

<b>STATE OF IOWA</b> <b>DEPARTMENT OF CORRECTIONS</b>  <b>POLICY</b> <b>AND PROCEDURES</b>		Policy Number HSP-912	Applicability <input checked="" type="checkbox"/> DOC <input type="checkbox"/> CBC
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Chapter 6 HEALTH SERVICES	Sub Chapter INFECTION CONTROL	Related DOC Policies N/A	Administrative Code Reference N/A
Subject HEPATITIS C MANAGEMENT		ACA Standards 5-ACI-6A-15	Responsibility Dr. Jerome Greenfield
		Effective Date November 2020	Authority Beth Skinner Director Signature on file at Iowa DOC

**I. PURPOSE**

To ensure appropriate management and treatment of patients infected with the Hepatitis C virus (HCV) in the Iowa Department of Corrections (IDOC).

**II. POLICY**

It is the policy of the IDOC to identify patients with HCV, monitor the disease, and treat with Direct Acting Antiviral (DAA) agents.

**III. DEFINITION** - See IDOC Policy **AD-GA-16** for Definitions. See **Appendix 1** for list of abbreviations.

**IV. PROCEDURE**

A. The Hepatitis C Committee (The Committee)

The Committee shall consist of the IDOC Health Services Administrator, DOC Medical Director/designee, DOC Nursing Administrator, two staff physicians, three Nursing Directors, and a DOC Pharmacy Supervisor.

1. The Committee shall establish the clinical guidelines for management of Chronic Hepatitis C (CHC).
2. The Committee maintains the Hepatitis C Clinical Case Registry (HCV-CCR), an electronic database composed of all patients in IDOC with a "Current" diagnosis of CHC in ICON Medical. The registry tracks patient specific data including age, institution, date of admission, MPD, TDD, laboratory testing (AST, platelet count, and APRI), fibrosis staging, treatment status, and other relevant management information. The HCV-CCR database will be refreshed with updated data every 6 months.
3. The Committee shall meet quarterly and review the updated HCV-CCR for the following:
  - a. Liver fibrosis staging results.
  - b. Patients with cirrhosis.
  - c. Appropriate candidates to start DAA treatment.
  - d. Patients receiving DAA treatment.
  - e. Treatment outcomes.

B. Screening for HCV Infection

1. At intake, all patients shall be offered screening with HCVAB antibody immunoassay (with reflex to RNA by PCR) viral detection.
2. Patients may refuse the HCVAB testing. Information about the indications for testing shall be reviewed with the patient by the institutional medical provider or designee and a treatment refusal shall be signed.
3. At intake, patients readmitted to the IDOC who had a prior negative HCVAB screen shall be offered repeat screening. Patients readmitted to IDOC who had a prior positive HCVAB screen without RNA testing shall be offered HCV RNA viral detection testing.

C. Hepatitis C Diagnosis

1. Patients with detectable HCV RNA by PCR shall have a "Current" diagnosis of Hepatitis C.
2. All patients in IDOC with positive HCVAB testing shall be tested with HCV RNA by PCR virus testing. Patients with positive HCVAB without confirming HCV RNA testing shall have a "Current" diagnosis of Hepatitis C until ruled out with HCV RNA virus testing.

D. Clinical Guidelines for the Management of Chronic Hepatitis C

1. Baseline Labs. Patients with a new diagnosis of Hepatitis C shall have, at a minimum, CBC, CMP, HIV, INR, Hepatitis B surface antigen, and Hepatitis B core antibody performed. Additional laboratory testing may be ordered as clinically indicated.
2. All patients with a Current diagnosis of Hepatitis C shall have at a minimum:
  - a. A targeted History and Physical by a medical provider annually.
  - b. CBC and CMP annually.
  - c. INR in all patients with thrombocytopenia (Plts < 140k) or clinical diagnosis of cirrhosis.
  - d. An order for immunization for Hepatitis A and B if indicated.
  - e. Baseline liver fibrosis staging by liver elastography unless other staging tests such as liver biopsy, magnetic resonance imaging or computerized tomography done in past 12 months.
3. Counseling – Healthcare staff shall provide education and written information on lifestyle changes to avoid transmission and reduce progression of HCV infection; potential health complications of HCV infection; how CHC is managed and treated in the IDOC. Nurse encounter for *Patient Education Hepatitis C Frequently Asked Questions (HSF-912 F-3)*
4. At intake, nonspecific and transitory elevations of LFT's are often seen. These are usually the residual of alcohol and drug use and

lifestyle not solely the result of liver inflammation from HCV infection. If LFT's on intake are elevated, the test shall be repeated within 6 months or sooner as clinically indicated.

5. For patients with established diagnosis of cirrhosis, an ultrasound of the liver shall be obtained every 6 months for surveillance for hepatocellular carcinoma.

E. Selection for Treatment

1. The Committee shall assess each patient in the HCV-CCR to identify those at greater risk of complications and/or greater need for treatment. Patients shall be selected from the HCV-CCR as candidates for treatment if they meet any of the following criteria:
  - a. Metavir Fibrosis Stage 2 or greater on liver elastography or other staging tests such as liver biopsy, magnetic resonance imaging, or computerized tomography.
  - b. Patients with cirrhosis.
  - c. Patients with HIV coinfection.
  - d. Liver transplant patients.
  - e. Comorbid liver disease such as Hepatitis B virus infection, autoimmune hepatitis, hemochromatosis or non-alcoholic fatty liver disease.
  - f. Extra-hepatic manifestations of CHC such as cryoglobulinemia or renal insufficiency (GFR<60).

F. Screening for Treatment

1. Patients selected as candidates for treatment shall be further screened by the facility provider or designee using established exclusionary criteria in *HCV Treatment Screening Questionnaire (HSF-912 F-1)*.
2. Patients with the following contraindications shall not be considered for treatment:
  - a. Hypersensitivity to treatment agents
  - b. Hospice or life expectancy < 1 year

- c. Insufficient time to complete treatment. Facility provider shall obtain information from the patient's counselor with respect to any forthcoming parole review or other plans for discharge.
3. Treatment shall be "Deferred" if any of the following conditions apply:
  - a. Pregnancy
  - b. Pattern of noncompliance with medications, appointments or treatments within past 6 months.
  - c. Substance abuse incidents within past 12 months.
  - d. Documented incidents of high risk behavior for HCV in prison, including tattoos, within past 12 months.
  - e. Serious Mental Illness unless cleared by psychiatrist.
  - f. Serious concurrent medical conditions that may interfere or cause disruption of treatment with DAA's.
  - g. Current chemotherapy or radiation treatment for malignancy.
4. If the patient is excluded for treatment for any of the above reason, treatment will be "Deferred" and this information entered into the HCV-CCR. Patients who are Deferred shall be reviewed again for treatment no later than the following fiscal year.
5. Appeal Rights – The facility provider or designee shall meet with the patient to discuss the Committee's decision to Defer treatment. The patient shall be informed that they may appeal this decision by following the standard grievance process.
6. Informed consent – If the patient has no condition that would disqualify for treatment, the facility provider or designee shall review and obtain signed consent for treatment **(HSF-912 F-2)**.
7. Treatment Refusal - If a patient refuses treatment, the facility provider or designee shall obtain signed refusal **(HSF-912 F-2)**. This information shall be entered into the HCV-CCR. Patients who Refused shall be reviewed again for treatment no later than the following fiscal year.

#### G. Pre-Treatment Testing

Prior to DAA treatment, all patients must have the following required testing completed:

1. Laboratory tests (within past 6-12 months) – Hepatitis C Viral RNA Quantitative Real-Time PCR, Hepatitis C Genotype, Hepatitis B Core Antibody Total, Hepatitis B Surface Antigen, ANA, HIV, BMP, TSH, Ferritin, CBC and INR. NS5A resistance testing may be needed if indicated by HCV GT.
2. Liver ultrasound within the past year in patients with cirrhosis.
3. Refusal - If a patient refuses any of these tests, the facility provider or designee shall have the patient sign a Treatment Refusal (**HSF-305**) in ICON Medical. The Committee shall designate in the HCV-CCR that the patient "Refused". Patients who refused shall be reviewed again for treatment no later than the following fiscal year.

#### H. Pharmacy Clearance

The Committee shall review patient's medications in ICON Medical for currently prescribed medications with known hepatotoxicity and significant drug interactions with recommended DAA treatment. This information will be shared with prescribing provider with instructions to modify medication orders accordingly.

#### I. Starting Treatment

1. Once approved to start DAA therapy, The Committee shall select the appropriate DAA treatment option indicated by the AASLD based on key laboratory results and the clinical characteristics of the patient.
2. Treatment shall not be interrupted prior to and upon entry into the IDOC unless the provider believes that continued treatment is not in patient's best interest.
3. Hepatitis C patients in the IDOC may qualify for 340B medication coverage:
  - a. Prior to starting treatment under this program, patients shall receive an IDPH approved sexual service within the scope of the IDPH STD grant (cooperative agreement) which shall be

documented in the ICON Medical. Examples include but are not limited to: conducting a sexual history with the patient (**HSF-912 F-5**), testing (and treating if appropriate) for STDs (e.g., chlamydia, syphilis, gonorrhea) or STD risk reduction counseling. IMCC and ICIW receive in-kind support from the CDC STD cooperative agreement via the provision of chlamydia/gonorrhea test kits made available for patients at the two sites.

- b. Treatment shall be ordered by IDOC Medical Providers under the supervision of the IDOC Medical Director/designee; the IDOC Medical Director/designee is a medical provider with prescribing authority who has direct affiliation with the two STD 340B covered entities listed on the HRSA 340B OPAIS website—IMCC and ICIW.
  - c. Once documentation of the sexual health service and related HCV follow up is made in the ICON Medical, all patient HCV medications shall be provided by IDOC Pharmacies from supplies ordered through the 340B PPV Program. 340B medication supplies shall be maintained separately from all other IDOC medication inventories and used only for patients deemed eligible via the HRSA STD 340B designation.
4. Monitoring of Treatment (Example is for typical 12 week regimen)
- a. Medical provider encounter, CBC, LFT's, and HCV RNA at 4 weeks into the treatment, repeat HCV at 6 weeks if detectable. If still detectable at 6 weeks, discontinue therapy.
  - b. Medical provider encounter, CBC, and LFT's at 8 weeks into treatment.
  - c. Medical provider encounter, CBC, and HCV RNA at 12 weeks into the treatment.
  - d. Refusal. If a patient refuses any of these tests, the facility provider or designee shall have the patient sign a Treatment Refusal (**HSF-305**) in ICON Medical. The Committee shall designate in the HCV-CCR that the patient "Refused". Patients who refused shall be reviewed again for treatment no later than the following fiscal year.

5. Post-treatment
  - a. HCV RNA 12 weeks following completion of treatment.
  - b. Negative SVR-12 HCV results shall be considered a successful treatment of CHC and the diagnosis of Hepatitis C moved to "Resolved" in ICON Medical.

## Appendix 1

AASLD	American Association for the Study of Liver Disease
ALT	alanine aminotransferase
ANA	antinuclear antibody
APRI	AST to Platelet Ratio Index
AST	aspartate aminotransferase
BMP	Basic Metabolic Panel
CBC	complete blood count
CHC	Chronic Hepatitis C
CMP	Comprehensive Metabolic Panel
DAA	direct acting antiviral medication/direct acting antiviral medication
ESRD	end-stage renal disease
GFR	glomerular filtration rate
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCVAB	HCV antibody
HIV	Human Immunodeficiency Virus
INR	International Normalization Ratio
LFT's	liver function tests
NS5A	Nonstructural protein 5A
PCR	polymerase chain reaction (PCR)
RNA	ribonucleic acid
SOF	sofosbuvir
SVR	sustained virology response
SVR-12	absence of detectable virus 12 weeks after treatment
TSH	thyroid stimulating hormone