



**MONTANA DEPARTMENT OF CORRECTIONS
CLINICAL SERVICES DIVISION
PROCEDURE**

Procedure No.: CSD 4.5.11A	Subject: HEPATITIS C VIRUS (HCV) TREATMENT
Chapter 4: FACILITY/PROGRAM SERVICES	Page 1 of 8 and Attachments
Section 5: Clinical Services	Effective Date: 12/23/2016
Medical Director Signature: /s/ Liz Rantz, M.D.	Revised: 05/22/2018
Clinical Services Division Administrator Signature: /s/ Connie Winner	

I. PURPOSE

The Clinical Services Division of the Department of Corrections, using evidence-based clinical guidance, will provide appropriate monitoring for all Hepatitis C Virus Antibody positive (HCVAB+) / Hepatitis C Virus positive (HCV+) offenders, and will provide HCV antiviral drug treatment when determined by clinical indication and/or treatment criteria. The intent is to identify offenders with fibrosis stage 3 or 4 and progressing stage HCV liver disease from mild inflammation to fibrosis to cirrhosis.

II. DEFINITIONS

Directly Observed Therapy – Medication or other treatment provided directly by clinical services staff that is not appropriate for self-administration.

HCV Spreadsheet – A tracking system used by each site that identifies all HCV+ offenders and guides staff in the continued monitoring of disease and designation of potential treatment candidates, formatted according to the HCV Spreadsheet template.

Medical Review Panel (MRP) – A panel of qualified health care professionals that is comprised of the Clinical Services Division administrator, Medical Director, at least two additional health care providers (one of whom must be a physician), and the Department managed care RNs, all of whom are designated to review complex health care cases and health care topics relevant to the patient population under the care and custody of the Department of Corrections.

Mountain Pacific Quality Health Foundation (MPQH) – A federally designated Quality Innovation Network-Quality Improvement Organization (QIN-QIO) providing drug utilization review services to the Clinical Services Division of the Department of Corrections.

III. PROCEDURES

A. Education and Screening

1. All incoming offenders at all secure facilities are offered education about HCV that includes prevention of disease, healthy self-care, and abstaining from drugs and alcohol. Education is provided utilizing the [Hepatitis C: Get the Facts](#) publication and the [HIV and Hep C](#) presentation.
2. Department community corrections facility offenders will not be eligible for initiation of treatment except under special clinical circumstances because of their short length of

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

stay. These offenders will be referred to community resources for follow-up and treatment determination after release.

3. Offenders receiving treatment prior to and upon entry to a secure facility or community corrections facility will not have the treatment interrupted unless the physician believes that continuing treatment is not in the offender's best interest. If there is reason to suspect the offender has not been compliant with medication immediately prior to entry (e.g., discontinued while in jail), or if the offender engaged in high-risk activities prior to entry, the continuation should be discussed with the offender's community physician and Department medical director.
4. Providers and clinical services staff may refer to the [HCV Algorithm](#). A provider may deviate from this procedure and the algorithm only if, in the opinion of the provider, there are clinical reasons to do so.
5. All incoming offenders at all secure facilities are offered HCV antibody (HCVAB) screening except that:
 - a. Offenders will not be retested while they remain in Department custody unless there are clinical indications or if the offender has a specific history of exposure while incarcerated that suggests need.
 - b. If an offender is readmitted after a time in the community, they may be retested at the discretion of the provider or advised to obtain testing upon release.
 - c. If an offender self-reports HCV+ status and staff can readily obtain prior medical records, staff may rely on prior medical records and proceed accordingly. If prior medical records cannot readily be obtained, the offender will be offered screening for HCVAB.
6. All HCVAB+ offenders will be offered vaccination against Hepatitis A and B (Twinrix), regardless of expected length of stay, unless previous infection or vaccine has been documented or the provider believes that vaccination is unnecessary or contraindicated.
7. Offenders will be provided with a list of the dates and types of immunizations they received. Offenders discharging prior to completion of a vaccine series will be provided information to access the health department where they will be relocating.

B. Further Testing of HCVAB+ Offenders (Viral Load and Fib-4)

1. All HCVAB+ offenders will receive additional testing to determine viral load and genotype. The viral load test will either be positive, which means the virus is detected, or negative, which means the virus has "cleared."
2. All offenders who test positive for viral load will receive Fib-4 testing as a primary screening for liver function and staging of fibrosis or cirrhosis. Fib-4 is a simple calculation based on alanine aminotransferase (ALT), aspartate aminotransferase (AST), platelets and age.

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

3. After Fib-4 testing, offenders are grouped into the following categories as tracked in the [*HCV spreadsheet*](#):
 - I. Never infected, HCVAB-;
 - II. Infected but not viremic, HCVAB+ / viral load- (i.e. "cleared");
 - III. HCV+, but anticipated incarceration too short for treatment and/or treatment not desired;
 - IV. HCV+ but no or slow progression anticipated; or
 - V. HCV+ and potential treatment candidate.
4. Offenders with HCV disease who will be discharging the facility in less than 12 months after the physician has established the presence of ongoing liver inflammation will generally not be candidates for medication therapy during confinement. These offenders will be counseled regarding the risks and benefits of therapy and the need to receive therapy after release from the facility. Exceptions will be offenders whom the physician recommends for work-up for clinical reasons. However, in no case will medication therapy be initiated if that therapy cannot be completed, including 12-week test of cure.
5. The HCV spreadsheet will list all HCVAB+ offenders by name, identification number (AO number), discharge date, and infection status.
6. Category II and III offenders as defined in III.B.3 above will be entered into the HCV spreadsheet for statistical purposes as follows:
 - a. Category II offenders will be entered with a note stating "no viral load."
 - b. Category III offenders will be entered with a note stating "not eligible for treatment" or "treatment not desired," as appropriate.
7. Category IV offenders are those who are HCV+ with a Fib-4 score < 1.45. They will be entered into the HCV spreadsheet, but will not be highlighted as potential treatment candidates. Category IV offenders will receive education regarding healthy lifestyle choices and be scheduled for the facility's annual monitoring as described below.
8. Category V offenders are those who are HCV+ and have a Fib-4 score > 1.45. Category V offenders will be highlighted in the HCV spreadsheet as potential treatment candidates, and further testing and evaluation will be performed as described elsewhere in this procedure. Staff may not inform Category V offenders that they will be treated, as the decision is complex and requires several further steps.
9. Each facility will perform annual monitoring of all offenders who are viral load positive (Categories IV and V) within a single month chosen by that facility so there is order to the process. The annual monitoring will consist of drawing a comprehensive metabolic panel (CMP) and complete blood count (CBC), and staff will calculate a Fib-4 score. Unless an offender is being followed for other serious clinical reasons, the screening test will not occur more than once a year.
10. The HCV spreadsheet will be reviewed at least annually by a physician or designated mid-level provider.

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

11. The HCV spreadsheet will list each offender's three most recent Fib-4 scores with the date of testing. If an offender already has three scores listed at the time of a new test, the oldest will be removed so the new score can be entered.
12. If an offender's Fib-4 score increases from < 1.45 to > 1.45 from one test to the next, the offender will be entered into the HCV spreadsheet as Category V and will be highlighted as a potential treatment candidate.

C. Assessment of Category V Offenders

1. Treatment decisions for Category V offenders should not be based on a single Fib-4 score. A Category V offender will be provided additional testing to determine liver function and staging of fibrosis or cirrhosis and to rule out other pathology only if the offender:
 - a. will be in the facility at least 12 more months; and
 - b. wants treatment.
2. Additional testing options may include transient elastography (TE) (preferred, if available), Fibrosure, imaging, and/or other clinically appropriate tests.
3. If a Category V offender declines treatment or will not be in the facility at least 12 more months, the offender will be entered into the HCV spreadsheet as a Category III offender with an explanatory note as described above. The offender will not be provided additional testing, but will continue to be monitored and referred to community resources for post-discharge care as appropriate.
4. If additional testing of a Category V offender reveals that the stage of fibrosis or cirrhosis is F3, F4, or F2 with rapid progression, the provider will review relevant information and visit with the offender to provide education regarding healthy lifestyle choices, make determinations relating to diagnosis and treatment potential, and assess criteria for treatment.
 - a. The provider will identify:
 - 1) alternative causes of liver disease;
 - 2) the extent of liver disease and, specifically, whether decompensated cirrhosis is present;
 - 3) any contraindications to medication therapy for HCV; and
 - 4) social and demographic characteristics that may lead the provider to either support or not support medication therapy aimed at HCV.
 - b. Offenders for whom medication therapy is contemplated will evidence characteristics consistent with the following **inclusion** criteria:
 - 1) the offender is well informed regarding the disease and proposed therapy;
 - 2) the offender is willing and competent to sign informed consent for treatment, or for youth, consent can be obtained from a parent, guardian, or facility administrator as for any other medical treatment;

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

- 3) previous treatment is documented (affects choice of drug and time of treatment);
 - 4) no evidence of HCV risk behavior or correctional issues in previous six months, including prison tattoos and illicit drug use;
 - 5) offender agrees to illicit drug screening at the provider's discretion before and during treatment;
 - 6) medical and mental health concerns have been addressed and corrected if necessary;
 - 7) offender is expected to attain reasonable benefit from treatment as indicated by improved quality of life or life span;
 - 8) priority will be given to offenders with advanced fibrosis stage 3-4;
 - 9) offenders less than or equal to stage 2 fibrosis will not be treated except with MRP permission for special considerations and/or rapid disease progression;
 - 10) treatment is usually indicated for HCVvirus +/-HIV+, HCVvirus +/-HEPB+, and nephrotic syndrome; however, this needs to be reviewed annually as evidence is changing the guidelines for HCV management as new drugs are approved.
- c. Offenders will likely not be provided treatment with medication if they evidence the following **relative exclusion** criteria, which are not punitive, but based on evidence of success of treatment; however, the decision will be reevaluated if the condition improves or the provider has other criteria to recommend treatment:
- 1) clinical signs of liver failure or decompensated cirrhosis, any history of ascites, variceal bleeding, hypersplenism, hepatic encephalopathy, etc. (it may be necessary to do further testing like EGD to R/O varices, U/S of spleen, serum ammonia);
 - 2) evidence shows that the virus can be cleared, but portal hypertension does not reverse;
 - 3) serious anemia of any cause (hemoglobin below 12g percent in men and below 11g percent in women) or bone marrow compromise indicated by neutrophils below 1500 or platelets below 100,000;
 - 4) creatinine clearance greater than the upper limit of normal (needs nephrology consult to clear);
 - 5) serious cardiac disease;
 - 6) serious cerebrovascular disease;
 - 7) poorly controlled thyroid disease;
 - 8) poorly controlled blood dyscrasias;
 - 9) poorly controlled cancer;
 - 10) poorly controlled seizures;
 - 11) poorly controlled diabetes mellitus (hemoglobin A1C > 8.5), except that this will not be a relevant exclusion factor for an offender who evidences effort to control diabetes through behaviors including diet and coming to insulin pass because treating HCV may improve diabetes management;
 - 12) presence of retinopathy;
 - 13) HIV infection with CD4 count <200 cells/ml or undergoing treatment for opportunistic infection (must have Infectious Disease consult);

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

- 14) other serious illness that is not well controlled;
 - 15) continuing or recent (previous six months) treatment of a serious mental disorder, especially including psychosis producing disorders or depressive disorders, unless clearance has been received from a psychiatrist and the offender will be followed during treatment;
 - 16) history of documented abuse of drugs or alcohol within the preceding 12 months, expectation that injection drug or alcohol use will resume upon release from incarceration or failure to successfully complete substance abuse therapy;
 - 17) pregnancy or refusal to avoid pregnancy during and for at least six months after cessation of therapy (two methods of birth control used simultaneously must be intended);
 - 18) history of non-adherence to medical therapy during the previous 12 months;
or
 - 19) inability to give informed consent.
5. Offenders who failed treatment with older, less effective regimens may be considered for retreatment. These offenders will be evaluated as above, except old records may replace repeat studies as appropriate.
 6. All offenders who are F3 and F4 will be offered appropriate pneumococcal vaccine per CDC guidelines.

D. Pre-Authorization Form for Medication Treatment

1. If the provider determines a Category V offender is an appropriate candidate for medication, the provider initiates the [*HCV Treatment Pre-Authorization Form*](#), filling out the appropriate portions of the form such as the provider summary, clinical requirements, and treatment recommendation.
2. Once the provider completes portions of the form, the chronic care nurse ensures the form is completed by gathering information from correctional and other staff and obtaining the offender's acknowledgment of offender readiness criteria. The chronic care nurse submits the completed form to a managed care nurse at CorMedical@mt.gov.
3. The managed care nurse reviews the form, in consultation with the medical director as appropriate, to ensure it is complete and indicates a need for medication treatment. If necessary, the managed care nurse poses questions to the chronic care nurse and updates the form. The managed care nurse forwards the reviewed form to the MRP.
4. The MRP reviews the form. The MRP may request additional information, recommend additional diagnostic testing, recommend continued monitoring of the patient, or forward the form to MPQH.
5. If MRP does not forward the form to MPQH, the provider may appeal.

E. MPQH Review

1. MPQH reviews the form submitted to it and recommends:

Subject: HEPATITIS C VIRUS (HCV) TREATMENT

- a. drug regimen approval as submitted;
 - b. drug regimen approval subject to additional evidence-based clinical requirements; or
 - c. denial with supporting clinical rationale.
2. The managed care nurse communicates the MPQH recommendation to designated facility nursing staff. If MPQH has recommended a drug regimen, the managed care nurse confirms MPQH-approved medications for the provider to prescribe.

F. Other Treatment Considerations

1. Treatment will be individualized, in consultation with the Department Medical Director, MRP, with pre-authorization review by MPQH, and at times involving an external Infectious Disease Specialist.
2. Each secure care facility will be responsible for initiating the treatment request, providing treatment, and monitoring during the treatment period. Following conclusion of treatment, continued monitoring, testing and data reporting by each facility is required. Each facility is responsible to submit required data to CorMedical@mt.gov.
3. Current HCV antiviral agenda all have a protocol including treatment plan, individualizing doses, duration, and testing. These protocols will be followed unless an infectious disease physician recommends adjustment.
4. The appropriate medication will be used, taking into consideration risk of side effects, length of treatment, genotype, cost, etc. All treatment will be Directly Observed Therapy.
5. All offender treatment issues and concerns will be directed to the offender's treating provider.
6. Offenders who are receiving HCV drug treatment will be monitored during treatment. The treating provider will:
 - a. monitor at appropriate intervals for CBC, creatinine, LFT, TSH, and high sensitivity HCV viral load;
 - b. assess for depression and other side effects at each visit;
 - c. follow-up as clinically indicated, usually every 1 – 4 weeks during active treatment; and
 - d. ensure the 12-week test of cure (SVR 12) is performed and results submitted to CorMedical@mt.gov, to be forwarded by a managed care nurse to MPQH.
7. All treatment and monitoring related forms, information and data will be included in the offender's medical record.

V. CLOSING

Questions concerning this procedure should be directed to the Department Medical Director or the Clinical Services Division Medical Bureau Chief.

VI. REFERENCES

Subject: **HEPATITIS C VIRUS (HCV) TREATMENT**

- A. *53-1-203, MCA*
- B. *DOC Policy 4.5.11 Infection Control Program*

VII. ATTACHMENTS

[HCV Treatment Pre-Authorization](#)

[HCV Spreadsheet Template](#)

[Hepatitis C: Get the Facts](#)

[HIV and Hep C Presentation](#)

[HCV Algorithm](#)