
| Treatment Week | Lab Data | 11-6 | 11.4 | MADE | DI T | A1.T | ACT | All: Dhaa | Takal Dili | C | (Specified | HCV RNA | Weight | Pregnancy |
| week | Lab Date | Hgb | Hct | WBC | PLT | ALT | AST | Alk Phos | Total Bili | Creat/GFR | weeks) | (Specified weeks) | (kg) | Test |
| Pre-Treatment | | | | | | | | | | | | | | |
| Treatment Start Week 0 | | | | | | | | | | | PHQ-9 | HCV RNA | | |
| optional | | | | | | | | | | | | | | |
| Week 2 | | | | | | | | | | | | | | |
| optional | | | | | | | | | | | | | | |
| Week 4 | | | | | | | | | | | | HCV RNA | | |
| optional | | | | | | | | | | | | | | |
| optional | | | | | | | | | | | | | | |
| Week 8 | | | | | | | | | | | | | | |
| optional | | | | | | | | | | | | | | |
| optional | | | | | | | | | | | | | | |
| Week 12 | | | | | | | | | | | PHQ-9 | HCV RNA | | |
| optional | | | | | | | | | | | | | | |
| 3 months post treatment | | | | | | | | | | | PHQ-9 | HCV RNA | | |

Labs recommended for each follow up visit: CBC, CMP, pregnancy test (females of childbearing age), and HCV RNA as specified.

Please note the following critical values. These may require modification of dosage or discontinuation of causative med. Contact ANTHC Liver Disease Specialists with any questions.

*GFR <30 If GFR is <30, do not start treatment; consult with Liver Disease Specialists.

Hgb <10.0 gm/dL If hemoglobin drops below 10, reduce ribavirin dose to 600mg (refer to Sofosbuvir package insert). If hemoglobin <8.5, hold ribavirin & consult ANTHC Liver Disease Specialists.

GFR <50 If GFR is <50, decrease ribavirin dose (refer to ribavirin package insert) and consult ANTHC Liver Disease Specialists.

PLTs <50 K/uL If platelet count drops below 50, consult ANTHC Liver Disease Specialists.