WCHS/ Twelve Clans Unity Hospital

Hepatitis C Treatment Protocol

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Hepatitis C Clinic Provider: Date

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Table of Contents

Rationale/Statement of Need

Hepatitis C (HCV) is an infectious disease with a substantial impact on quality of life. HCV progression may require hospitalizations, and if left untreated, may lead to chronic liver failure, cirrhosis or hepatocellular carcinoma. In efforts to prevent or delay patients from developing chronic liver failure, cirrhosis or hepatocellular carcinoma, treatment options should be implemented and monitored.

According to the Centers for Disease Control and Prevention, in 2016, the rate of HCV infection was 1.0 per 100,000 which has increased from previous years. The highest rates of acute hepatitis C infections are found among American Indians/Alaska Natives.

In September 2021, there were 240 patients tested for chronic HCV within the WCHS/ 12 Clans Unity Hospital, with 24 (10 percent) of those found to have an active infection that is untreated. It is estimated that these numbers are higher given the lower screening rates at the facility. Currently, patients are screened for HCV only if they are thought to be at risk and therefore screening rates are not at goal. Increased screening and treatment of HCV will greatly improve the health of the community by decreasing transmission rates as well as disease progression.

Treatment may include medication(s), laboratory monitoring, and/or vaccination for other types of hepatitis. Utilization of a pharmacist-managed, protocol-driven HCV service will accomplish both improved patient outcomes and reduced provider workload while expanding clinical services in a financially responsible manner.

Objectives and Goals

Objectives

- Implement improvement initiatives designed to promote the Centers for Disease Control (CDC), American Association For The Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) treatment and recommendations for patients with HCV
- Improve medical care and education of patients hospitalized, discharged, and/or followed in an outpatient setting with a diagnosis of HCV
- Achieve a SVR, defined as undetectable HCV RNA in the blood 12 or more weeks after completing antiviral treatment

Goals

- Treat all patients with HCV and to provide appropriate medication therapy with collaboration with a primary care provider and specialist
- To decrease provider workload and expand clinical pharmacy services
- To collaborate and determine the appropriateness of therapy with the Primary Care Provider (PCP), Project ECHO HCV specialists and other designated practitioners to

provide care of Hepatitis C patients based on current evidence and guidelines for patients with HCV
- Reduce the number of patients that develop end stage liver disease, cirrhosis, hepatocellular carcinoma or liver failure due to HCV
- Measure meaningful outcomes from the management of HCV including: percentage of patients who engage in care, begin treatment, complete treatment, respond to treatment, achieve SVR, do not respond to treatment, and stop therapy due to side-effects
- Vaccinate patients with Hepatitis A and B series where indicated
- Educate patients on prevention, transmission, prognosis, and treatment to improve their individual physical, spiritual, and mental health
- Educate patients on interventions which can decrease the progression of liver fibrosis (weight control, abstinence from alcohol, etc)

Clinic Functions (Policy, Procedures, Referral)

- Patients may be referred by any provider who has completed the initial HCV clinical evaluation. Any patient testing positive for HCV (reactive antibody plus detectable viral load) may be referred to the pharmacy-managed clinic.
- Alternatively, patients testing positive may also be referred to the eAvera telehealth Gastrointestinal Provider instead of pharmacy clinic if patient needs specialized care or patient meets any contraindication criteria listed below.
- Clinic pharmacist or the PCP must complete initial HCV evaluation visit before treatment can begin. This includes ordering and reviewing appropriate lab values and possible contraindications for therapy.
- Contraindications include, but are not limited to:
    - Severe uncontrolled psychiatric disease
    - Currently on seizure or other medications known to interfere with HCV medications
    - Certain autoimmune disorders in which ribavirin or interferon are contraindicated
    - Severe uncontrolled endocrine disorders (diabetes, thyroid disease)
    - Serious uncontrolled concurrent medical diseases – severe hypertension, heart failure, coronary heart disease, COPD, diabetes, thyroid disease
    - Platelet count <75,000 or Hg<10.5 g/dl for ribavirin therapies (consult HCV specialist)
    - GFR<30 for ribavirin and sofosbuvir therapies
    - Failure to complete pretreatment evaluation
    - Pregnancy
- Patients with decompensated cirrhosis who require ribavirin therapy will be treated by eAvera HCV specialist.
- Prior to initiating therapy, patients must have viral load, genotype, liver fibrosis staging, liver ultrasound, and other pertinent labs (CBC, CMP, etc) documented for consideration of treatment.

- ***Outpatient Clinic Visits:***
  - Initial screening will be provided by a physician, mid-level practitioner, or telehealth provider. The primary care provider will refer appropriate patients to pharmacy for initiation of treatment and/or follow-up care. The following will be evaluated before referral to pharmacy to initiate treatment or follow-up with therapy:
    - Patients born from 1945 – 1965. Additionally, an initial screening for patients age 18 and above should be performed at least once regardless of risk factors.
    - Patients determined as high-risk for hepatitis c infection:
      - Patients who have ever injected illicit drugs
      - Patients that received clotting factor concentrates made before 1987
      - Patients that received blood transfusions or solid organ transplants before July 1992
      - Hemodialysis patients
      - HIV-positive individuals
      - Children born to mothers infection with HCV
    - HCV Pre-Evaluation:
      - If cirrhotic, exclusion of hepatocellular carcinoma based on appropriate imaging study within the prior 6 months
      - Previous HCV treatment history and outcome
      - Perform a medication interaction check; interactions will change as new studies are completed
    - Baseline Labs/screens:
      - HCV genotype (including subtype, e.g., 1a or 1b)
      - HCV RNA (quantitative viral load)
        - Detectable when treatment is being considered
        - Recent viral load within 60 days of treatment initiation
      - HIV status and, if HIV seropositive, current antiretroviral regimen and degree of viral suppression
      - CMP, CBC w/differential, alcohol, PT/INR, drug screen, lipid panel, iron panel, Fibrosure, and calculation of APRI and FIB-4
    - Women's Clinic: for women of childbearing age/potential
      - Negative HCG at initiation of treatment and every 4 weeks during treatment
      - Documented use of two forms of birth control in patient and sex partners in whom a ribavirin-containing regimen is chosen and for 6 months post treatment
    - Cardiac Evaluation
      - ECG/stress test if needed
    - Mental Health Evaluation

- ❖ PHQ9 at screening and periodically throughout treatment based on treatment regimen
- ❖ Refer to Behavioral Health for severe/uncontrolled mental health condition

- Initial Visit: the pharmacist is authorized to:
  - ❖ Order and interpret relevant lab results to determine appropriate initial therapy and duration of treatment for referred patients based on current treatment guidelines (AASLD and IDSA). Pharmacists will utilize the most up to date guidelines as recommendations change.
  - ❖ Assess liver function tests, substance use history, and readiness for treatment (PREP-C tool)
  - ❖ Provide needed vaccinations:
    - Hepatitis A, Hepatitis B, Influenza, and Pneumonia
  - ❖ Provide patient education to include: medications, disease state, adherence, drug interactions check
  - ❖ Perform limited physical assessments as needed
  - ❖ Assess the patient's current medical conditions; take past medical, family, social and medication histories; and provide disease state and medication education
  - ❖ Order, modify, or discontinue HCV medications as recommended by Project ECHO specialists
  - ❖ Submit all documents necessary for a prior authorization (PA) with patients whom have insurance to cover high costs of mediations.
  - ❖ Will attempt to enroll patients whom do not have insurance in available patient assistance program (PAP) to help cover cost of medications.
  - ❖ Document interventions in the electronic medical record
- ***Follow-up Visits:*** the pharmacist is authorized to:
  - Assess the patient's current medical conditions; take past medical, family, social and medication histories; and provide disease state and medication education
  - Order and interpret lab results to determine safety and effectiveness of ongoing therapy
  - Make changes to treatment regimen based on lab and physical exam results
  - Follow-up with patients in person or via telephone no more than 2 weeks after initiation of treatment to assess tolerance to side effects from medications and patient compliance

        - Monitor if patients request a refill for medications to ensure compliance with treatment plan
        - Document in the electronic medical record
    - ***Completion of Therapy***
        - The pharmacist will order HCV RNA viral load and other labs according to regimen
        - The pharmacist will order HCV RNA viral load to determine if SVR12 has been achieved (3 months post therapy)
        - The patient will be seen by the pharmacist to discuss lab results
        - The pharmacist will notify the referring provider of lab results
    - One year post-therapy:
        - ❖ The patient will be seen by the ordering provider for the one year post therapy follow-up visit
- ***Discharge Procedures***
    - Patients may be discharged from the service for any of the following reasons:
        - ❖ Failure to show up for two consecutive appointments
        - ❖ Failure to actively participate in treatment plan (medication, laboratory directions, avoidance of alcohol, avoidance of street drugs)
        - ❖ Attainment of treatment goals with completion of therapy and no detectible viral load
        - ❖ Failure to attain treatment goals due to either failed treatment response or changes in laboratory values that have resulted in discontinuation of therapy
    - Documentation of the discharge is made in the patient's chart along with a current treatment regimen
- ***Other relevant information***
    - Primary Care Provider may assist in the care of patients at any time during treatment
    - Pharmacists may consult referring provider or HCV specialist at any time during treatment
    - Pharmacists will administer the PHQ-9 depression screening at appropriate appointments (initial visit, every 4 weeks, and as indicated throughout treatment)
    - Total Score Depression Severity 1-4 Minimal depression 5-9 Mild depression 10-14 Moderate depression 15-19 Moderately severe depression 20-27 Severe depression
    - Provider will be notified of significant changes in score
    - If score is greater than or equal to 9, will notify primary care provider
- Clinical pharmacists and nurses will operate under the direction of the clinic protocol
- Pharmacist may administer AUDIT-C test to assess for alcohol use disorder at initial visits

- Follow-up appointment dates are recorded and given to each patient
- All patient visits will be documented in the patient's chart
- Pharmacists may administer required vaccinations during pharmacy visit
- Pharmacy students may routinely accompany pharmacists and may assist in the care of patients

Quality Assurance/Performance Improvement

• Performance improvement activities will be completed on a yearly basis. Quality indicators to be evaluated include:

- Documentation of Hepatitis A and B vaccination initiation or completion by clinic
- Labs ordered as instructed in protocol with regard to HCV treatment
- Documentation of percentage of patients completing prescribed therapy
- Documentation of screening rates of eligible patients
- HCV Cure rates (SVR12 acheived)

Outcome Studies

• The following outcomes were established prior to clinic's inception and will be reported to the clinic supervising physician and WCHS/12 Clans Unity Hospital P&T committee yearly:

- Total number of patients who have received treatment by pharmacy service
- Total number of patients who did not respond to treatment (SVR not achieved)
- Total number of patients who required discontinuation of treatment due to side effects or laboratory abnormalities (or refusal, noncompliance)
- Total reimbursement from clinic services
- Total number of patients who achieved SVR
- Total number of patients lost to follow-up

Clinical Staff Credentialing/Training

• Pharmacist credentialing will consist of a yearly performance review with the following types of continuing education in the management of HCV:

- Review of HCV treatment guidelines
- Pharmacist must demonstrate knowledge base in the management of HCV, including patient assessment skills, and the appropriate medications that may be utilized in treating HCV
- Pharmacists choosing to practice in the clinic will be required to have an understanding of the service protocol and complete a peer reviewed pharmacy competency assessment annually
- Completion of the training certification process will be documented and placed in the pharmacist's file in the pharmacy

Patient Education

• Patients enrolled in the HCV service will be provided education regarding treatment, monitoring, prevention, and lifestyle adaptations associated with a diagnosis of HCV. In addition, patients will be given patient education information. The following are patient education topics discussed with patients and included in patient information:

- Drug therapy including frequency of lab and office visits
- Compliance with therapy
- Adverse effects of drug therapy and steps to take to prevent or decrease occurrences
- Dietary recommendations
- General information concerning how patients live with a diagnosis of HCV and what possible complications one might expect
- Education on lifestyle concerns
- Patients may voluntarily participate in a support group to promote other forms of wellbeing

References

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