

# State HCV Treatment Guidelines - COLORADO

COLORADO DEPARTMENT OF CORRECTIONS

CLINICAL SERVICES

CLINICAL STANDARD AND PROCEDURE FOR HEALTH CARE PROVIDERS

Standard Title: Hepatitis C – Gastroenterology

Health Care Services

Origination Date: January 2000

Revision Date: February 2002

Related Standards: ACA 3-4330; 3-4356; 3-4360

Related DOC AR's: 700-1; 700-2

## I. PURPOSE

The purpose of this standard is to define the guidelines for the management of patients with hepatitis C infection within the Colorado Department of Corrections (CDOC). This standard establishes guidelines for the identification and treatment of patients with hepatitis C infection.

## II. STANDARD

A. All offenders within the CDOC, who are diagnosed with chronic hepatitis C, potentially have access to treatment.

B. In order to receive treatment, offenders with this diagnosis must meet certain criteria and comply with certain rules specified in the procedure component of this standard. A simplified version of this is delineated in Attachment A.

C. Primary Care Providers are responsible for treatment in conjunction with Dr. John Bloor, who works for CDOC at the Denver Reception and Diagnostic Center (DRDC).

## III. DEFINITIONS

A. Access Correctional Care: A subsidiary of a health maintenance organization 2 contracted with the Colorado Department of Corrections to provide third part administrative services, such as prior authorization, concurrent review, and claims processing to assist in managing offender health care.

B. Health Care Providers: Physicians, and Physicians' Assistants and Nurse Practitioners.

C. Hepatitis: Refers to hepatic inflammation. It can be caused by many things including alcohol, viruses, medications, other chemicals, and various other diseases. Viruses that cause hepatitis

include: the five (5) hepatitis viruses (A-E), adenovirus, Epstein-Barr Virus, herpes simplex virus, and others.

D. Hepatitis C: This virus, which causes one type of hepatitis, was identified in 1989 and subsequently shown to be responsible for more than 90% of post-transfusion (non-A, non-B) hepatitis. The predominant route of transmission is parental (blood-to-blood) although there may be a very low rate of transmission by sexual and vertical (mother to fetus) routes. The majority of new cases are associated with injection drug use, nasal cocaine use, tattooing and body piercing, lower socioeconomic class, and high risk sexual behavior (although sexual transmission of the virus is generally very low). Blood transfusions are now an uncommon route of infection, due to the advent of sensitive testing for the virus.

There are both acute and chronic forms of hepatitis C; about 80-90% of acute hepatitis C becomes chronic. The prevalence of chronic hepatitis C in the prison population is estimated to be 20-30%. 3

#### IV. PROCEDURE

A. Identification of Patients with Chronic Hepatitis C Infection begins during the

Intake Process at DRDC.

1. During intake at DRDC, the medical records and intake labs are reviewed. If ALT is noted to be greater than 50 U/L (greater than 1.25x upper limit of normal) and if no previous hepatitis C antibody (HCV-Ab) result is in the chart, an HCV-Ab will be ordered.

2. If the HCV-Ab is positive and if the ALT has been greater than 50 U/L for at least six (6) months, the patient has chronic hepatitis C. 3. If the antibody is positive but elevation of the ALT for at least six (6) months cannot be documented, the patient has hepatitis C, but the chronicity must be established. These patients should have a repeat liver panel done in six (6) months, at their permanent facility.

4. If the HCV-Ab is negative, then the labs should be repeated in six (6) months or another cause for the ALT elevation should be sought. Initial Lab HCV-Ab Action

ALT > 50 Positive → for > 6mo → See if pt is eligible for hep C treatment Positive → for < 6mo → Recheck ALT every 6mo.; if elevated for > 6mo, consider treatment for hep C Negative → AST OR ALT > 120 → Evaluate for other liver disease Negative → AST AND ALT < 120 → Repeat in 6 months

5. Hepatitis B surface antigen (HBsAg) and antibody (HBsAb), hepatitis B core IgG antibody (HBcIgG), or hepatitis B core total antibody (HBcAb), and hepatitis A total antibody (HAVtAb) should be ordered at the same time as the HCV-Ab.

6. Results of the above serologies (in #5) will help narrow the differential diagnosis and provide information about whether immunization against hepatitis A and/or B viruses is needed.

7. When a patient is diagnosed with and requests treatment for hepatitis C, the provider is responsible for educating the patient about the disease process and the treatment available. Attachment B can be utilized for patient education. 5

8. All CDOC patients with chronic hepatitis C should be offered vaccination

against hepatitis A and/or hepatitis B after first determining whether or not they already have immunity against these viruses.

- a. Vaccinating those who are already immune is not dangerous, it is just a waste of money.
- b. Immunity against hepatitis B is indicated by the presence of HBSAB or, if HBsAg is negative, by HBcIgG.
- c. Presence of total antibody against the core antigen (HBcTotal Ab) in a patient who does not have acute hepatitis also indicates immunity.
- d. Immunity against hepatitis A is indicated by the presence in the serum of HAVtAb (or HAV-IgG).

9. The vaccination schedule for hepatitis A consists of an initial shot (usually given during intake at DRDC), and a second shot six-twelve (6-12) months later (Note: the second shot is usually given at six (6) months). The vaccination schedule for hepatitis B consists of an initial shot (usually given during intake at DRDC), a second shot one (1) month later, and a final booster six (6) months after the start of the series. If the vaccination series for either A or B is interrupted the patient can receive the remaining shots at anytime in the future without needing to start the vaccination series again from the beginning.

#### B. Selecting Patients Eligible for Treatment for Hepatitis C

1. Specific criteria have been established to determine eligibility for treatment. These must be satisfied before doing a liver biopsy. The criteria are listed below and in Attachment C.

a. The Attachment C form must be completed for any patient with chronic hepatitis C who wants to receive treatment for the infection.

b. When completed, please fax the form to Dr. John Bloor at DRDC (303) 307-2309.

c. Dr. John Bloor will review the information and respond to the provider as to whether or not the patient may be eligible for treatment. 6

2. To be eligible for treatment for hepatitis C, a CDOC patient must: a. Enroll in and sign a contract (Attachment D) agreeing to attend a substance abuse program (including aftercare programs such as AA and/or NA) for twelve (12) months before starting treatment and continue to attend the program during the period of treatment. (See Attachment A, paragraphs 4-6 for details on the implementation of this requirement.)

(1) If the patient can show documentation of previous attendance, for at least a year, in drug and alcohol treatment programs, the requirement of twelve (12) months of attendance before evaluation for treatment will be waived. (Documentation must be a "hard copy" in the form of certificates, letters, attendance lists, etc. A verbal statement from the patient indicating he or she meets the educational requirements is NOT sufficient documentation).

(2) For this previous class time to count the patient must have no-thing\ to indicate that he has used drugs or alcohol since completing the classes. This must be confirmed by the case manager or social worker, in writing. If there is evidence of drug or alcohol use (arrests, parole violations, COPD writeups, hot UAs) this is evidence that the previous classes didn't work. The patient must take another year of D&A education before starting treatment regardless of how many programs

they have taken before.

(3) The patient must still sign the contract to enroll in and attend an education program while receiving treatment for hep C.

(4) It is the patient's responsibility to periodically provide medical services with proof of continuing attendance while receiving treatment.

(5) If the patient claims to have become infected with the hepatitis C virus by some route other than intravenous or intranasal use of illicit drugs and has no evidence of drug or alcohol abuse and no record of drug or alcohol related crimes, the drug and alcohol class and urine testing requirements (B.2.a. and B.2.b., above) can be waived. Any claims for waiver under this provision must be confirmed in writing by a case manager or social worker. The provider should also review the patients' profile on DCIS for evidence of drug- or alcohol-related crimes.

b. Consent to and sign a contract (Attachment D) for random urine testing for alcohol, drugs of abuse, and nicotine at least four (4) times a year during the pre-treatment year and during the period of treatment. If a sample tests positive and there is no satisfactory medical explanation, treatment will be stopped.

(1) If the patient can demonstrate prior attendance in drug and alcohol treatment programs sufficient to waive the pretreatment educational requirement, then the urine testing required before beginning treatment will also be waived. (This does not alter the urine testing required during treatment). However, an initial urine test prior to the start of treatment will be required in addition to the four (4) tests normally conducted during treatment.

(2) After the contract is signed, the provider needs to write an order for a referral to mental health and send them a copy of the signed contract and the Referral Form for Drug and Alcohol Classes for Patients Wanting Treatment for Hepatitis C (Attachment E).

c. Have at least two (2) years remaining in CDOC before their mandatory release date.

d. Have values within the normal range for albumin, prothrombin time, TFTs, and TSH (the patient can be taking thyroid replacement medication)..

e. Have ALT greater than 1.25 times the upper limit of normal for at least six (6) months, HCV-Ab positive, and have a detectable HCV viral load.

f. Have a hematocrit of greater than 30%; creatinine less than 1.5 mg/dl; platelets greater than 75,000; WBC greater than 3000; ANC greater than 1000.

g. Understand the risks of a liver biopsy and agree to have a liver biopsy before starting treatment.

h. Understand the risks and side-effects of interferon/ribavirin therapy and agree to receive therapy if liver biopsy findings are compatible with treatment.

i. Understand that by agreeing to treatment, a facility move may be required to accommodate treatment and that while receiving treatment, they may not be eligible for assignment to certain CDOC facilities.

3. CDOC patients will not be offered treatment if they:

a. Have a documented history of the use of illicit drugs (including tobacco products) or alcohol within CDOC in the past twelve (12) months.

b. Have a major medical illness (COPD, CHF, CAD/ASVD, depression, diabetes, hypertension, etc.) that is poorly controlled. However, if this is the only exclusion criterion, it may be waived at the discretion of the facility physician and after discussion with Dr. John Bloor.

c. Are over sixty-five (65) years of age or have a reasonable life expectancy of less than twenty (20) years.

d. Have an autoimmune disorder or are an organ transplant recipient or are on the waiting list for organ transplantation. This can be waived, if appropriate, after discussion with Dr. John Bloor.

e. Have evidence of decompensated liver disease. This includes ascites, history of variceal bleeding, hepatic encephalopathy, and abnormal liver function tests (albumin, bilirubin, prothrombin time).

(1) It should be noted that most of these patients will have cirrhosis on liver biopsy and would not be treatment candidates anyway.

(2) Elevation of total bilirubin alone or an abnormal value for GGT is not an indication of cirrhosis.

f. Have a history of refusal to comply with a medication contract.

4. If the patient satisfies the criteria listed above in B.2.a-i, and B.3.a-f, a liver biopsy will be recommended.

a. The biopsy is necessary to accurately evaluate the extent of liver damage present.

b. In patients with chronic hepatitis C, transaminase elevation (and other liver tests) does not correlate well with the extent of hepatic injury seen on biopsy.

5. From the biopsy the grade (severity of inflammation) and stage (extent of hepatic fibrosis) can be determined. Both parameters range from "0" to "4" where "0" is normal liver.

a. In order to be eligible for treatment, a patient must have at least grade 1 inflammation and at least stage 1 fibrosis. Patients without inflammation or fibrosis have been found to be unlikely to progress to more severe liver disease even when not treated. They are judged to not need treatment. However, because a few of these patients can progress, a liver panel should be done every 6-12 months to see whether they may eventually need treatment.

b. They will not be treated if they have cirrhosis (stage 4 fibrosis). The likelihood of clearing the virus with treatment in patients with cirrhosis is extremely low.

### C. Risk of Liver Cancer

1. Patients with cirrhosis from any cause, and those who are chronically infected with hepatitis B or C (even without cirrhosis), are at increased risk for developing hepatocellular carcinoma (HCC, hepatoma).

2. In patients with HCV infection and cirrhosis, the risk of HCC increases by 1- 4% per year.
3. Even without cirrhosis, patients who have had HCV infection for twenty (20) years are at risk for HCC with the risk increasing by 1-5% per year.
4. Patients with long standing (greater than twenty (20) years) infection or with clinical or histological evidence of cirrhosis should have yearly measurement of alpha fetoprotein (AFP, a marker for HCC) and a yearly hepatic ultrasound.
5. AFP can be elevated in a patient with hepatitis or cirrhosis but without malignancy, but a value of greater than 300 ng/mL should engender a very high suspicion of hepatoma. AFP is also elevated in certain types of germ cell tumors, usually found in young men.

#### D. Treatment Plan for Chronic Hepatitis

1. Patients who are eligible for treatment for hepatitis C will be started on interferon alpha 2b (Intron A) 3 million units, three (3) times per week (preferably Monday-Wednesday-Friday) and ribavirin (Rebetol). The dose of ribavirin is 10 600 mg in the morning and 400 mg in the evening if the patient weighs # 75 Kg (165 lbs) or 600 mg twice a day if the patient weighs > 75 Kg.
  - a. Other interferons may also be used, at equivalent doses, depending on what is on the CDOC formulary.
  - b. The first dose (and perhaps subsequent doses) should be given in the evening so that most of the side effects will occur while the patient is sleeping.
  - c. The patient should take 650 mg of acetaminophen about one (1) to two (2) hours after each shot. Flu-like symptoms usually become noticeable about four (4) to six (6) hours after the shot and can often be reduced or prevented with acetaminophen.
2. A CBC must be done within one (1) week prior to starting treatment then one (1) week, two (2) weeks, and monthly during the treatment. A schedule for these and other labs needed before, during, and after treatment is attached (Attachment F) to this standard.
3. **RIBAVIRIN IS VERY TERATOGENIC. ANY WOMAN TAKING RIBAVIRIN MUST HAVE A PREGNANCY TEST EVERY MONTH. IF SHE IS SEXUALLY ACTIVE, SHE MUST USE TWO METHODS OF CONTRACEPTION. ANY MAN TAKING RIBAVIRIN WHO IS SEXUALLY ACTIVE MUST ALSO USE TWO METHODS OF CONTRACEPTION.**
4. A reduction in interferon dose will usually be needed if the ANC falls below one thousand (1000) or the platelet count drops below seventy-five thousand (75,000). A reduction in ribavirin dose will usually be needed if the hematocrit decreases below 25% (hemoglobin < 9 gm/dl).
5. Treatment monitoring will be done by providers at the facilities. Any questions or problems should be directed to Dr. John Bloor at DRDC.
6. Monthly lab results will be reviewed by the providers at the patient's facility. Guidelines are provided in the lab monitoring sheet attached to this standard (Attachment F). A check list (Attachment G) is also provided to help with this and to bring the labs together for comparison, making it easier to identify trends.
  - a. If there are changes in the labs that you think may require a dose change, or any labs about which providers are concerned or puzzled, please call Dr. John Bloor at DRDC (303) 307-2322.

b. If the monthly labs appear satisfactory to the provider, there is no need to contact Dr. John Bloor about them.

c. Pre-treatment labs, post treatment labs, and any other results about which you are concerned should be faxed to Dr. John Bloor at (303)307-2309. Providers need to indicate in the fax exactly what the concern is and what question(s) they would like answered.

#### E. After Six (6) Months of Treatment

1. After a patient has received interferon and ribavirin for six (6) months, a liver panel and HCV viral load must be done.

2. If the ALT is normal and the viral RNA is undetectable at this point, the patient is considered a responder to combination therapy.

3. If the ALT remains elevated and the viral RNA is detectable, the patient is considered a treatment failure (nonresponder) to interferon combination

(interferon + ribavirin) therapy (see G., below).

#### F. Interferon and Ribavirin Responders

1. In patients with no detectable virus and normal ALT after six (6) months of treatment, interferon and ribavirin should be continued for six (6) more months (total treatment period of twelve (12) months).

2. A CBC should be done each month during treatment.

3. At the end of twelve (12) months of treatment, the interferon and ribavirin should be stopped and a liver panel and HCV viral load should be ordered. If they are normal, then both should be repeated six (6) months after the end of treatment.

4. If they are still normal at six (6) months post treatment, they are considered a treatment success. It is likely that the viral load and ALT will remain normal in these patients.

5. The HCV RNA (viral load) should be repeated yearly to determine whether the virus has been eliminated.

#### G. Interferon and Ribavirin Nonresponders (treatment failures)

1. Patients who have detectable HCV RNA after six (6) or twelve (12) months of combination therapy, or six (6) months after completing treatment, are considered to be treatment failures (nonresponders).

2. If the patient is still receiving treatments, they should be discontinued.

3. Patients should be told there is no other treatment for hepatitis C at this time. If new treatments become available, they may be candidates for them.

H. Attachment F is a summary of laboratory monitoring required for patients being considered for

treatment or being treated for chronic hepatitis C.

I. Acute hepatitis C can occur when a person who has not had hepatitis C or who had chronic hepatitis C that was successfully treated is exposed to hepatitis C.

1. In CDOC this usually occurs through use of intravenous drugs or through new tattoos. There is also a small chance that a patient might have been exposed to the virus just before reaching CDOC. Because of the incubation period the disease might not become evident until after they got to CDOC.

2. Most patients with an acute infection will be asymptomatic with normal labs. Practically, there is no way to identify these patients at this time.

3. Some patients with acute hepatitis C develop the typical symptoms of acute hepatitis. These include jaundice, serum transaminase (AST, ALT) elevation, and symptoms of hepatitis (fatigue, nausea, muscle and joint aches, headaches, fever, loss of appetite, etc.). If they do not have evidence for acute hepatitis A (anti-HAV-IgM) or acute hepatitis B (anti-HBcIgM), do not have antibody against hepatitis C, and have no other identifiable cause for acute hepatitis (e.g. medications, gallstones, other diseases), then they may have acute hepatitis C.

4. There is no good test at this time for acute hepatitis C. After other causes of acute hepatitis have been excluded, identification of a recent potential exposure to HCV (e.g. a new tattoo, evidence of recent IV drug use) can be helpful in making the diagnosis. HCV RNA should be done since it usually can be detected about two (2) weeks after an exposure. HCV Ab is not useful since it doesn't become detectable until at least six weeks after an exposure. However, if HCV Ab is positive it makes an acute hepatitis C infection very unlikely.

5. It is important to identify acute hepatitis C whenever possible because recent investigation has shown that early treatment (within the first six weeks, if possible) with interferon apparently can result in clearance of the virus in most or all patients. This is an important finding although most cases of acute hepatitis C still cannot be identified for reasons given above. If you think that you may have identified a case of acute hepatitis C please call Dr. John Bloor at DRDC (303- 07- 2322) to discuss diagnosis and treatment. 13

6. Treatment for acute hepatitis C is supportive. It should include rest, fluids, and SAIDS to relieve the flu-like symptoms. The acute illness generally resolves in week or two. Prompt treatment of the hepatitis C infection probably ecreases the risk of developing chronic hepatitis C, as noted above. 14

COLORADO DEPARTMENT OF CORRECTIONS

CLINICAL SERVICES

CLINICAL STANDARD AND PROCEDURE FOR HEALTH CARE PROVIDERS

IMPLEMENTATION / ADJUSTMENTS

Standard Title: Hepatitis C – Gastroenterology Health Care Services

Origination Date: January 2000

Revision Date: February 2002

Related Standards: ACA 3-4330; 3-4356; 3-4360

Related DOC AR's: 700-1; 700-2

FACILITY OR WORK UNIT NAME: \_\_\_\_\_

The above named work unit will accept and implement this Standard for Health Care Providers:

As written  With the following adjustments to meet localized operations/conditions.

\_\_\_\_\_

Clinical Team Leader Date

\_\_\_\_\_

Primary Care Physician Date

\_\_\_\_\_

Chief Medical Officer (if applicable) Date 15

If this standard is not implemented as written, the proposed adjustments must be submitted to the Chief

Medical Officer for approval.

COLORADO DEPARTMENT OF CORRECTIONS

CLINICAL SERVICES

CLINICAL STANDARD AND PROCEDURE FOR HEALTH CARE PROVIDERS

SIGNATURE APPROVAL PAGE

Standard Title: Hepatitis C – Gastroenterology

Health Care Services

Origination Date: January 2000

Revision Date: February 2002

Related Standards: ACA 3-4330; 3-4356; 3-4360

Related DOC AR's: 700-1; 700-2

The signature below indicates this standard has been reviewed and approved as an acceptable

level of Medical practice within the Colorado Department of Corrections. Each Clinical Team Leader and Primary Care Provider is responsible for ensuring that these established guidelines are implemented and followed as written. This standard will be reviewed annually and revised as indicated.

Joseph McGarry, MD Date

Chief Medical Officer

Hepatitis C – Gastroenterology Attachment A-1

### The CDOC Stepped Approach to Treatment of Hepatitis C

Any inmate in CDOC potentially has access to treatment for chronic hepatitis C. However, in order to actually receive treatment they must meet certain criteria and comply with certain rules. A simplified version of what they need to do is outlined below.

1. The patient must see a medical provider and request treatment for hepatitis C.
2. The Initial checklist for CDOC patients who want to be considered for treatment of hepatitis C (Attachment C) must be completed satisfactorily (see the checklist). If the ALT is persistently less than 50 U/L (i.e. 1.25 x 40 U/L which is the upper limit of normal for the test), the patient should be discouraged from pursuing treatment since, if the ALT is < 50 U/L at the time treatment would start, they will not be offered treatment.
3. The patient must understand the risks of a liver biopsy and the risks and side-effects of interferon therapy. They must understand that a liver biopsy is required before they can receive treatment but that they will not get the biopsy until after they have completed at least a year of substance abuse education.
4. The patient must sign the "Contract for attendance of substance abuse education classes and for random testing of urine for substance for abuse (Attachment D) or must provide documentation of having satisfactorily completed at least a year of a substance abuse education class while in CDOC. The only exceptions to this are patients who have already received a liver biopsy under the old guidelines (but see #9 below). These patients do not need to complete a year of class before being offered treatment.
5. After the contract is signed the provider needs to write an order for referral to mental health and send them a copy of the signed contract and of the Referral form for drug and alcohol classes for patients wanting treatment for hepatitis C (Attachment E). The provider also needs to write an order for urine testing for alcohol, drugs of abuse, and nicotine (be sure to specify that testing is for all of these). The order should specify four (4) dates picked at random over the next year on which these tests will be done. For example: "Patient is to be called to medical on 2/8/00, 5/27/00, 8/11/00, and 10/14/00 to give a urine sample for testing for alcohol, drugs of abuse, and nicotine. Be sure that the patient is not told the dates that you select. This order needs to be written (with new dates) each year until treatment is completed.
6. After completing a year of substance abuse education and having four (4) urine screens negative for substances of abuse, the patient must have a liver biopsy. On the biopsy there must be at least mild inflammation (Stage 1 or greater) and fibrosis (Grade 1 or greater) and there

cannot be cirrhosis (Grade 4 fibrosis).

#### Hepatitis C – Gastroenterology Attachment A-2

7. The “labs needed before starting treatment” (Attachment F) on the Laboratory Monitoring Sheet need to be done and faxed/sent to Dr. John Bloor at DRDC. If the ALT is > 50 U/L, he will review each patient and recommend for or against starting treatment. The patients need to be aware they must continue in the substance abuse education classes throughout any treatment they receive. Please let Dr. John Bloor know the exact date when a patient starts on treatment.

8. Once treatment has started, the “labs needed during treatment” (Attachment F) must be done on a scheduled basis. Although interferon and ribavirin are generally quite safe, side effects in some patients can be serious. It is very important that the labs be done and reviewed regularly.

A check list (Attachment G) is provided to help with this and to bring the labs together for comparison, making it easier to spot trends.

9. The labs should be reviewed by the providers at the facilities. If they change dramatically or are worrisome, please contact Dr. John Bloor. If you are comfortable with them and do not think that a dose change is needed, initial and date them and file them in the chart. If you think that they are problematic or you are not sure, please call Dr. John Bloor to discuss them. The reasons indicated for the labs and the most important “critical values” are on the Laboratory Monitoring sheet. The only labs that need to be seen by Dr. Bloor are any HCV RNAs (viral loads) done.

10. There may be exceptions to who is treated. In particular, if a patient has both chronic hepatitis B and C or other chronic liver disease, they will be treated. If they are having serious extrahepatic complications from the hepatitis C (i.e. renal failure, severe vasculitis, porphyria cutanea tarda, and others), they will be treated. These will need to be decided on a case-by-case basis but the primary care providers should watch for these problems and notify Dr. Bloor when providers think these conditions are present. In these patients the requirement for drug and alcohol classes before starting treatment will usually be waived. They must still enroll and have urinalysis done during treatment.

11. Please note section IV. A. 8, about vaccinating hepatitis C patient against the hepatitis A and B viruses. Patients with hepatitis C (or another acute or chronic liver disease who have exposure to these viruses are more likely to have serious complications than patients with hepatitis C. This is similar to the situation with alcohol and hepatitis C. Completion of even part of the series for each virus confers some immunity. The specific vaccines to be used will be determined by the Pharmacy. The vaccination schedule for hepatitis B will usually be zero (0), one (1), and six (6) months, but the series can be continued even if the second or third shots are missed. The vaccination schedule for hepatitis A is usually zero (0) and six (6) months but the series can be continued even if the second shot is missed.

#### Hepatitis C – Gastroenterology Attachment B-1 Colorado Department of Corrections Information Sheet for Chronic Hepatitis C and Treatment of Chronic Hepatitis C

##### Chronic Hepatitis C Infection

Hepatitis C is a virus that infects your liver. It is usually transmitted “blood-to-blood.” Currently the most common route of infection is illicit intravenous and intranasal drug use. High-risk sexual behavior (mostly large numbers of homosexual or heterosexual partners), tattooing, body

piercing, and acupuncture can also transmit the infection. Long-term sexual relations with a single partner carries little risk of infection. Blood transfusions used to (before 1990) be an important source of infection.

Currently the risk of getting infected from a blood transfusion is between 1 in 10,000 and 1 in 100,000.

Most people don't know when they get the infection because they don't feel ill. However, if you are exposed, the chance of developing a chronic infection (one that doesn't go away) is 80-90%. Many people go for years without knowing they are infected and without having any symptoms of liver disease.

The longer a person has the infection the more likely it is they will develop liver cirrhosis or liver cancer. However, studies have found that even after twenty (20) to thirty (30) years, only one (1) in four (4) patients will develop liver cirrhosis. The risk of cirrhosis is greatest in men, those who drink alcohol heavily, and those who got the infection after they were forty (40) years old. About one (1) in seven (7) (15%) will develop liver cancer in five (5) to ten (10) years after cirrhosis is present. Most people with chronic hepatitis C will not die of liver disease.

#### Treatment of Chronic Hepatitis C Infection

The main medicine used to treat this viral infection has been interferon. There are several different types but all of them are used in the same way and are about equally effective. Another drug, ribavirin (Rebetrol), is now being used together with interferon in what is called combination therapy. In the United States, interferon alone seems to cure (eliminate the virus) in about 10 to 20% of the people treated. Combination therapy appears to cure about 35 to 40%. In CDOC, we use combination therapy because of its greater effectiveness. Interferon is a natural medicine that is made by the white blood cells in your body when you get a viral infection such as influenza (flu). When it is injected into your body, many people get the same symptoms as when you get the flu, i.e., muscle and joint aches, a mild fever, chills, tiredness, loss of appetite, nausea and vomiting, and diarrhea. There are ways to lessen the effects of these symptoms, and they usually spontaneously decrease in severity by about four (4) to six (6) weeks into treatment. Interferon can also cause hair loss (temporary), depression, and dry, itchy skin. Hepatitis C – Gastroenterology Attachment B-2 These symptoms are common, but they can be treated. Interferon also causes a decrease in the number of white blood cells and platelets in your blood and can make your thyroid gland act up. This is seldom bad enough to affect treatment, but we check your blood frequently to be sure to catch this type of problem before it can become dangerous. If the changes are too great, the dose of interferon is decreased or treatment is stopped and the blood counts are allowed to return to normal. Interferon sometimes causes depression or worsens depression if you have it already. This can be treated but you need to tell us if it occurs. It goes away when the medication is stopped. Ribavirin decreases the number of red blood cells. As with interferon, the treatment for this complication is to stop the medicine.

#### Liver Biopsies

Before your hepatitis C can be treated with interferon, a liver biopsy is required. This allows us to look at exactly how much damage there is to your liver. Liver biopsies are also used to examine the liver for other types of liver disease.

To do a liver biopsy, a thin needle is inserted into the liver between two (2) of the lower ribs on your right side. You are given pain medicines (usually lidocaine, versed, and fentanyl or demerol) before this is done and afterwards, as needed. Your vital signs are carefully monitored during the biopsy and for about four (4) hours afterward to watch for any complications that may occur. Although the procedure is generally quite safe, there is a small (less than 1 in 100) chance of

having internal bleeding, severe pain, or a collapsed lung. There is also a very small (less than 1 in 1000) chance of having a bad reaction to the pain medicines you are given. Most (95%) of the problems occur by four (4) hours after a biopsy. If everything is looking "OK" at that time, you will be returned to your permanent facility. For two (2) weeks following a liver biopsy you should not do any heavy lifting (>10 pounds), including weight lifting, and should not take any aspirin, motrin, or other non-steroidal anti-inflammatory medicines. If you have pain, use tylenol to treat it. Tylenol in usual doses is safe even if you have hepatitis C. It is normal to have some soreness in your side (where the needle was inserted) or sometimes in your right shoulder following a liver biopsy.

Revised 2-19-2002 Hepatitis C – Gastroenterology Attachment C-1

#### Initial Checklist for CDOC Patients Who Want to Be Considered for Treatment for Hepatitis C

If a CDOC patient wants to be considered for treatment for chronic hepatitis C, the following checklist must be completed and reviewed by Dr. John Bloor before treatment will be offered. If the answer is "NO" to any of questions 1-5 or "YES" to questions 6 or 7, the patient is not and cannot become eligible for interferon treatment for their chronic hepatitis C within CDOC. If the answer is "YES" to one of the questions 8-10 and that is the ONLY reason for disqualification from treatment then it is left to the provider's discretion whether or not the patient should be treated.

Patient Name CDOC # Date evaluation started

1. Does the patient have chronic hepatitis C? YES NO

First ALT value Date:

Second ALT value Date:

HCV antibody Date:

2. Does the patient have at least two years from today's date to his Institutional Discharge (Mandatory Release) Date?

3. Is the patient less than 65 years old with a life expectancy, in your judgement, of at least 20 years?

4. Are T4 and TSH both normal?

5. Are the patient's hematocrit >30%, platelets >75,000, WBC > 3000, ANC >1000, and creatinine <1.5 mg/dl?

6. Does the patient have an autoimmune disorder (including HIV infection) or have they received or are they on the waiting list for an organ transplant?

7. Does the patient have evidence of decompensated cirrhosis? This can include ascites, variceal bleeding, hepatic encephalopathy, or abnormal values for total bilirubin, albumin, or prothrombin time. (Elevation of total bilirubin alone or an abnormal value for GGT is not an indication of cirrhosis.)

8. Does the patient have a major medical illness that is poorly controlled?
9. Does the patient have any history of substance abuse (including tobacco use) in the past 12 months within CDOC? (Check with case management if you are unsure.)
10. Does the patient have an established pattern of refusing to comply with medication contracts in the past five years? Revised 2-19-2002

#### Hepatitis C – Gastroenterology Attachment D-1

#### Colorado Department of Corrections

#### Contract for Attendance of Substance Abuse Education Classes and for Random Testing of Urine for Substance Abuse

Testing has demonstrated that you are chronically infected with the hepatitis C virus. This infection is usually acquired by the introduction of blood containing the hepatitis C virus into your circulation. In the past (before 1990), this could happen during blood transfusions. Now, most new cases are caused by sharing of needles and syringes among intravenous drug abusers, sharing of straws among nasal cocaine users, and from tattoos and body piercing using contaminated equipment. Treatment for hepatitis C is expensive and, even if it is successful, it does not prevent you from becoming reinfected if you do things that expose you to the virus again. CDOC does not believe that treatment should be given to patients who are likely to become reinfected. For this reason, anyone who wants to receive potentially curative treatment for hepatitis C (interferon + ribavirin) is required to enroll in AND ATTEND classes and activities which can teach them to avoid returning to habits that can lead to reinfection. This MUST include the formal drug and alcohol classes taught by the division of mental health. After this is completed you must continue in some other program which can include AA or NA (that is, an aftercare program). However, regardless of what program you are in, you must provide proof that you are attending their meetings.

Continued substance abuse while incarcerated in CDOC strongly indicates that a person is not sufficiently interested in receiving treatment to change their habits and follow medical recommendations. Proof that a patient is not abusing drugs, alcohol, or tobacco - all of which are substances of abuse in CDOC - will be required in the form of random urine testing.

Compliance with the following requirements is MANDATORY for anyone wishing to start treatment for hepatitis C or to continue treatment once it is begun:

1. You must enroll in and attend a substance abuse education program for one year before starting treatment. If you do not enroll or if you skip meetings, you will not be offered treatment. However, if you provide written proof that you have already completed at least a year in this type of program in or out of CDOC and there is no record that you have abused drugs or alcohol or been arrested for a drug- or alcohol-related crime since completing the program, you will receive credit for that time and will not be required to take another year before starting interferon.
2. You must continue in a substance abuse education program throughout the time that you are receiving treatment. If you skip meetings, your treatment will be stopped and not restarted.
3. You must undergo random urine testing at least four times a year for the year preceding the start of treatment and throughout the time that you are receiving treatment. Failure to submit a specimen when asked or the occurrence of a "hot" urine will prevent you from being offered

treatment or, if you are receiving treatment, it will be stopped and not restarted.

4. You must sign this agreement and follow it or you will not be offered treatment for your hepatitis C. I have read this document carefully, understand it, and want to receive treatment for my chronic hepatitis C infection. I understand that if I don't follow these rules I will not be started on treatment or, if treatment has begun, it will be stopped and not restarted.

Patient's Name CDOC # Date

Hepatitis C – Gastroenterology Attachment E-1

Referral For Drug and Alcohol Education Classes

For CDOC Patients Wanting Treatment for Hepatitis C

TO: Drug and Alcohol Education,

Patient's CDOC Facility

FROM: Clinical Services, , Provider

Name of Referring Provider

RE: Enrollment of in Alcohol and Drug Education

Class

Name and CDOC # of Patient

DATE:

The patient named above has been diagnosed with chronic hepatitis C infection and has requested treatment for this disease. This infection is transmitted "blood-to-blood," that is, by transfer of blood from an infected person to an uninfected person. Currently the most common route of infection is illicit intravenous and intranasal drug use. High-risk sexual behavior (large numbers of homosexual or heterosexual partners), tattooing, body piercing, and acupuncture can also transmit the infection. Although treatment for hepatitis C infection is available, successful treatment (i.e. eradication of the virus) does not confer any protection against reinfection. In addition, since alcohol consumption compounds the liver disease, effort should be made to minimize future exposure to alcohol. As part of the treatment of these patients, CDOC Clinical Services is requiring that they participate in a drug and alcohol abuse treatment program beginning one year prior to treatment and continuing through the end of the one year treatment period. It is hoped that this will maximize the benefit of the prolonged and relatively expensive antiviral therapy. In order to meet this requirement each patient initially must show (to Clinical Services) proof of enrollment. Then, throughout the pretreatment "waiting period" and during treatment they must show proof of attendance in the classes. Initially, they must be enrolled in whatever formal alcohol and drug education classes are available at their facility. Once all available formal classes have been completed they must attend Alcoholics Anonymous, Narcotics Anonymous, or another equivalent aftercare/support group at least once a week. Although such support groups are, technically, voluntary, the patients must get signed proof from the person (not another offender) responsible for the group. This proof must be available for clinical services to review on at least a monthly basis. These requirements are not intended to increase the work of those who teach or run these programs. It is the inmate's responsibility to

request the signatures and to show the proof of enrollment and attendance to clinical services. This is a new program and any suggestions that you have that may improve how it works are appreciated and will be given careful consideration. Please contact the provider shown above at your facility or Dr. John Bloor at DRDC for any comments or questions. Revised 2-19-2002

#### Hepatitis C – Gastroenterology Attachment F-1

##### Laboratory Monitoring of Patients Being Treated for Chronic Hepatitis C

The pretreatment labs will be reviewed by Dr. John Bloor to decide whether or not to start treatment.

Monitoring during treatment will be done primarily by the providers at the patient's permanent facility. If abnormalities or changes are noted that are concerning, please call Dr. John Bloor for further evaluation and recommendations.

##### Labs needed before starting treatment:

CBC with differential, HCV RNA (viral load; quantitative), Chem 20 (ACP), HBsAg, HBSAB, HBcAb, HAV total antibody, PT/INR, TSH, TFTs AMA, ANA, aSMAb, Fe/TIBC/Ferritin, Pregnancy test (women receiving ribavirin), HIV.

##### Labs needed during treatment:

CBC with differential Weeks 1, 2, 4, then at least monthly while on treatment.

ALT Monthly while on treatment.

HCV RNA (Quant.) Months 6 and 12, then 6 months after completion of treatment.

TSH Monthly while on treatment (at the discretion of the primary care provider)

##### Purpose of the labs:

###### Pretreatment:

Labs are to establish a baseline for liver function and hematologic values and to screen for other causes of liver disease that may be comorbid with hepatitis C.

###### During treatment:

Platelets, absolute neutrophil count (ANC), and hemoglobin are used to monitor side effects and to make dose reductions if needed. ALT and HCV RNA are used to monitor viral response to treatment. TSH is to monitor thyroid function. Interferon can cause both hyper- and hypothyroidism.

#### Hepatitis C – Gastroenterology Attachment F-2

Critical values which may require dose reductions:

Hemoglobin < 10 g/dl OR if there is a > 2 g/dl decrease in any four week period

WBC <  $1.5 \times 10^3$  / mL (or cc)

Platelets <  $50 \times 10^3$  / mL (or cc)

Absolute Neutrophil Count (ANC) <  $0.75 \times 10^3$  / mL (or cc)

(To calculate ANC, multiply WBC by % neutrophils. For example, if WBC are reported as 4.2 thousand/cu-mm and neutrophils are reported as 45%, the ANC is  $4200 \times 0.45 = 1890$  or  $1.89 \times 10^3$  / mL.)