SPIRIT LAKE HEALTH CENTER
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Hepatitis C Treatment Services Protocol

Spirit Lake Health Center

Pharmacy

I. Rationale / Statement of Need

According to the Centers for Disease Control and Prevention, in 2014 an estimated 2.7-3.9 million people in the United States have chronic hepatitis C, with an estimated 30,500 cases of acute hepatitis C virus (HCV) infections. The highest rates of acute hepatitis C infections are found among American Indians/Alaska Natives at 1.32 per 100,000.

Hepatitis C is a disease state with historically complex and evolving regimens, requiring rigorous lab monitoring, and long-term morbidity and mortality if left untreated. Treatments are available and are often cost prohibitive, though produce cure rates of over 90%.

Utilization of a pharmacist-managed, protocol-driven hepatitis C treatment clinic will accomplish both improved patient outcomes and reduced provider workload while expanding pharmacy clinical services in a financially responsible manner.

II. Purpose & Goals

Purpose:

- To accomplish the goals below and improve the quality and efficiency of are for hepatitis C patients in our facility. This will be accomplished by allowing pharmacists to manage patients utilizing a systematic, coordinated program under a pharmacy-based protocol. Pharmacists will collect appropriate subjective and objective data, initiate therapeutic plans and provide follow-up care. All patient visits will be documented in the patient's electronic health record (HER).

Goals:

- Provide appropriate medication therapy for the purpose of achieving definite outcomes that improve the patient's quality of life.
- Determine the appropriateness of therapy in specific patients.
- To collaborate with the Clinical Director and other designated practitioners to provide care of hepatitis C patients through the most current evidence-based medicine and practice guidelines.
- Enhance the identification of potential drug-drug and drug-food interactions involving treatment.
- Decrease physician workload, expand pharmacy clinical roles, and obtain appropriate reimbursement for clinical pharmacy services.
- Provide a peer-reviewed, organized, and standardized protocol for provider credentialing, supervision, patient care management and coordination, communication and documentation, laboratory monitoring, and patient selection and perform physical assessment, initiation of therapy, maintenance and routine monitoring of therapy, patient education, and patient outcomes.
- To provide formalized patient education to help the patient understand the diagnosis, treatment options, medications available, and monitoring parameters.

III. Daily Clinic Functions

Screen for HCV antibodies in the following patient categories:

- Patients born from 1945 to 1965 (one-time screening), which national data has shown constitutes 75% of reported cases [5]. Additional age ranges may be included in this screening where local data suggests an elevated HCV burden may exist.
- Patients determined as high-risk (routine screening unless otherwise noted):
    - Vietnam Veterans serving between 1964 and 1975
    - HIV-positive individuals (at least annual screening for HIV-positive men who have sex with men)
    - Patients who have ever injected illicit drugs, including those who injected drugs just once or a few times many years ago (at least annual screening for current injection drug users)
    - Patients with certain medical conditions, such as those with hemophilia with receipt of clotting factor concentrates before 1987, those on current or with a history of long-term hemodialysis, and those with persistently abnormal alanine aminotransferase levels
    - Patients who received a transfusion or organ transplant before July 1992 or received blood from a donor who later tested HCV-positive

    - Patients with recognized exposure, for example, health care workers exposed after needle sticks, sharps, or mucosal exposures to HCV-positive blood, and children born to HCV-positive mothers
- The patient's medical provider must refer eligible patients into the pharmacy-managed hepatitis C treatment clinic. The referring medical provider will provide the following information on the patient referral notice:
    - Contraindications/precautions to medication therapy
    - Renal/hepatic impairment
    - Mental illness
    - Alcohol use
    - Compliance/adherence
    - Pregnancy/breast feeding
    - Cardiovascular risk (hypertension, angina, arrhythmias, peripheral vascular disease, myocardial infarction)
- Patients presenting with a history of mental illness may be referred to behavioral health if deemed necessary prior to receiving treatment. The pharmacist may consult with the behavioral health provider or primary care provider (PCP) about the most appropriate medication therapy.
- PCP agrees to pharmacy prescribing protocols unless contraindicated or specifically limited by PCP at initial referral or at subsequent follow up.

Policies and Procedures:

The pharmacist responsibilities will include the following when possible.

- Receive and manage all referrals to the clinic from the patient's PCP.
- Review patient chart and collect all necessary lab documents regarding the patient's hepatitis C quantitative viral load and genotype, treatment history, social history contributing factors, and patient compliance with successfully completing medication treatment plan.
- Review most current treatment algorithms from the American Association for The Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA).
- Present patient information to teleECHO clinic group if needed and determine most appropriate treatment course.
- Discuss selected therapy with patient's PCP and finalize the treatment plan.
- Order, change, discontinue, and interpret laboratory tests in consultation with PCP for HCV genotype and viral load, hepatitis A and B serologies, HIV test, CMP, LFT, INR, FLP, TSH, fT4, CBC with differential, ferritin, iron saturation, ANA, CRP.
- Submit all documents necessary for a prior authorization (PA) for patients who have insurance to cover high costs of medications.
- Consider enrolling patients who do not have insurance in available patient assistance programs (PAPs) to help cover cost of medications.

- Consult patients on treatment plan and stress importance of compliance.
- Discuss all labs and side effects with the patient and PCP and monitor if required.
- Recommend and administer vaccinations such as Hepatitis A and B prior to initiating treatment if patient is due.
- Follow up with patients and consult with PCP as appropriate.

Follow-up Care:

- Pharmacist will follow up with referred patients either in person or via telephone 2 weeks after initiation of treatment to assess tolerance of and side effects from medications, as well as patient compliance.
- Pharmacist will monitor medication refill requests to ensure patients are in compliance with the treatment plan.
- At the end of the treatment plan, all necessary lab values will be assessed to gauge success of treatment, and follow up with the PCP and patient.

IV. Quality Assurance and Outcomes

Outcomes will be reported at least annually to the Chief Pharmacist and Clinical Director. Collected data will be used to improve and update the Pharmacy Based Hepatitis C Program. Outcomes for review will include:

- Total number of patients treated
- Number of patients with completed treatment
- Number of patients with End-of-Treatment Response (ETR)
- Number of patients with Sustained Virological Response (SVR)
- Number of patients who failed treatment
- Number of patients who discontinued treatment for other reasons (refusal, noncompliance, adverse effects, labs, etc.)
- Number of patients lost to follow-up

Data to be compiled annually by calendar year:

- Total number of patients treated
- Categorized by outcomes as described above

Data will be provided to the Chief Pharmacist and/or Clinical Director for reporting to Medical Staff.

V. Clinic Staff Credentialing

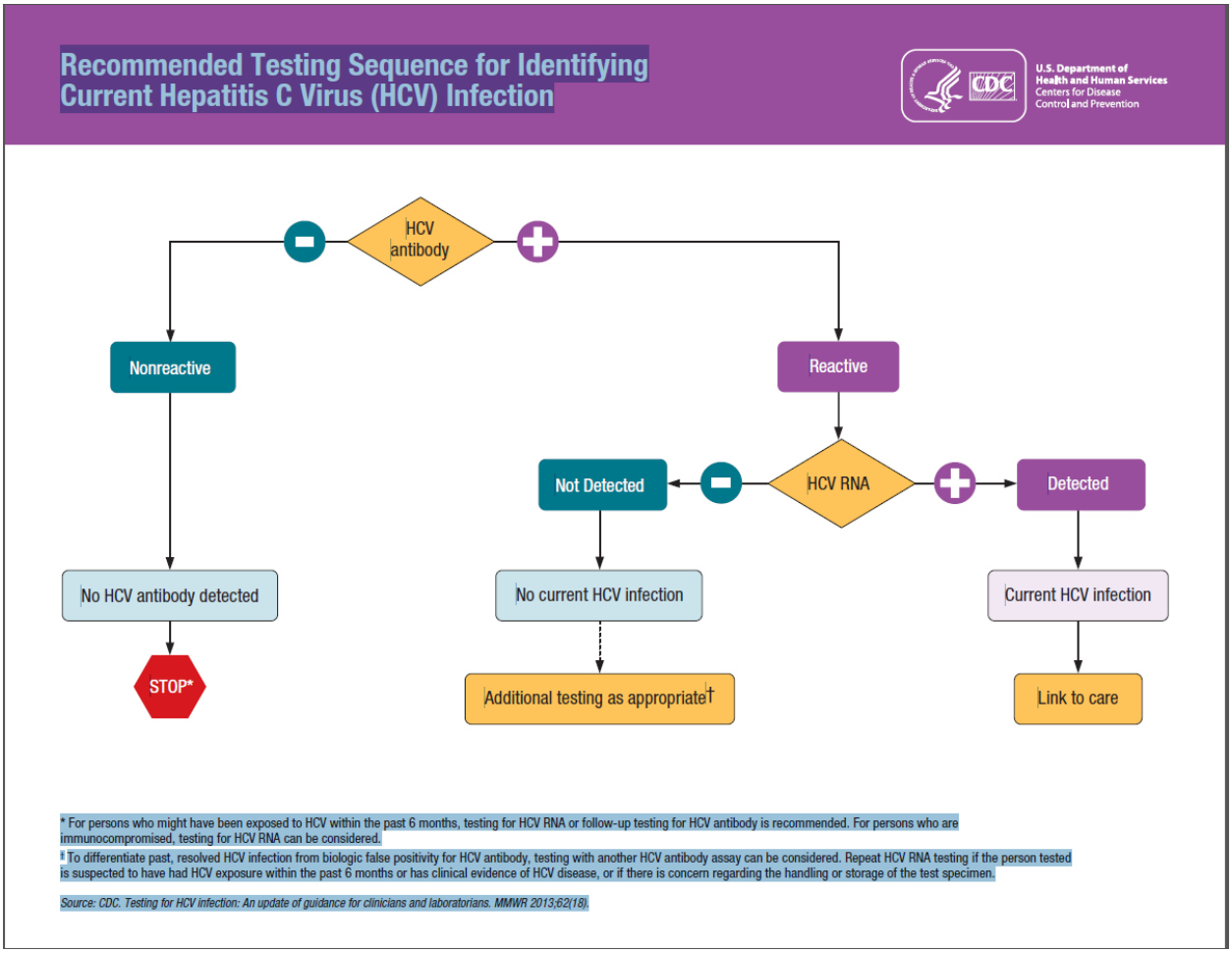
- Pharmacists working the Hepatitis C clinic should complete the HCV Clinician Partner Training with Project Echo. Pharmacist should also attain the required continuing education relevant to the disease state.
- Pharmacy Competency Assessment will be conducted by the Hepatitis C Clinic manager

VI. Business Plan

The clinic, as its primary billing objective, will continue to monitor for "provider-deemed" status for pharmacist providers from CMS and third-party payers. In addition, the Pharmacy Hepatitis C Treatment team will attempt to collect reimbursement through the recent Current Procedural Terminology (CPT) billing codes to bill third-party payers when providing Medication Therapy Management (MTM) services. The American Medical Association CPT Editorial Panel approved three permanent, category I codes effective January 1, 2008 to be used to bill any health plan that provides a benefit for MTM services, including those covered under the new Medicare Part D Prescription Drug Benefit, which began January 1, 2006.

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

https://www.cdc.gov/hepatitis/HCV/PDFs/hcv_flow.pdf



References

1. U.S. Department of Health and Human Services. Viral Hepatitis – Hepatitis C Information. Atlanta: Centers for Disease Control and Prevention, Division of Viral Hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. [Accessed 2016 Sept 26].

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Spirit Lake Health Center Pharmacy

Medical Staff Approval date: 10.28.20

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Clinical Director Date	CEO Date
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Director of Pharmacy Date	Pharmacist Date
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Nurse Practitioner Date	Nurse Practitioner Date
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Pharmacist Date	Pharmacist Date