State of Iowa Department of Corrections
Policy and Procedures

Policy Number: HSP-912
Applicability: DOC
Policy Code: Public Access
Iowa Code Reference: N/A
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
PREA Standards: N/A
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Effective Date: January 2024
Authority:

1. PURPOSE

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

2. POLICY

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

3. DEFINITIONS:

A. Hepatitis C - A liver infection caused by the hepatitis C virus, which is spread through contact with blood from an infected individual, and is the most common chronic blood borne infection in the United States.

B. Cirrhosis - For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 SCORE >3.25 or any of the following:

a) Transient Elastography (FibroScan) score of >12.5 kPa

b) Other known noninvasive serological tests indicating cirrhosis

c) Clinical evidence of cirrhosis

d) Prior liver biopsy showing cirrhosis

C. Compensated Cirrhosis - For the purpose of this guidance, a patient is considered to have compensated cirrhosis if they meet the definition of cirrhosis (see above III.B), have a Child-Turcotte-Pugh (CTP) score < 7, and do not have clinical signs or symptoms of decompensated cirrhosis.

D. IDOC Policy **AD-GA-16** for additional definitions. See **Appendix 1** for list of abbreviations.

4. PROCEDURE

A. The Hepatitis C Committee shall consist of the following:

- IDOC Health Services Administrator
- IDOC Nursing Administrator
- One IDOC Pharmacy Supervisor
- Two staff providers
- Two Nursing Directors

1. The Committee shall establish the clinical guidelines for management of Chronic Hepatitis C (CHC).

2. The Committee maintains the Hepatitis C Virus Clinical Case Registry (HCV-CCR), which identifies all IDOC patients with a current Hepatitis C diagnosis.

3. The Hepatitis C Committee shall meet quarterly to update the HCV-CCR regarding the following:

    a. Newly diagnosed Hepatitis C patients

    b. New intake Hepatitis C patients

c. Transient Elastography (FibroScan) Scores

d. AST to Platelet Ratio Index (APRI) Scores

e. Relevant changes to patient history that may impact treatment eligibility (ex: new medical diagnoses, clinical changes, change in discharge date, etc)

f. Identify eligible patient for starting Direct-acting antiviral (DAA) therapy.

g. Review patients actively receiving DAA therapy.

h. Review outcomes of patients who have recently completed DAA therapy.

B. Screening for HCV Infection

1. HCV-antibody with reflex HCV RNA should be offered to the following individuals:

    a. All intake patients.

    b. Patients readmitted to IDOC who were previously HCV negative.

2. HCV RNA screening shall be offered to the following individuals:

    a. Intake patients with prior positive HCV-antibody without a documented HCV RNA.

    b. Intake patients who have been previously treated for Hepatitis C (to rule out reinfection).

3. If patients refuse HCV-antibody or HCV RNA screening then information about the indications, risks, and benefits for screening shall be reviewed with the patient by the institutional medical provider or designee and a treatment refusal shall be signed.

C. Hepatitis C Diagnosis - The diagnosis of Hepatitis C is made based on a reactive HCV-antibody <u>and</u> a detectable HCV RNA.

1. Patients found to have a diagnosis of Hepatitis C should have Hepatitis C added to their electronic medical record under "current diagnoses."

2. If HCV-antibody is reactive without a documented HCV RNA, then HCV RNA should be ordered to confirm or rule out Hepatitis C. A diagnosis of Hepatitis C should be added under "current diagnosis" until results are confirmed.

3. If HCV-antibody is reactive and HCV RNA is undetectable, then the patient would not have an active diagnosis of Hepatitis C*. These patients should not have a diagnosis of Hepatitis C under "current diagnosis."

   *In certain situations (i.e. suspected HCV exposure within past 6 months, clinical evidence of Hep C disease, concerns regarding handling or storage of test specimen), follow up HCV RNA may be considered. See CDC recommendations for additional guidance.

D. Clinical Guidelines for the Management of Chronic Hepatitis C

1. Baseline labs for patient with new diagnosis of Hepatitis C

   - CMP (LFT's and BMP)
   - CBC
   - INR
   - HIV
   - Hepatitis B surface antigen
   - Additional labs as clinically indicated

2. All patients with a Current diagnosis of Hepatitis C shall receive at minimum:

   a. Annual medical provider encounter, to educate patient about Hepatitis C, and to evaluate for signs and symptom of worsening liver disease.

   b. Annual Labs

- CMP (LFT's and BMP)
- CBC
- Additional labs as clinically indicated.

c. Immunization for Hepatitis A and B if indicated.

d. Baseline liver transient elastography (FibroScan).

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. If LFT's on intake are significantly elevated, the test may 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

All patients with a *current* diagnosis of Hepatitis C are eligible for direct acting antiviral therapy. The large volume of Hepatitis C patients prevents the IDOC from treating all patients simultaneously. Therefore, the DOC will review the HCV-CCR quarterly and determine those patients most in need of therapy based on the following.

1. Medical comorbidities
2. Clinical presentation
3. Transient elastography score (Fibroscan)
4. Laboratory results

F. Pretreatment Assessments

1. Patients selected as candidates for Hepatitis C treatment will require a pretreatment assessment prior to starting therapy.

2. Patients **without cirrhosis**, based on a transient elastography (FibroScan) score of ≤ 12.5 kPa, shall be assessed using pretreatment assessment **HSF-912 F1a**.

3. Patients **with presumed cirrhosis**, based on a transient elastography (FibroScan) score of >12.5 kpa, shall be assessed using pretreatment assessment **HSF-912 F-1b**.

4. Patients within the IDOC may qualify for 340 B medication pricing. Patients should therefore have an IDPH approved sexual history screen (HSF-912 F-5) performed, which shall be documented within Medical Icon. Patients should receive further STD testing and treatment, if clinically indicated, based on results.

5. Informed consent- If a patient is considered to be eligible for treatment, then the facility provider or designee shall review and obtain singed consent **(HSF-912 F-2).**

6. Patients found to be **not eligible** for treatment, based on the pretreatment assessment, shall be reviewed by the Hepatitis C Committee.

    a. Patients found to be **not eligible** for treatment following a Hepatitis C Committee review shall be considered "deferred" and this information shall be entered into the HCV-CCR.

    b. These patients shall be reviewed quarterly to determine if their eligibility status has changed.

    c. 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.

7. Treatment Refusal - If a patient refuses treatment, the facility provider or designee shall obtain signed refusal **(HSF-912 F-2)**.

    a. This information shall be entered into the HCV-CCR.

    b. Patients who refuse therapy shall be reviewed quarterly to determine if their status has changed.

c. A patient may determine that they do not want to be reassessed quarterly for treatment, and this should be documented within their treatment refusal.

G. Treatment

1. Upon completing the *pretreatment assessment*, the primary provider will inform the Hepatitis C Committee of the pretreatment assessment findings.

2. A treatment regimen will be selected by the Hepatitis C Committee following completion of the *pretreatment assessment*, and taking into consideration the patient's medical history, HCV genotype, and potential for resistance to therapy.

3. The Hepatitis C Committee shall assist in reviewing patient medications in ICON Medical to help with identifying significant drug interactions with recommended DAA treatment. This information will be shared with prescribing provider, with instructions to modify medication orders accordingly.

4. Patients already receiving Hepatitis C antiviral therapy, upon entry into the DOC, shall not have therapy interrupted unless a specific medical indicated is identified.

H. Monitoring of Treatment - Following a *pretreatment assessment*, eligible patients will be categorized into two treatment categories and monitored as outlined below. The definition of *cirrhosis* and *compensated cirrhosis*, as it pertains to this guidance, can be found above (Definitions; section III-2 and III-3).

1. Treatment-Naive Adults **Without** Cirrhosis

a. Monitoring During Treatment

1) Patients taking diabetes medication should be informed of the potential for symptomatic hypoglycemia, and monitoring for hypoglycemia is recommended as clinically indicated.
2) Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for

subtherapeutic anticoagulation is recommended as clinically indicated.

3) A medical provider or nursing encounter may be scheduled for patient support, assessment of symptoms, or if starting new medications as clinically indicated.

4) No additional laboratory monitoring is required during time of treatment.

b. Post-Treatment Assessment of Cure

1) **HCV RNA and LFT's** should be performed **12 weeks following completion** of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.

2) Assessment for other causes of liver disease is recommended for patients with elevated transaminases after achieving sustained virologic response (SVR).

c. Follow-Up After Achieving Sustained Virologic Cure (SVR)

1) No liver-related follow up is required for non-cirrhotic patients who achieve SVR.

2) Patients should be counseled about measures to reduce the risk of Hepatitis C reinfection and to avoid the future use of excessive alcohol.

d. Follow-Up for Patients Who Do *Not* Achieve Virologic Cure

1) Patient should be evaluated for retreatment by a specialist in accordance with AASLD/IDSA guidelines.

2) Patients should receive assessment for disease progression **every 6 months to 12 months** with **LFT's, CBC,** and **INR** until retreatment occurs.

2. Treatment-Naïve Adults **With Compensated** Cirrhosis

a. Monitoring During Treatment

1) **CBC, LFT's, and BMP** (monitoring Cr) should be ordered **monthly** while receiving HCV antiviral treatment.

2) A **medical provider encounter** should be performed **monthly** while receiving HCV therapy to monitor for liver injury (jaundice, abdominal pain, ascites, etc.).

3) Patients taking diabetes medication should be informed of the potential for symptomatic hypoglycemia, and monitoring for hypoglycemia is recommended as clinically indicated.

4) Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended as clinically indicated.

b. Post-Treatment Assessment of Cure

1) **HCV RNA and LFT's** should be performed **12 weeks following completion** of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.

2) Assessment for other causes of liver disease is recommended for patients with elevated transaminases after achieving sustained virologic response (SVR).

c. Follow-Up After Achieving Sustained Virologic Cure (SVR)

1) Patients should be counseled about measures to reduce the risk of Hepatitis C reinfection and to avoid the future use of excessive alcohol.

2) Patients with a diagnosis of cirrhosis should continue to receive regular monitoring and management of cirrhosis as clinically indicated.

d. Follow-Up for Patients Who Do *Not* Achieve Virologic Cure

1) Patient should be evaluated for retreatment by a specialist in accordance with AASLD/IDSA guidelines.

2) Patients should receive assessment for disease progression **every 6 months to 12 months** with **LFT's, CBC, BMP (monitoring Cr),** and **INR** until retreatment occurs.

3) Patients with a diagnosis of cirrhosis should continue to receive regular monitoring and management of cirrhosis as clinically indicated.

3. Patients who refuse recommended monitoring shall have a Treatment Refusal **(HSF-305)** signed and scanned into ICON Medical. The primary medical provider and the Hepatitis C Committee may review refusals on a case by case basis to determine if the patient may proceed with therapy or if the therapy requires discontinuation.

Appendix 1

AASLD	American Association for the Study of Liver Disease
ALT	alanine aminotransferase
ANA	antinuclear antibody
APRI	AST to Platelet Ratio Index
AST	apartate 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	sofusbuvir
SVR	sustained virology response
SVR-12	absence of detectable virus 12 weeks after treatment
TSH	thyroid stimulating hormone