



Origination 01/2019
Last Approved 04/2024
Last Revised 06/2022
Next Review 04/2025

Owner Gary Elam: Chief Pharmacist
Policy Area Pharmacy

Pharmacy Hepatitis C Clinic Protocol

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.

Treatment may include medication(s), laboratory monitoring, diagnostic procedures and/or vaccinations. Utilization of a pharmacist-managed, protocol-driven Hepatitis C 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), Infectious Diseases Society of America (IDSA), and Extension for Community Healthcare Outcomes (ECHO) treatment guidelines and recommendations for patients with Hepatitis C
- Achieve a sustained virological response (SVR), defined as undetectable HCV RNA in the blood 12 or more weeks after completing antiviral treatment

Goals:

- Treat all patients with an active Hepatitis C infection that do not have a contraindication for treatment

- Reduce the number of patients that develop end stage liver disease, cirrhosis, hepatocellular carcinoma or liver failure due to Hepatitis C
- Reduce extrahepatic manifestations (renal, skin, lymphoma, etc.)
- Implement a patient care process based on current evidence and guidelines for patients with Hepatitis C
- Measure meaningful outcomes from the management of Hepatitis C 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 if indicated
- Educate patients on prevention, transmission, prognosis, and treatment to improve their individual physical and mental health
- Educate patients on interventions which can decrease the progression of liver fibrosis (weight control, abstinence from alcohol, etc)

Clinic Functions (Policy and Procedures) and Referral

Clinic Procedures:

- Clinic Visits
 - Patients may be referred by any Northeastern Tribal Health System provider once the patient has had a positive HCV antibody. Confirmatory labs (HCV RNA QNT) will be ordered to determine if the patient has an active infection
 - Pharmacist may complete initial HCV evaluation visit before treatment begins
 - The following will be evaluated prior to initiation of treatment or follow-up with therapy:
 - HCV Pre-Evaluation
 - If cirrhotic, exclusion of hepatocellular carcinoma based on appropriate imaging study within the prior 6 months
 - If performing the initial screening, pharmacist will consult with primary care provider to interpret imaging study
 - If cirrhotic, the patient will need an ultrasound every 6 months for the rest of their life for hepatocellular carcinoma surveillance and will need to follow-up with primary care provider
 - Previous HCV treatment history and outcome
 - Hepatitis A Antibody, CMP and CBC w/differential. If cirrhotic or if otherwise indicated, PT/INR, PTT, iron panel, Fibrosure, AFP, Vitamin D and liver ultrasound
 - Calculation of APRI and FIB-4 to assess liver fibrosis

- Contraindications to hepatitis C therapies will be according to package labeling and treatment guidelines
 - Pharmacists need to be knowledgeable on the contraindications to therapy and drug interactions
 - Pharmacists treating hepatitis C are responsible for performing a medication interaction check
- HCV genotype (including subtype, e.g., 1a or 1b)
- HCV RNA (quantitative viral load)
 - Detectable when treatment is being considered
 - Recent viral load within 90 days of treatment initiation
- HIV status and, if HIV seropositive, patient will be referred to Infectious Disease provider
- Hepatitis B status: If patient has active hepatitis B, he/she must be treated for hepatitis B before hepatitis C treatment begins. Patient will be referred to Infectious Disease provider for treatment evaluation. If the patient is found to have had hepatitis B in the past, the pharmacist will monitor for elevated liver enzymes and take appropriate action as needed. Hepatitis B status is determined by:
 - Hepatitis B Surface antigen
 - Hepatitis B Core Antibody
 - Hepatitis B Surface Antibody
- 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
- **Initial Visit:** the pharmacist is authorized to
 - Obtain signed consent form from the patient
 - Pharmacist may order hepatitis C treatment based on current AASLD and ECHO guidelines (Pharmacists will be provided with the most up to date guidelines as recommendations change)
 - Patient cases may be presented to ECHO consortium for assistance in managing therapy
 - Perform a medication interaction check
 - Take past medical, family, social and medication histories
 - Provide patient education to include: medications, disease state,

- adherence
- Order and interpret lab results to determine appropriate initial therapy and duration of treatment for referred patients based on current treatment guidelines
- Evaluate and notify nursing of needed vaccinations
 - Hepatitis A, Hepatitis B, Influenza, and Pneumonia
- Begin process of obtaining medications for patient
- Schedule the patient for a return visit to initiate treatment once medication has been received
- Document in the electronic medical record
- **Follow-up Visits:** the pharmacist is authorized to
 - Order and interpret lab results to determine effectiveness of therapy
 - Make changes to treatment regimen based on lab results
 - Administer and evaluate results of the PHQ-9 depression screening tool when appropriate
 - Document in the electronic medical record
- **Completion of Therapy**
 - Completion of treatment
 - The pharmacist will order HCV RNA viral load and other labs according to regimen
 - Three months post-therapy
 - The pharmacist will order HCV RNA viral load to determine if SVR12 has been achieved
 - The patient will be seen by the pharmacist to discuss lab results
 - The pharmacist will notify the referring provider of lab results
- Discharge Procedures
 - Patients may be discharged from the pharmacy-managed service and placed back in care of referring provider for any of the following reasons:
 - Failure to show up for two consecutive appointments
 - Failure to actively participate in treatment plan (medication, laboratory directions)
 - Attainment of treatment goals with completion of therapy and no detectable 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
 - Providers 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
 - Hepatitis C privileged pharmacists and nurses will operate under the direction of the clinic protocol
 - Patients will have appropriate labs done on each clinic appointment
 - Follow-up appointment dates are recorded and given to each patient
 - Laboratory tests ordered prior to next appointment will be ordered by a pharmacist, nurse or provider
 - All patient visits will be documented in the patient's chart utilizing current template
 - Pharmacy and nursing students may routinely accompany pharmacists and nurses and may assist in the care of patients with patient's consent

Performance Improvement Process

- A Hepatitis C Privileged Pharmacist will run quarterly reports to identify the following:
 - Patients who may have missed a follow-up appointment (including SVR12)
 - Check if patients have been getting their hepatitis C medications filled in a timely manner
 - Patients who have failed or stopped treatment
 - The pharmacist will check the medication inventory quarterly to ensure these high cost medications are accounted for correctly and take appropriate action when necessary
 - Documentation of Hepatitis A and B vaccination initiation or completion by clinic
 - Labs ordered as instructed in protocol with regard to Hepatitis C treatment
 - Documentation of percentage of patients completing prescribed therapy
- The results from these activities will be used to identify areas of concern so the process can be continually improved
- Each pharmacist will be peer reviewed at least twice a year. The results will be used to address areas of concern and improve the pharmacists performance
- These results will be reported to the Medical Director on an annual basis

Outcome Studies

- The following outcomes will be reported to P & T yearly:

- Total number of patients who have received treatment by pharmacy service
- Total number of patients who have responded to treatment after completion of treatment regimen
- Total number of patients who did not respond to treatment
- Total number of patients who required discontinuation of treatment due to side effects or laboratory abnormalities
- Total number of patients who achieved SVR

Training and Local Certification

- Pharmacist credentialing will consist of a yearly performance review with the following types of continuing education in the management of Hepatitis C:
 - Review of Hepatitis C treatment guidelines
 - Pharmacist must demonstrate knowledge base in the management of Hepatitis C, including the appropriate medications that may be utilized in treating Hepatitis C
 - Completion of the University of Washington Hepatitis C Course Modules and subsequent editions
 - Completion of the training certification process will be documented and placed in the pharmacist's credentialing file

Patient Education

- Patients enrolled in the Hepatitis C service will be provided education regarding disease state, treatment, monitoring, prevention, and lifestyle adaptations associated with a diagnosis of Hepatitis C. 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 Hepatitis C and what possible complications one might expect

References

1. Ghany, M.G., Nelson, D.R., Strader, D.B., Thomas, D.L. and Seeff, L.B. (2011), An Update on Treatment Genotype 1 Chronic Hepatitis C Virus Infection, 2011 Practice Guideline by the American Association for

the Study of Liver Diseases. Hepatology, 54: 1433-1444. doi: 10. 1002/hep.2461

2. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. 17 Feb. 2015. Web. 7 May 2015. Available at: <http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf>

3. Yee HS, Chang MF, Pocha C, et al. Update on the Management and Treatment of Hepatitis C Virus Infection: Recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol, 24 Apr. 2012; doi:10.1038/ajg.2012.48. Available at: <http://www.hepatitis.va.gov/pdf/2012HCV-guidelines.pdf>

4. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; Accessed August 22,2018.

5. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; Accessed August 22, 2018.

6. Mavyret Pak [package insert]. North Chicago, IL: Abbvie, Inc.; Accessed August 22, 2018.

7. Recommendations for Testing, Managing, and Treating Hepatitis C. Available at <http://hcvguidelines.org/>. Accessed August 22, 2018.

8. Project ECHO Treatment Decision Trees. The University of New Mexico. Accessed August 22,2018

By order of the medical director, Hepatitis C privileged pharmacists under the direction of the Chief Pharmacist are authorized to initiate direct acting antivirals and/or Ribavirin, order pertinent labs and imaging for patients who fit the above criteria and do not have any contraindications for therapy.

Attachments

[Patient Consent Form](#)

[Standing Orders](#)

Approval Signatures

Step Description	Approver	Date
Medical Director	J. C. Eaton: Medical Director	04/2024
Chief Pharmacist	Gary Elam: Chief Pharmacist	04/2024