TDOC HCV Treatment Workflow

Based on the AASLD and IDSA Simplified HCV Algorithm for Treatment-Naïve Adults

Intake/New HCV Diagnosis/Pre TACHH Review- HCV RNA positive — HepCOR Status New Dx

1. Labs/diagnostics to be completed within 90 days of new diagnosis (HCV RNA Positive)
   a. CBC—CMP—INR—AFP—Genotype—HIV—HBV Panel (Surface Antigen, Surface Antibody, Core Antibody)—FibroSure—FibroScan—Ultrasound for F Stage 3 and 4
      i. **Any lab that does not have results must be redrawn every eight weeks until it is obtained.**
   b. The inmate will be placed in the HCV CCC, including VL, CBC, CMP, INR, FibroSure, and FibroScan every six months; US every six months if the inmate is cirrhotic (F Stage 4). **FibroSures and FibroScans are not needed once an inmate is determined to have a Fibrosis stage of F4.**
   c. Any diagnostic can be ordered at any time per the provider's discretion.
2. The provider or nursing designee must get the CR-3869 HCV Inmate Counseling and CR-3870 (Rev. 07-23) HCV Treatment Consent/Agreement forms signed and filed in the Medical Record before treatment.
   a. Education regarding the teratogenic effects of ribavirin should be given to both male and female inmates of childbearing age.
3. CR-1984 Refusal of Medical Services must be completed any time an inmate refuses any diagnostic service, consult/referral, or provider visit before starting treatment; **HepCOR Status Refused,** details in Status Comment **(refusal of US or FibroScan is not a refusal of treatment if all labs are complete; note refusal in Status Comment).**
   a. A refusal should document that the inmate understands that declining any part of the TACHH evaluation or treatment process prevents them from receiving HCV treatment; that untreated HCV may progress and lead to irreversible organ damage and death; that the refusal may be rescinded at any time; and that all required diagnostics, referrals, and recommendations must be completed or repeated before treatment can proceed.
   b. Inmates are to remain in HCV CCC with an offer of treatment every six months; if continuing to refuse treatment a new CR-1984 is to be completed.
4. Once all needed data is entered into HepCOR and Counseling and Consent forms are signed, change **HepCOR Status to Eligible**.

Post-TACHH Committee Evaluation

1. The HCV Treatment Coordinator or designee will send the completed TACHH Consultation Report to the site's HSA, Infection Control Nurse, site Medical Director, or designated provider.
2. The printed consultation report will be presented to a provider for review, and orders must be written within 72 hours of receipt at the site.
   a. A negative pregnancy test for female inmates is required immediately prior to initiation of therapy.

   i. If the inmate is prescribed ribavirin, the initial pregnancy test must be a serum pregnancy test. In addition, urine pregnancy testing is required monthly during therapy and for six (6) months after completion of treatment. (FDA-approved prescribing information for ribavirin)
   ii. Treatment must be held if the pregnancy test is positive, and the patient should be referred to OB/GYN.
b. If medication cannot be started within **15** days of receipt of the consultation report, the HCV Treatment Coordinator, Central Pharmacy, and vendor-appropriate Regional Medical Director will be notified via email.
c. All consults recommended to facilitate treatment are to be ordered as urgent.
   i. Refusing a needed consult is considered refusing treatment (refer to Intake section; step 3).

Treatment Stage HepCOR Status On DAA Tx

1. Inmate to be seen by a provider at the 2-week mark to evaluate for any compliance issues or complaints.
   a. Inmate to be seen any time changes are made to medication regimen.
2. Unless the recommendations per the TACCH Committee differ,
   a. Draw a CBC, CMP, and HCV RNA Quantitative (VL) at the **4, 7, and 11-week mark** while on treatment.
      i. Follow recommendations on the TACHH Consultation Report based on lab results.
3. Notify the HCV Treatment Coordinator if there are any questions about how to proceed.

Post HCV Treatment- HepCOR Status **Completed DAA Tx**

1. HCV VL to be drawn 12 weeks after treatment is completed.
   a. VL <12 (PLS) or <15 (Quest), make **HepCOR Status SVR**.
      i. Discharge from HCV CCC; F stage 3 and 4 place in Cirrhosis CCC. If RNA is positive, redraw VL in 8 weeks and make **HepCOR Status <12.**
   b. VL positive, make **HepCOR Status Failed Treatment**: CBC, CMP, INR, FibroSure and Genotype, US if pt is F Stage 3 or 4; pt to remain in HCV CCC (refer to Intake section, step 1b).
      i. Once labs are updated, note Eligible and the date in the Status Comment.
   c. If the genotype is different, change **HepCOR Status to Reinfected:** UDS, HIV, HBV panel, and a referral to BH due to HCV reinfection; pt to remain in HCV CCC (refer to Intake section, step 1b).
      i. BH will evaluate for needs related to barriers to successful treatment, including SU evaluation.
      ii. Once labs are updated, note Eligible and the date in the Status Comment.

TDOC Cirrhosis Chronic Care Clinic Guidelines

1. **F3**- Inmates may be discharged from Cirrhosis CCC when their Fibrosis Stage improves to F2 or better, except for those with HIV or HBV.
    a. Q 6-month CCC visit with Annual labs: CBC, CMP, INR, AFP, FibroSure
        i. If LFTs elevated HCV Qualitative.
        ii. If AFP elevated Ultrasound.
        iii. FibroScan per provider discretion.
2. **F3 with HIV and chronic HBV**- Inmates with comorbidity of HIV and HBV will remain in Cirrhosis CCC regardless of Fibrosis Stage improvement while in TDOC custody.
    a. Q 6-month CCC visit with q 6-month labs: CBC, CMP, INR, AFP, FibroSure
        i. If LFTs elevated HCV Qualitative.
        ii. If AFP elevated Ultrasound.
        iii. FibroScan per provider discretion.
3. **F4**- Inmates will remain in Cirrhosis CCC while in TDOC custody.
    a. Q 6-month CCC visit with q 6-month labs: CBC, CMP, INR, AFP, FibroSure
        i. If LFTs elevated HCV Qualitative.
        ii. If AFP elevated Ultrasound.
        iii. FibroScan per provider discretion.
    b. Ultrasound annually.

TDOC HCV Diagnostic Testing Protocol

Diagnostic Tests that may be ordered per this protocol.

- CBC—CMP—INR—Hepatitis Panel—HCV Quantitative (VL)—Genotype—HIV—HBV Panel (Surface Antigen, Surface Antibody, Core Antibody)—FibroSure—AFP—Pregnancy (female only)—FibroScan—Urine Drug Screen—NS5A RAS (if requested per TACHH)

The following is a timeline for specific diagnostic tests; however, tests may be ordered anytime. Any lab that does not result must be redrawn every eight weeks until obtained.

Intake/New HCV Diagnosis/Pre TACHH-Review- Within 90 days of Positive HCV RNA

- CBC—CMP—INR— HCV Quantitative (VL)—Genotype—HIV—HBV Panel (Surface Antigen, Surface Antibody, Core Antibody)—FibroSure—AFP—Pregnancy (female only)—Abdominal Ultrasound— FibroScan

Every six months. If not treated

- CBC—CMP— HCV Quantitative (VL) — INR— FibroSure— FibroScan

Within three days of receipt of the TACHH Recommendation Report

- Serum Pregnancy Test must be done before starting HCV tx.
- Only need to be ordered if indicated by the recommendation.
  - CBC—CMP—INR— HCV Quantitative (VL)—Genotype—HIV—HBV Panel (Surface Antigen, Surface Antibody, Core Antibody)—FibroSure—AFP—Abdominal Ultrasound—NS5A RAS—FibroScan

Treatment Stage

- CBC—CMP—HCV Quantitative (VL) at 4-week, 7-week mark and 11-week mark
  - If ribavirin started, CBC at 2-week mark, then q 4 weeks; if HGB less than 10, but more than 8, make CBC q 2 weeks; if HGB less than 8, hold Ribavirin and notify HCV Tx Coordinator.

Post HCV Treatment

- HCV Quantitative (VL)—to be done 12 weeks post-treatment.
  - VL <12, RNA Negative- Status = SVR
  - VL <12 but RNA remains positive- Status = <12
    - Recheck VL in 6 weeks.
  - VL >12/15-
    - ASAP draw CBC, CMP, INR, and Genotype repeat genotype q 8 weeks until obtained.
  - New Genotype- Status = Reinfected
    - Draw HIV and HBV panels and make a BH referral.

TDOC HCV Related FibroScan Guidelines

Orders may be written by a provider or per TDOC HCV Diagnostic Testing Protocol

1. FibroScan is to be ordered anytime an inmate is diagnosed with HCV.
2. FibroScan is to be ordered every six months until the inmate is treated for HCV and achieves SVR.
3. FibroScans may be ordered at the provider's discretion after the inmate achieves SVR.