TN Department of Correction

Chronic HCV Guidance:

Recommendations for Testing, Managing, and Treating Hepatitis C

Updated 1/01/16

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Introduction

Viral Hepatitis has been labeled “the silent epidemic” by the United States Department of Health and Human Services, but we in correctional healthcare have known little silence from this prevalent disease. (HHS) Hepatitis C Virus (HCV) Infection has become the most common cause of death from a viral illness in the United States surpassing HIV. Correctional populations have a much higher burden of disease related to HCV infection than the general population. Many who are affected may exhibit little to no symptoms of the infection. This guideline will assist providers in screening, diagnosis, and managing chronic hepatitis C patients within the Tennessee Department of Corrections. This document will serve as a replacement of the Pre-Treatment HCV Program last updated in April 2014.

Disease Progression

Those affected by HCV often progress gradually through different stages of disease. About 15-25% may resolve the initial infection and resolve the infection. Another 75-85% will progress to chronic hepatitis C infection. This is the main target patient population for this guideline.

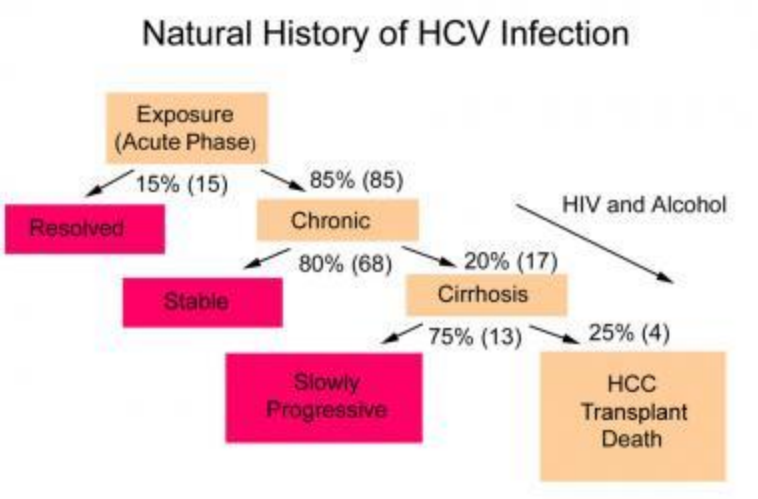


Figure 1 Natural Progression of HCV Infection

Reference: Medscape: http://emedicine.medscape.com/article/177792-overview

Acute Hepatitis C infection also known as “acute phase” should be treated on a case by case basis with supportive treatment being paramount. Some patients may need an admission into infirmary with serial laboratories drawn and IVF. Those patients that go on to resolution (Negative HCV RNA 6 months or more out from initial infection) should be followed like any other inmate in a preventative health program but should not be enrolled in Q90 day hepatitis C chronic care program, so long as he or she has no cirrhosis, complications, or related comorbidities. They should have clearly documented on the problem list that Hepatitis C has resolved and the date of resolution documented on CR Form 1894 Major Medical Conditions Problem List.

HCV Infection: Screening Criteria, Risk Factors, and Recommended Testing

Screening Criteria for testing for HCV infection is recommended for:

- Sentenced inmates with risk factors for HCV infection
- All inmates with certain clinical conditions
- Inmates who request testing.

Testing for HCV infection at the prevention baseline visit is recommended for sentenced inmates who have the following risk factors:

- Ever injected illegal drugs or shared equipment (including intranasal use of illicit drugs)
- Received tattoos or body piercings while in jail or prison, or from any unregulated source
- HIV or chronic hepatitis B virus (HBV) infection
- Received a blood transfusion or an organ transplant before 1992, or received clotting factor transfusion prior to 1987
- History of percutaneous exposure to blood
- Ever received hemodialysis
- Born to a mother who had HCV infection at the time of delivery

HCV testing is recommended for all inmates with the following clinical conditions, regardless of sentencing status:

- A reported history of HCV infection without prior medical records to confirm the diagnosis
- chronic hemodialysis – screen alanine aminotransferase (ALT) monthly and anti-HCV semiannually
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis

The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as HCV Ab or anti-HCV.

Note: Unless clinically indicated (see clinical conditions under Screening Criteria above), screening should ordinarily not be pursued for asymptomatic, highly mobile, nonsentenced inmates.

Refusal of testing of sentenced inmates who have risk factors for HCV infection, but who refuse testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits

Initial Evaluation of HCV+

Initial evaluation of anti-HCV positive (antibody positive) inmates includes:

- a baseline history and physical examination
- lab tests (see below)
- calculation of the APRI score to determine fibrosis
- Assessment of the need for preventive health interventions such as vaccines and screenings for other conditions
- Counseling on information related to HCV infection[1]

Recommended Lab Tests [2]:

- Complete blood count (CBC); prothrombin time (PT) with International Normalization Ratio (INR); liver panel (albumin, total and direct bilirubin, serum alanine aminotransferase [ALT] and aspartate aminotransferase [AST], and alkaline phosphatase); serum creatinine; and calculated glomerular filtration rate (GFR).
- Hepatitis B surface antigen (HBsAg) and HIV antibody (anti-HIV or HIV Ab).
- Quantitative HCV RNA viral load testing to determine if the inmate has active or resolved HCV infection.
- Ordinarily, testing for HCV genotype may be deferred until the time of pretreatment evaluation.
- Unless otherwise clinically indicated, testing for other causes of liver disease—e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin—are not routinely ordered in the evaluation of a positive HCV Ab test.

All inmates who are anti-HCV positive should be evaluated to assess the need for the preventive health interventions, including the following:

- Hepatitis B vaccine: Indicated for susceptible inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination.
- Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.
- Hepatitis A vaccine: Indicated for susceptible inmates with chronic HCV infection who have other evidence of liver disease. For foreign-born inmates, consider prescreening for hepatitis A immunity prior to vaccination.
- Influenza vaccine: Offer to all HCV-infected inmates annually.
- Inmates with cirrhosis are high priority for influenza vaccine.

Assess for Hepatic Cirrhosis and Decompensation

Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement with fibrotic scar tissue. The natural history of HCV is such that 50–80% of HCV infections become chronic. (FBOP, 2015) Progression of chronic HCV infection to fibrosis and cirrhosis may take years in some patients and decades in others—or, in some cases, may not occur at all.

[1] See Attachment I
[2] See Attachment II

STAGES OF FIBROSIS — Noninvasive tests of hepatic fibrosis attempt to predict the stage of hepatic fibrosis that would be seen histologically. There are several histologic scoring systems for chronic liver disease. Many use five-point scales such as the METAVIR score. Many authors will drop the "F" prefix and simple call F3, for example, Stage 3.

- F0: No fibrosis
- F1: Portal fibrosis without septa
- F2: Few septa
- F3: Numerous septa without cirrhosis
- F4: Cirrhosis

Patients are typically considered to have significant fibrosis if their fibrosis score is ≥F2. (UpToDate)

Most complications from HCV infection occur in people with cirrhosis. Patients with advanced hepatic fibrosis (primarily stage 3) have a 10% per year rate of progressing to cirrhosis (stage 4). Those with cirrhosis have a 4% per year rate of developing decompensated cirrhosis, and a 3% per year rate of developing hepatocellular carcinoma.

Physical exam in a hepatitis C patient may be normal until end-stage disease. Some common findings of end-stage disease include:

- Skin changes: Spider angiomata, palmar erythema, jaundice, scleral icterus, ecchymoses, caput medusa, hyperpigmentation
- Hepatomegaly (small liver in end-stage disease)
- Splenomegaly if portal hypertension
- Central obesity
- Abdominal fluid wave, shifting dullness if ascites
- Gynecomastia
- Dupuytren contractures
- Pretibial, presacral pitting edema and clubbing (especially in hepatopulmonary syndrome)
- Asterixis; mental status changes
- Muscle wasting, weakness

Assessing for cirrhosis is important for prioritizing inmates for treatment of HCV and in determining the need for additional health care interventions.

Cirrhosis may be diagnosed in several ways:

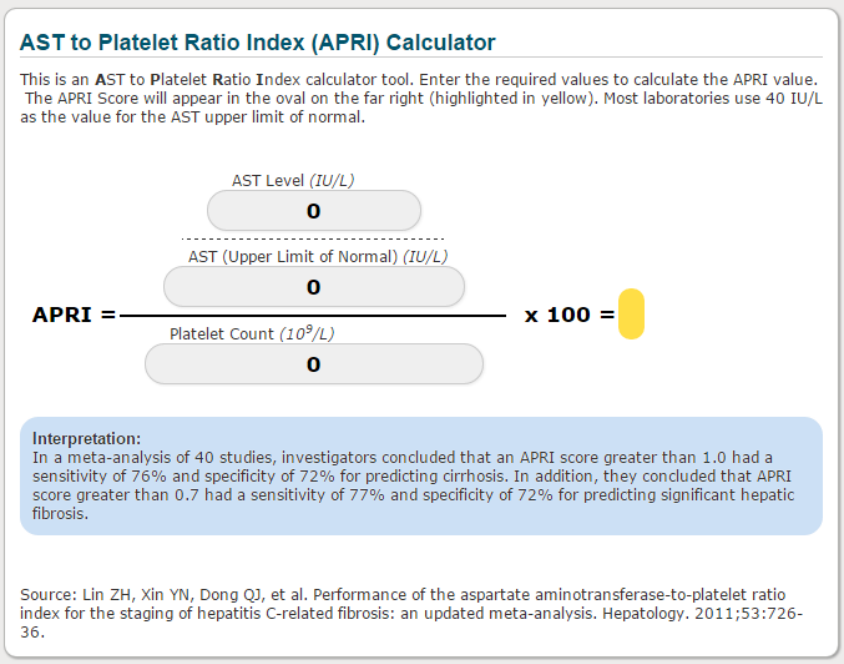
- Symptoms and signs that support the diagnosis of cirrhosis may include: low albumin or platelets, elevated bilirubin or INR, ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.
- The AST to Platelet Ratio Index (APRI) or APRI score has been used by both the AASLD and BOP as the preferred method for non-invasive assessment of hepatic fibrosis and cirrhosis:
    - The APRI score, a calculation based on results from two blood tests (the AST and the platelet count), is a less invasive and less expensive means of assessing fibrosis than a liver biopsy. The formula for calculating the APRI score is [(AST/AST ULN) x 100 / (platelet count x 103/µL / 1,000).
    - An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis. At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see

abdominal imaging studies below in this list). Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.

- An APRI score is not necessary for diagnosing cirrhosis if cirrhosis has been diagnosed by other means.

- The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4). Using a cutoff of ≥ 1.5, the sensitivity is 37% and specificity is 95% for significant fibrosis.

- APRI calculators (click here for APRI Score) are readily available on the Internet at: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri. This is an **A**ST to **P**latelet **R**atio **I**ndex calculator tool. Enter the required values to calculate the APRI value. The APRI Score will appear in the oval on the far right (highlighted in yellow). Most laboratories use 40 IU/L as the value for the AST upper limit of normal.



Source: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

- Abdominal imaging studies such as ultrasound or CT scan may identify findings consistent with or suggestive of cirrhosis (nodular contour of the liver), portal hypertension (ascites, splenomegaly, varices), or hepatocellular carcinoma (HCC).
  - Initiation of a referral for assessment for cirrhosis by onsite ultrasound will be necessary.
- A Liver biopsy is no longer required to confirm diagnosis unless otherwise clinically indicated. However, the presence of cirrhosis on a prior liver biopsy may be used to meet the criteria for HCV treatment.

Decompensation of liver disease has been closely linked to prognosis. Decompensation can be differentiated from compensated through the following method:

- The AASLD and FBOP have used the Child-Turcotte-Pugh (CTP) score as a tool to help determine the severity of cirrhosis and is used by to distinguish between compensated and decompensated liver disease. (AASLD)
  - CTP calculators are readily available on the Internet at: http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp
  - Once cirrhosis has been determined, the CTP can assess the severity of cirrhosis and help in distinguishing between compensated and decompensated liver disease.
  - The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in the table below:

CTP Score	CTP Class	Hepatic Compensation
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	

  - A CTP score of 5 or 6 is considered to be compensated cirrhosis, while a score of 7 or greater is considered decompensated. Please note CTP class or CTP grade can be used interchangeably.
  - It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition because the dosages of DAA medications are not well-established with severe hepatic impairment. These cases should be referred to the TACHH[3].
  - Inmates with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for medical furlough in accordance with current TDOC Policy Medical Furloughs(Policy# 511.01.1)
  - Consider all patient with a CTP >7 for medical furlough as prognosis increases with increased score.
  - On all patient with CTP>7 please provide MELD score for further prognosis
    - Prognosis for patient with liver disease can be estimated based on CTP and MELD score
    - Found at: http://www.hepatitisc.uw.edu/page/clinical-calculators/meld

Prognosis	
CTP Score	**½ year Survival**
Total 5-6 = Class A or well compensated:	100%/85%
Total 7-9 = Class B or significant functional compromise:	80%/60%
Total 10-15 = Class C or decompensated:	45%/35%

[3] TDOC Advisory Committee on Hepatitis C and HIV

- Consider all patient with a CTP >7 for medical furlough as prognosis increases with increased score.
- On all patient with CTP>7 please provide MELD score for further prognosis

- The Model for End Stage Liver Disease (MELD) predicts survival for patients with advanced liver disease. It has been used to estimate 3-month mortality for severe liver disease patients.
  - Prognosis for patient with liver disease can be estimated based on CTP and MELD score
  - Source found at: http://www.hepatitisc.uw.edu/page/clinical-calculators/meld
- The estimated 3-month mortality is based on the MELD score. The higher the score the higher likelihood of mortality within the time range.

MELD Scoring	
MELD Score	**Mortality Risk**
40 or more	71.3% mortality
30-39	52.6% mortality
20-29	19.6% mortality
10-19	6.0% mortality
<9	1.9% mortality

Source: Kamath PS, Kim WR; Advanced Liver Disease Study Group. The model for end-stage liver disease (MELD). Hepatology. 2007;45:797-805

Special Considerations for Patients with Cirrhosis:

- Pneumococcal vaccine: Offer to all HCV-infected patients with cirrhosis who are 19 through 64 years of age
- Hepatocellular carcinoma (HCC) screening: Liver ultrasound is recommended every six months for patients with both cirrhosis and chronic HCV infection.
- Esophageal varices screening: Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis. Initiation of a referral to GI or Hepatology will be necessary.

Other healthcare interventions recommended for patients with cirrhosis may include:

- Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
- Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
- Optimized diuretic therapy for ascites.
- Lactulose and rifaximin therapy for encephalopathy.

In general, NSAIDs should be avoided in advanced liver disease/cirrhosis, and metformin should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of these guidelines. Other resources should be consulted for more specific recommendations related to this condition.

TDOC Criteria for HCV Treatment[4]

Priority Level 1- Highest

- Cirrhotics
- CTP 7-9 are highest priority
- Liver transplant candidates
- Hepatocellular Carcinoma*
- Comorbid conditions like certain lymphomas, hematologic malignancies and cryoglobulinemia with renal disease or vasculitis
- Continuity of Care for those already on medications prior to incarceration

Priority Level 2- High Priority

- APRI ≥ 2.0 without other clinical findings
- HBV
- HIV
- Comorbid liver disease
- Advanced fibrosis of F3 (Metavir Stage, bridging fibrosis) or worse

Priority Level 3- Intermediate Priority

- Stage 2 Fibrosis on liver biopsy
- APRI score 1.5 to < 2
- DM
- Porphyria cutanea tarda

Priority Level 4- Routine Priority

- Stage 0 to Stage 1 fibrosis on liver biopsy
- All other cases of HCV infection meeting the eligibility criteria for treatment.

[4] Based on FBOP Priority Levels (FBOP, 2015)

Pretreatment Assessment

Recommended Treatment Regimens for HCV continue to evolve, but still depend on several factors:

- HCV genotype
- Prior HCV treatment history
- Compensated vs. decompensated liver disease

Pretreatment assessment should be accomplished within three months of the projected start of treatment and should include the following:

- Laboratory tests including CBC, PT/INR, liver panel, serum creatinine, calculated GFR, quantitative HCV RNA viral load sensitive to ≤ 25 IU/ml, HCV genotype, and urine drug screen.
- Calculation of the APRI score using results from the pretreatment labs. (An APRI score is not needed if there is confirmed cirrhosis.)
- Calculation of current CTP score for inmates with known or suspected cirrhosis.
- Assessment for significant drug-drug interactions and current/prior medication adherence.
- Review of incident report history for high-risk behaviors (alcohol/drug possession/use; tattooing).
- For ribavirin-containing regimens: In addition to the above, a pretreatment ECG is recommended for inmates with preexisting coronary heart disease.
- For interferon-containing regimens: In addition to the above, pretreatment evaluation should include a WBC with differential, TSH/free T4. Such regimens should also include a mental health evaluation.

Antiviral Treatment[5]

Patient should be referred to the TDOC Advisory Committee on Hep C and HIV (TACHH) for antivirals. Those patients found to qualify for treatment will be referred to our hepatitis C consultant. Preferred treatment regimens are beyond the scope of this document and will be determined by the TACHH and hepatitis C consultant. Please refer to the AASLD/IDSA/IAS-USA guidelines (www.hcvguidelines.org) for recommended treatment regimens.

Based on the Centurion Guideline, updated on March 2015, patients currently being considered for antiviral treatments will be qualified based on fibrosis and staging. (Centurion, 2015) Those that have moderate to high risk for advanced hepatic fibrosis are worked up and staged using APRI/FIB4 and other modalities to ensure proper staging. Those with F3 to F4 staging should be referred to the TACHH to be qualified for antiviral administration.

[5] Review information noted in the Attachment III: HEPATITIS C TREATMENT CONSENT/AGREEMENT

Special Consideration for antiviral treatment. Patient should have:

- No contraindications to or significant drug interactions with any component of the treatment regimen
- GFR ≥ 30
- Not to be pregnant, especially for riba and IFN regimen
- Life expectancy of greater than 18 months
- Willingness and ability to adhere to a rigorous treatment regimen and abstain from risky behaviors
- At least 9 months on prison sentence from the start of medications

Contraindications to antivirals treatment include (at the time of medication administration):

- GFR less than 30.
- Contraindications to, or significant drug interactions with, any component of the treatment regimen
- Life expectancy of less than 18 months
- Less than 9 months remaining on their sentence in the TDOC to complete a course of treatment (relative contraindication).
- Pregnancy is a relative contraindication, especially for any regimen that would require ribavirin or interferon
- Received a tattoo within the last year
- Caught using/or in possession of illicit drugs, non-prescribed medications, alcohol or injectable drug apparatus in the last year
- Inability to give informed consent
- Solid organ transplant recipient
- Non-compliant or prefers to continue risky behavior
    - Demonstrate an unwillingness and an inability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated

On-Treatment Monitoring

On-treatment monitoring should include the following:

- *An outpatient clinic visit* at 2 weeks and 4 weeks after starting therapy, and monthly thereafter; more frequently as clinically indicated.
- *Labs drawn 4 weeks after the start of therapy* should include CBC, creatinine, calculated GFR, liver panel, and quantitative HCV viral load; others as clinically indicated.
- *For regimens containing interferon and/or ribavirin:* A CBC should also be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly; more frequently as clinically indicated. Interferon and/or ribavirin dosage adjustments may be required.
- *Increases in the ALT may require more frequent monitoring or early discontinuation.* Early discontinuation of HCV treatment is recommended if ALT increases by tenfold, or by a less than tenfold increase if accompanied by symptoms related to hepatic dysfunction. Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks.

- If the quantitative HCV viral load is detectable after 4 weeks of treatment, it should be repeated 2 weeks later. Early discontinuation of HCV treatment is recommended only if there is > 1 log increase from the nadir in HCV viral load after 6 weeks or more of treatment.

Note: HCV viral load testing is no longer required at the end of treatment, but should be obtained in all cases that failed to achieve undetectable levels during treatment.

- A test for thyroid stimulating hormone (TSH) is recommended every 12 weeks only for patients receiving regimens containing interferon. For a 12-week regimen, a TSH should be drawn at the end of treatment, in addition to the pretreatment baseline.
- *Pregnancy testing is required prior to treatment with ribavirin-containing regimens*, and then periodically during and after treatment—usually monthly during treatment and for 6 months after completion of treatment.
- Testing for HCV drug-resistant mutations is not routinely recommended at this time.

Post-Treatment Monitoring

- A quantitative HCV RNA viral load assessment is recommended at 12 weeks after completion of treatment; if HCV is undetectable, it defines a sustained virologic response (SVR).
- If the HCV viral load is again undetectable at 6 to 12 months after the end of treatment, the inmate may be removed from the chronic care clinic, so long as he or she has no cirrhosis, complications, or related comorbidities.
- *Recurrent viremia following an SVR may be due to relapse or reinfection. To help distinguish between the two in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained.*

Ongoing Monitoring

Periodic monitoring is recommended for all those with active infection, including acute HCV infection, HCV treatment failures, relapse of HCV infection or reinfection, and those with chronic HCV infection who are not yet treated.

- *For cases without advanced fibrosis, cirrhosis, or complications,* annual evaluation is appropriate. This evaluation should include a focused review of systems and patient education relevant to HCV, vital signs and a focused physical examination, and lab monitoring (CBC, PT/INR, liver panel, serum creatinine, calculated GFR, and calculation of the APRI score).
- *For patients with cirrhosis or significant comorbidities*, evaluation is recommended at least every six months; more frequently as clinically indicated.
- *In cases of acute HCV infection*, monitoring for spontaneous clearance of the infection with ALT and quantitative HCV RNA levels every four to eight weeks, for six to twelve months, is recommended. If viremia persists after that time, continue to monitor and manage the case as a chronic infection.
- In most cases of acute HCV infection, treatment may be deferred to allow for spontaneous clearance of viremia. However, in some cases there may be a compelling reason to treat the acute infection in order to prevent severe complications, e.g., HCV infection superimposed on established cirrhosis or advanced fibrosis.

Appendix

- Attachment I: Hepatitis C Patient Counseling
- Attachment II: Initial Lab Studies to Order
- Attachment III: Hepatitis C Treatment Consent/Agreement
- Attachment IV: Hepatitis C Pre-Treatment Evaluation Work Sheet
- Attachment V: Hepatitis C Treatment Algorithm
- Attachment VI: Hepatitis C Treatment Monitoring Schedule

Attachment I

HEPATITIS C PATIENT COUNSELING

1. Information on Disease Natural History:

- ☐ Most people with Hepatitis C can remain healthy, manage the disease and lead full, active lives.
- ☐ The risk of developing serious liver disease is small ranging from 5% to 25% over a period of 25-30 years in most cases.
- ☐ It is difficult to predict which HCV-infected persons will develop cirrhosis or who will respond to treatment.

2. Information on Evaluation:

- ☐ The provider may have to extract a sample of the patient's liver with a needle to determine the extent of liver damage. In most instances, there are no complications, however rarely internal bleeding may occur, as well as leak of bile from the liver and gallbladder.
- ☐ It is mandatory that the patient makes it to his/her scheduled provider visits as well as allow for blood draws during evaluation and treatment. Patients who refuse a blood draw will be terminated from the treatment program.
- ☐ Patient may undergo random blood or urine testing for illegal substances and that any positive test may result in stopping, or loss of eligibility for, treatment.
- ☐ Certain medical-mental health conditions/medication intolerance/pregnancy many prevent a patient from being treated safely and effectively.
- ☐ An adequate amount of time must be available to safely and effectively treat the patient while incarcerated to maximize good patient outcomes while minimizing side effects.

3. Information on Treatment:

- ☐ Current treatment is very effective with some risk of serious side effects.
- ☐ Initial (first few weeks) side effects may include flu-like symptoms with some drug regimens, but should gradually improve.
- ☐ Current treatment regimens include a medication that may be injected every week for up to 48 weeks.
- ☐ Adherence to the drug regimen is mandatory to increase the likelihood of cure. Patients who are non-compliant will be terminated from the treatment program.
- ☐ Treatment will continue to evolve over the next few years as experts develop new medications that will work even better, and better tolerated by the patient.

4. Prevention:

- ☐ The infection can be spread even if the patient "feels fine".
- ☐ Patient should not shoot drugs, use alcohol, have sex with other inmates, get a tattoo or body piercing.
- ☐ Patient should not share personal items that might have be tainted with blood, such as; tooth brushes, nail files, clippers or razors.
- ☐ Patient should cover cuts and skin sores to keep blood from contacting other people.

My signature below signifies my understanding of, and agreement to comply with the information above. I understand that failure to comply may result in loss of eligibility for treatment or discontinuation of treatment in progress. Reconsideration for treatment is not guaranteed but may occur on a case by case basis if activity is stopped.

Patient Name: _____TDOC ID#_____

Patient Signature: _____

Clinician Name: _____

Clinician Signature: _____Date_____/_____/_____

Attachment II

INITIAL LAB STUDIES TO ORDER *

1.	CBC with Differential • Includes red blood cell indices (MCV) and platelet count
2.	CMP (Complete Metabolic Profile) • Includes creatinine, alkaline phosphatase., total bilirubin, ALT, AST and albumin (Calculated GFR)
3.	PT/INR
4.	TSH
5.	Hep C Antibody
6.	If Hep C antibody is positive then check for below: • Hepatitis B Antigen o If not done in previous 6 months. Do not repeat if previously positive • HIV Antibody Screen o If not done in previous 6 months. Do not repeat if previously positive
7.	• HCV RNA

*** If not obtained within last 90 days**

Note: see attachment VI for recommendations for labs pre-treatment and during antiviral therapy.

Attachment III

HEPATITIS C TREATMENT CONSENT/AGREEMENT

Treatment of Hepatitis C is reserved for eligible patients who understand the commitment to therapy, will tolerate and comply with the course of treatment, and agree to avoid all activities that may worsen their liver disease or infect themselves or others with the Hepatitis C virus or other blood borne pathogens. Every patient who is considered for treatment must complete this agreement before a liver biopsy is performed and/or before initiation of therapy.

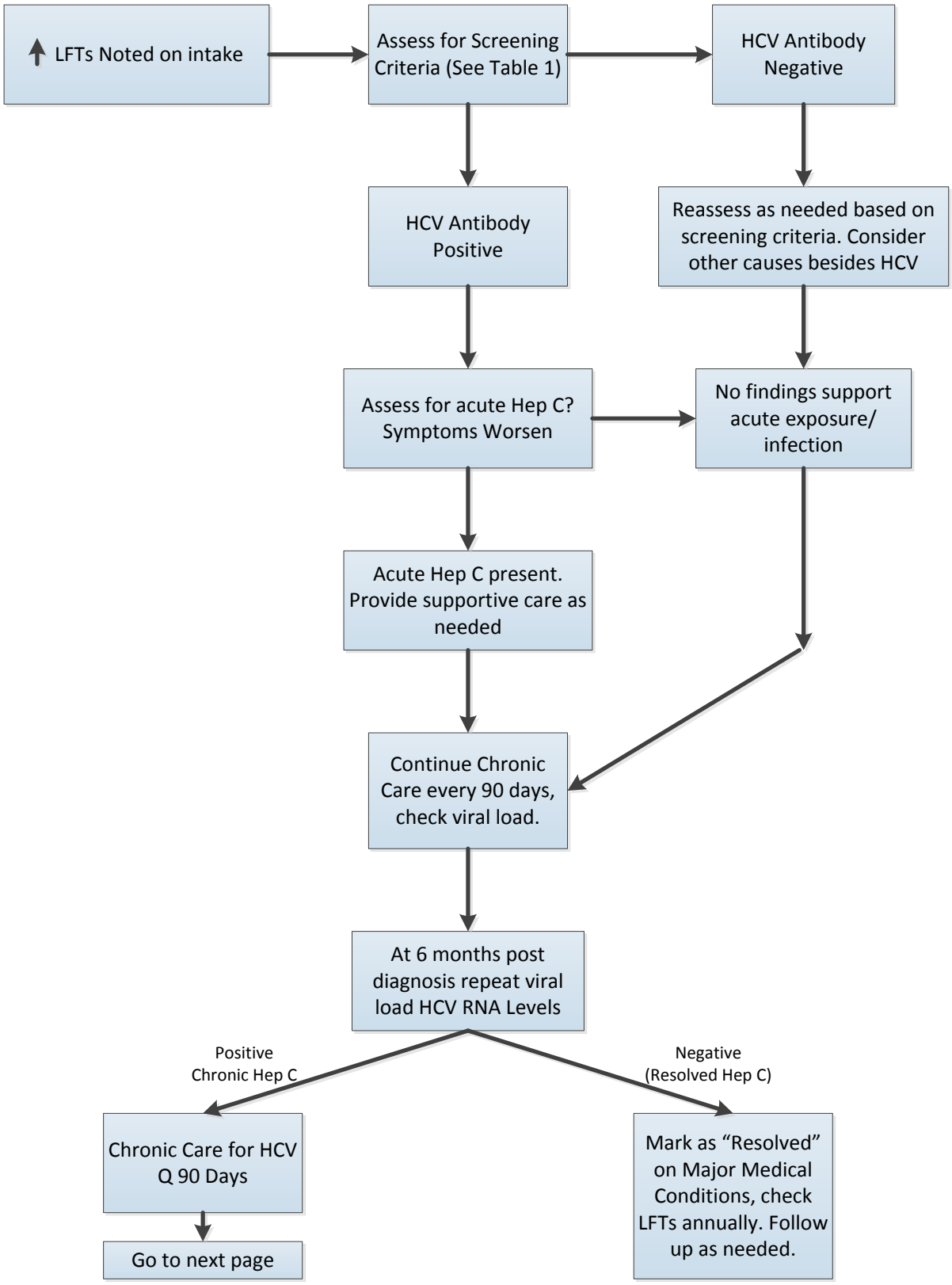
Patient's Initials	
	I understand that the therapy may be of no benefit to me, and that it may not free or clear me of the Hepatitis C infection.
	I have been informed that side effects of treatment of Hepatitis C may include fatigue, body aches and other serious side effects that may continue throughout my treatment with the medication.
	I understand that I may be tested for HIV before beginning treatment as the presence of the HIV virus could seriously affect my Hepatitis C infection and its treatment.
	I understand that the treatment with medication may continue for up to 12 months and that frequent blood testing will be needed to check for side effects or other problems.
	I understand that treatment for Hepatitis C may cause mental health side effects, especially depression.
	I understand that I must not become pregnant or attempt to impregnate my partner during my Hepatitis C antiviral treatment or for 6 months after stopping treatment. I understand that I must use two forms of birth control during heterosexual activity while taking medication, and for 6 months after medication ends.
	I understand that my failure to comply with the medication, blood testing, or regular appointments may result in my provider stopping the therapy.*
	I understand that alcohol injures the liver and drinking alcohol is forbidden.
	I understand that I must abstain from any activity that may transmit the Hepatitis C virus or other blood borne pathogens. This includes tattooing, sexual activity in prison, IV drug use and intranasal drug use. This activity may result in loss of eligibility for treatment or stopping treatment in progress.*
	I understand that I may be required to undergo random blood and urine testing for illegal substances and that any positive test may result in stopping, or loss of eligibility for treatment . *
	I understand that completion of this agreement does not guarantee that I will be approved for Hepatitis C treatment.
	My initials and my signature below signify my understanding of, and agreement to comply with the requirements. I understand that failure to comply may result in loss of eligibility for treatment or discontinuation of treatment in progress. *

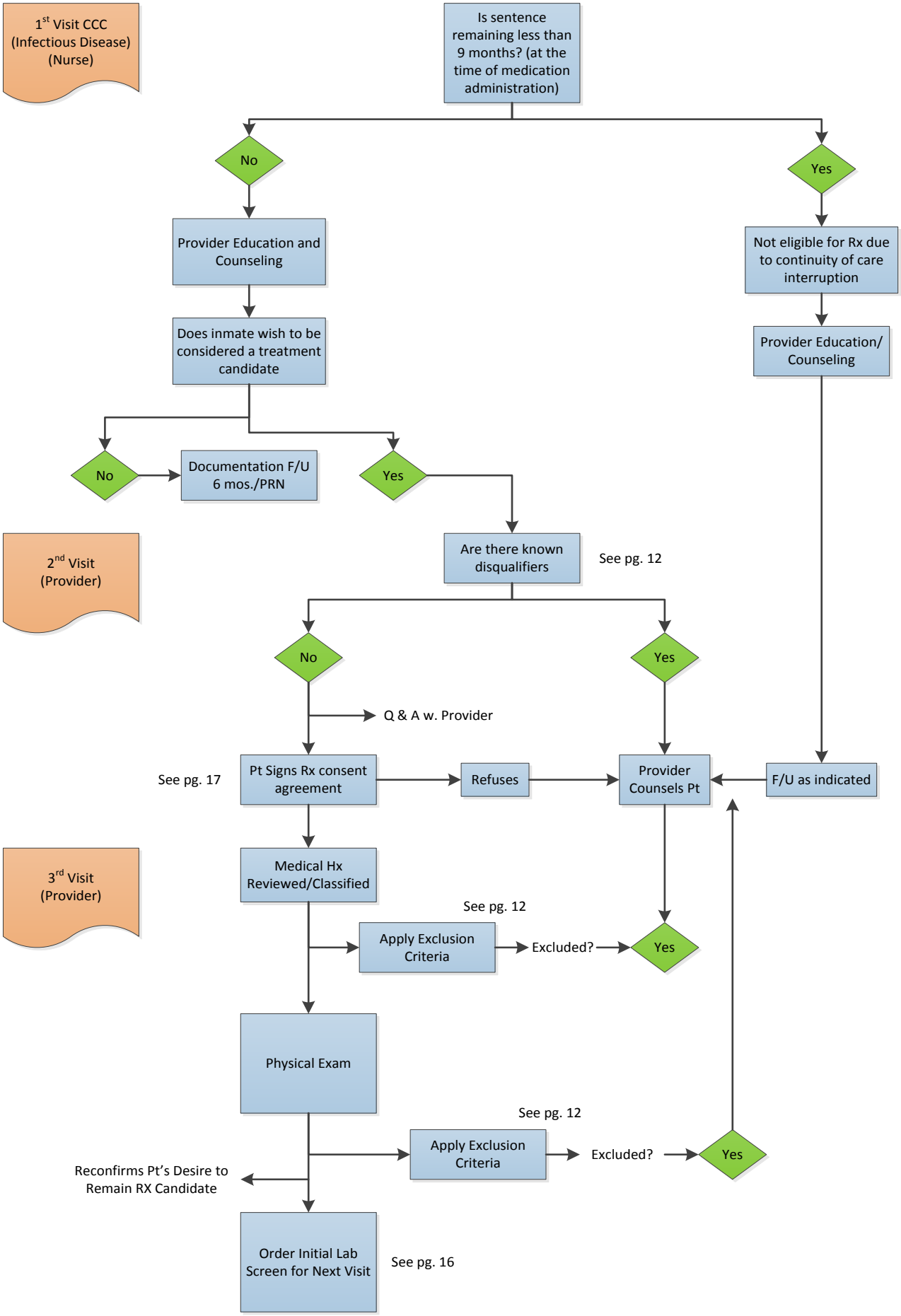
*** Loss of eligibility or treatment stopped for minimum of 1 year. Reconsideration for treatment not guaranteed, but may occur on case by case basis if activity is stopped.**

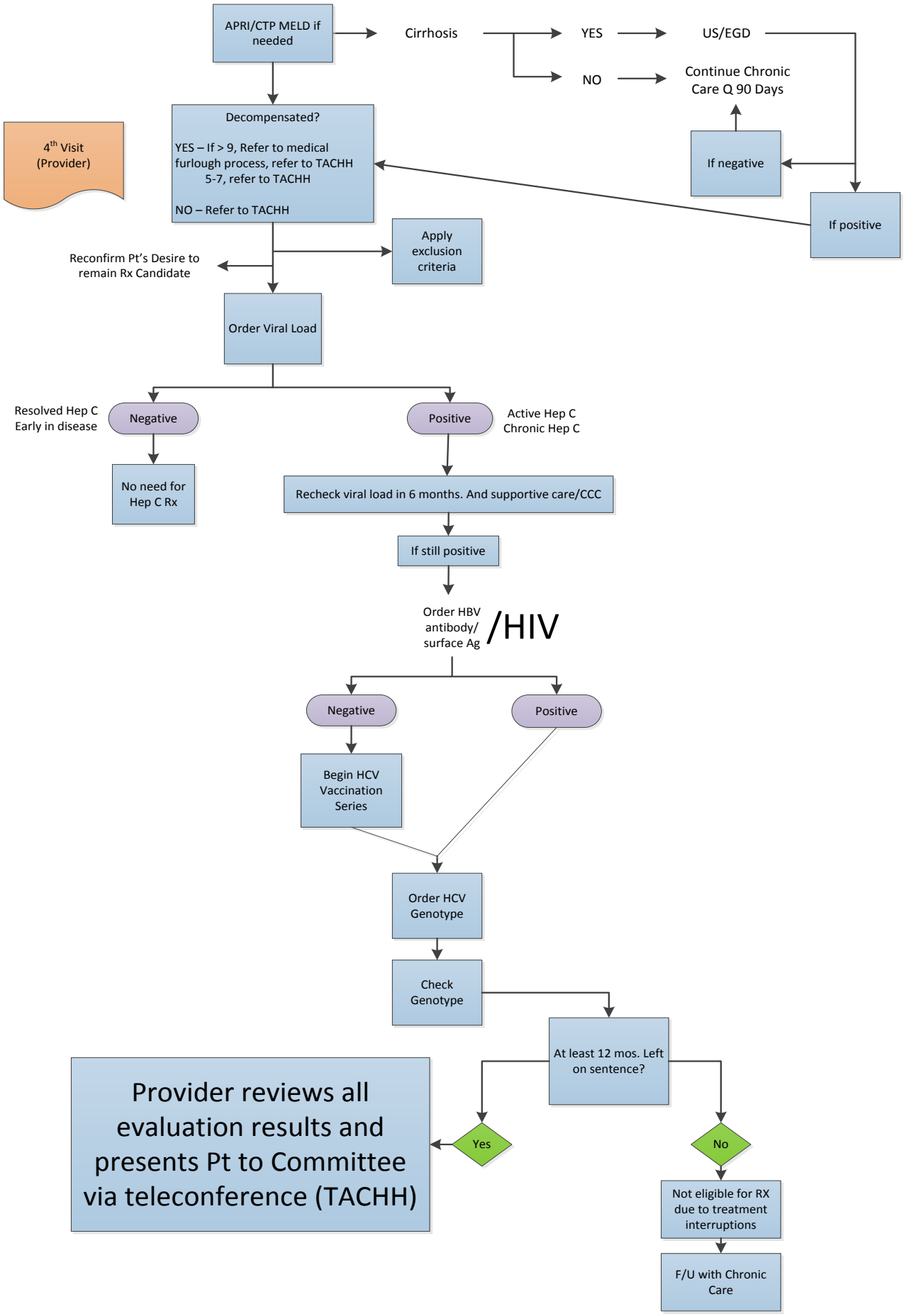
Patient Name Last:_____ First: _____MI_____ TDOC# _____ D.O.B._____	Patient Signature:_____ Clinician Name:_____ Date:___/___/___ Clinician Signature:_____

Attachment IV

Recommended Initial Pathway for HCV Management




1st Visit CCC (Infectious Disease) (Nurse)
Is sentence remaining less than 9 months? (at the time of medication administration)
No
Yes
Provider Education and Counseling
Not eligible for Rx due to continuity of care interruption
Does inmate wish to be considered a treatment candidate
Provider Education/ Counseling
No
Documentation F/U 6 mos./PRN
Yes
2nd Visit (Provider)
Are there known disqualifiers
See pg. 12
No
Yes
Q & A w. Provider
See pg. 17
Pt Signs Rx consent agreement
Refuses
Provider Counsels Pt
F/U as indicated
3rd Visit (Provider)
Medical Hx Reviewed/Classified
See pg. 12
Apply Exclusion Criteria
Excluded?
Yes
Physical Exam
See pg. 12
Apply Exclusion Criteria
Excluded?
Yes
Reconfirms Pt's Desire to Remain RX Candidate
Order Initial Lab Screen for Next Visit
See pg. 16


APRI/CTP MELD if needed
Cirrhosis
YES
US/EGD
NO
Continue Chronic Care Q 90 Days
If negative
If positive
4th Visit (Provider)
Decompensated?
YES – If > 9, Refer to medical furlough process, refer to TACHH 5-7, refer to TACHH
NO – Refer to TACHH
Apply exclusion criteria
Reconfirm Pt's Desire to remain Rx Candidate
Order Viral Load
Resolved Hep C Early in disease
Negative
Positive
Active Hep C Chronic Hep C
No need for Hep C Rx
Recheck viral load in 6 months. And supportive care/CCC
If still positive
Order HBV antibody/ surface Ag /HIV
Negative
Positive
Begin HCV Vaccination Series
Order HCV Genotype
Check Genotype
At least 12 mos. Left on sentence?
Yes
No
Not eligible for RX due to treatment interruptions
F/U with Chronic Care
Provider reviews all evaluation results and presents Pt to Committee via teleconference (TACHH)

Attachment V

HEPATITIS C PRE-TREATMENT EVALUATION WORK SHEET

Submit with request for consult TDOC Advisory Committee on Hepatitis and HIV (TACHH)

Patient Name:_____ (Last Name, First Name) TDOC #:_____	Date of Projected Parole/Sentence expiration _____	Previous Antiviral Treatment (Y/N)? If so, what med? How long?

Refer to Pre-Treatment Evaluation Flow Chart

1.0	Patient educated and counseled about Hepatitis treatment		Yes/No
2.0	Consent Form signed		Yes/No
3.0	HIV/HBV co-infection or other liver disease?		Yes/No
	Labs ordered		Yes/No
	Medical History reviewed/Exclusion criteria applied ☐ Sentenced inmate with 9 months remaining on sentence to complete a course of treatment prior to hallway house (RRC), home confinement, or GCT/Full Term release. ☐ No sanctions for drug or alcohol/intoxicant possession/use, or tattooing within previous 1 year. ☐ No documented non-adherence to prior therapy, failure to complete pretreatment evaluation process, or unwillingness to commit or consent to HCV treatment. ☐ No contraindications or drug interactions with requested treatment regimen ☐ No uncontrolled or unstable medical or mental health conditions ☐ No current pregnancy		Yes/No
	Physical Completed		Yes/No
4.0	Age: DOB: Race:		
	TSH: PT-INR:		
	Albumin (g/dl): Bilirubin (MG/dl): Creatinine:		
	Platelets Count: AST:		
	APRI: APRI Date:	Stage (0-5) : _____ ☐N/A ☐None Amount of Fibrosis: ☐Portal ☐ Periportal ☐ Bridging ☐Cirrhosis	
	Child-Turcotte-Pugh Score (CTP):	MELD:	Yes/No
	Viral load ordered Viral load: EQ/ml		Yes/No
5.0	Hepatitis B antibody/surface antigen ordered		Yes/No
	Hepatitis B vaccine given		Yes/No
	Genotype:		

6.0	TDOC HIV-HEP C Advisory Committee	Yes/No
	Liver biopsy Fibroscan Fibrotest Date:	Yes/No
	Treatment Approved	Yes/No
	Required Documentation – include copies of the following with this request: ☐ CBC, serum creatinine and eGFR, liver panel, INR (dated within 90 days of request) ☐ HCV RNA viral load (reported as IU/ml) and genotype (dated with 90 days of request) ☐ HIV Ab – if positive, include CD4 and HIV viral load (dated within 90 days of request) and current antiretroviral medication regimen ☐ Hepatitis B serology (sAb and sAg) – if sAg reactive, include eAg, eAb, and HBV DNA viral load ☐ Liver biopsy report (if performed) ☐ For regimens with peginterferon include WBC differential, TSH & free T4 (dated within 90 days of request) and a mental health assessment (dated within 6 months of request) ☐ If cirrhosis (defined by pathology or clinical findings), include abdominal US or CT and EGD ☐ Pregnancy test if woman with child-bearing potential (dated within 90 days of request) ☐ Signed consent to Hepatitis C Treatment form	
	Comments: (other pertinent diagnosis or facts that will affect Treatment)	

Submit with request for TACHH/Hepatitis C consultant

Attachment VI

Hep C Treatment Monitoring Schedule

Evaluation*	Baseline (anti-HCV positive)	Pretreatment (Within 90 days of Tx)	On-Treatment Monitoring (by week of treatment)**							12 wks post-treatment	6–12 mos post-treatment
			2	4	8	12	16	20	24		
Clinician evaluation	X	X	X	X	X	X	X	X	X	X	X
HIV Ab, HBsAg, HBsAb, Anti-HAV (IgG)	X										
Prothrombin Time / INR	X	X									
CBC	X	X	X	X	every 4 weeks during treatment						
Serum creatinine + eGFR	X	X		X						X	X
ALT, AST, bilirubin, alkaline, phosphatase, albumin	X	X									
APRI & CTP scores***	X	X									
HCV RNA, quantitative****	X	X		X	See footnote					X	X
HCV genotype		X									
Assess for drug-drug interactions & adherence		X	At each clinician evaluation during treatment								
Review incident report history for high risk behavior (alcohol / drug possession / use; tattooing)		X	if indicated								
Urine drug screen		X	if indicated								
Urine pregnancy test (if childbearing potential)		X		X	X	X	X	X	X	monthly x 6 mos	

* Conduct further diagnostic evaluations as clinically warranted to identify other potential causes of the patient's liver disease such as hemochromatosis, Wilson's disease, or autoimmune hepatitis (e.g., serum iron, serum copper,ANA/ ESR). If any of these conditions are diagnosed or are strongly suspected, a liver biopsy should be considered prior to treatment.

** More frequent monitoring may be required if clinically indicated.

*** A CTP score is calculated only for cases with known or suspected cirrhosis.

****For treatment regimens recommended in this document, the routine schedule of HCV RNA testing includes baseline and pretreatment testing, after 4 weeks on treatment, 12 weeks after completion of therapy, and if undetectable, again 6 to 12 months after completion of treatment . If the quantitative HCV viral load is detectable after 4 weeks of treatment, it should be repeated 2 weeks later. An HCV RNA is no longer necessary at the end of treatment unless undetectable levels were not achieved during treatment.

RIBAVIRIN-CONTAINING REGIMENS: A pretreatment ECG is recommended for inmates with preexisting coronary heart disease. A CBC should be obtained two weeks after starting treatment in addition to the routine monitoring schedule.

INTERFERON-CONTAINING REGIMENS: Pretreatment evaluation should include a WBC with differential, TSH / free T4 and a mental health evaluation. During treatment, a WBC with differential should be included with all CBCs, and TSH / free T4 should be checked every 12 weeks.

Source: FBOP Guidance on Evaluation and Management of Chronic HCV Infection

Note: TDOC guidance follows baseline labs evaluation with the addition of TSH

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