PATIENT ENCOUNTER RESOURCE PACKET FOR PRESCRIBERS EVALUATING PERSONS WITH HEPATITIS C VIRUS (HCV) FOR HCV TREATMENT

While HCV management has historically been a specialty-oriented task in the past, new breakthroughs in the pharmacological treatment of HCV through direct acting antivirals (DAAs) have streamlined the pretreatment assessment, simplified the pharmacological prescribing regimes, dramatically reduced the side effects of treatment, all while increasing the overall cure rates above 98%. In addition to this, Louisiana has launched the Nation’s first-of-its-kind HCV elimination plan, Hep C Free LA. This 5-year plan is centered around having unrestricted access to the authorized generic for Epclusa (Sofosbuvir/Velpatasvir) for Medicaid patients and anyone incarcerated in Louisiana.

With the Hep C Free LA plan, the dream of eliminating HCV as a public health threat from Louisiana will only be possible by partnering with primary care providers throughout the state to ensure access to all people in need. This document was created to help provide a road map to assist our partnering prescribers and help support you in our collective fight to end the epidemic.

The following documents serve as a reference guide for any providers looking to offer HCV testing and treatment services in their clinics. This document was designed to give a framework for HCV patient encounters, but each provider has the liberty to practice as they see fit. With COVID-19 driving increased demand for virtual patient encounters and telemedicine, there is a part of this document focusing on transitioning from in person to virtual patient encounters. The Department of Health also maintains a live clinical access warm line at (919) 920-6707 staffed by physicians to provide clinical support for prescribers across the State.
KEY HISTORY ASPECTS FOR PERSONS WITH HEPATITIS C VIRUS (HCV)

- Identify Risk factors for HCV Acquisition
- Alcohol History
- Injection Drug Use History
- Psychiatric History
- Prior Staging of Liver Fibrosis
  - Liver biopsy, it is important to document resulting Fibrosis score
  - Fibrosis staging via alternative method, like Fibrosure or Fibroscan
- Complications of Liver Disease
  - Prior Diagnosis / hospital admissions for:
    - Ascites
    - Hepatic Encephalopathy
    - Jaundice
    - Gastrointestinal bleeding
- HCV-Associated Extrahepatic Manifestations
  - Most common symptoms in patients who had extrahepatic manifestations are: arthralgia, paresthesia, myalgia, pruritus, and sicca syndrome
- Prior HCV Treatment
  - Have they ever been treated?
    - Successful / Unsuccessful
      - Documented Cure / Sustained Virologic Response (SVR12)
    - Type
    - Duration
    - Degree of adherence
    - Adverse effects
- Comorbidities
  - Non-Alcoholic Fatty Liver Disease (NAFLD)
  - Obesity (past or current)
    - Strongly associated with the development of NAFLD.
  - Insulin resistance or Diabetes
  - Dyslipidemia or Hypertriglyceridemia
  - Known history of other liver diseases
- Significant Coinfections
  - Hepatitis A virus (HAV)
  - Hepatitis B virus (HBV)
  - Human immunodeficiency virus (HIV)
KEY PHYSICAL EXAMINATION AND DIAGNOSTIC TESTING ASPECTS FOR PERSONS WITH HEPATITIS C VIRUS (HCV)

KEY ASPECTS OF PHYSICAL EXAMINATION

- Height and weight to determine the body mass index (BMI)
- Clinical signs associated with liver disease:
  - Ascites
  - Lower extremity edema
  - Distended abdominal veins
  - Gynecomastia
  - Scleral icterus
  - Jaundice
  - Palmar erythema
  - Spider nevi (Spider angiomas)/ Telangiectasias
  - Leukonychia, characterized by ground glass opacification of nearly the entire nail, obliteration of the lunula, and a narrow band of normal, pink nail bed at the distal border (Terry’s nails)
  - Neuro:
    - Assess alertness, orientation and cognition

KEY ASPECTS OF LABORATORY TESTING

- HCV RNA Viral Load
  - Confirmatory testing for + HCV antibody screening
    - Qualitative or quantitative PCR
- General Labs:
  - Complete blood count (CBC)
  - Complete metabolic profile (CMP)
  - Thyroid function tests (TSH)
- Coinfection Assays:
  - Hepatitis A antibody
  - Hepatitis B surface antigen
  - Hepatitis B core antibody total
  - Hepatitis B surface antibody
  - HIV antibody
KEY ASSESSMENT AND TREATMENT PLAN ASPECTS FOR PERSONS WITH HEPATITIS C VIRUS (HCV)

- Immunizations for Persons Living with HCV (if not immune or up to date)
  - Hepatitis A
  - Hepatitis B
  - Pneumococcal
  - Routine adult vaccines:
    - Yearly influenza
    - Tetanus Diphtheria Acellular Pertussis (Tdap) or Tetanus Diphtheria (Td) booster every 10 years.
- Screening for other causes of liver disease
  - Alcoholic Liver Disease with counseling on alcohol cessation
  - Nonalcoholic Fatty Liver Disease (NAFLD) with counseling on weight loss, strict glycemic and lipid control
- Consideration of starting HCV treatment
  - Need to get initial evaluation of labs back prior to starting treatment
    - Ideally staging should be done before treatment initiation (Fibroscan, FIB-4, APRI, Fibrosure)
  - Decide whether ultrasound needed before starting treatment
    - Recommend ultrasound if liver tests are abnormal
    - Not required before initiated treatment for confirmed HCV
  - Check patient medication list for potential drug / drug interactions
  - Educate patient on HCV, transmission, treatment, risks for progressive liver disease (i.e. EtOH, fatty liver), authorized generic Epclusa treatment details: efficacy, side effects and drug-drug interactions
  - Discuss compliance with medication
  - Outline follow up
  - Link to complimentary services
    - Addiction services if indicated
    - SSP if ongoing risk factors (PWID)
- Follow-up
  - Based on Hep B exposure status and stage of liver fibrosis
  - Check HCV Viral RNA and hepatic function 12 weeks after last dose
CONSIDERATIONS FOR HEPATITIS C VIRUS (HCV) MANAGEMENT IN THE VIRTUAL OFFICE VISIT (TELEMEDICINE)

Virtual office visits are rapidly becoming an integral part of many prescribers’ daily work routine. Studies have shown comparable SVR12 (cure) rates in patients who underwent traditional in person office visits and those who were managed via telehealth services. The previous document outlined how to approach any visit with a patient with HCV. This document aims to highlight considerations that might impact the success of a telemedicine encounter. These include patient, provider, clinic, laboratory/radiology factors to think about and address, if needed, to optimize the telemedicine experience and outcome.

PATIENT FACTORS

- Medical literacy and understanding
  - Have a support person also present for the visit so that person can assist with the HCV evaluation and help with HCV treatment understanding and compliance
- Substance use and mental health issues
  - Fully explore patient’s substance use and mental health issues to assess how they may impact HCV treatment, and inform your decision to start treatment via telemedicine
- Medical complexity and stability
  - Fully explore any ongoing medical issues or evaluations that may interfere with completing the HCV evaluation or treatment
- Assessment of patient compliance
  - Take into consideration the issues mentioned above along with your impression during the telemedicine visit and determine if patient compliance may interfere HCV evaluation and treatment
- New versus established patient
  - Since providers are usually more familiar with established patients it may be easier to start HCV treatment on the telemedicine visit if the patient has already been established. For a new patient, the provider may need more time to understand and explore the above considerations and prefer waiting to prescribe HCV treatment until a follow-up appointment. Although the evaluation for HCV (i.e. labs and staging) can be ordered at the first telemedicine visit
  - HCV treatment can be started at or soon after the first telemedicine visit based on provider comfort

PROVIDER FACTORS

- Provider comfort and confidence with HCV evaluation and treatment
  - The more comfortable and/or experienced a provider is with HCV evaluation and treatment it will likely be easier to initiate therapy via telemedicine
CLINICAL FACTORS

- Clinic plans for in person visits
  - Assess readiness for clinic to see patients in person vs via telemedicine to maximize safety and minimize wait times.
- Quick and clear communication between the provider and the clinic staff, and then the clinic staff and the patient
  - One the same day of the appointment the provider should make it clear to the clinic staff what the patient needs done. The clinic staff on the same day should follow up with the patient regarding the plan, any upcoming lab/radiology appointments, and follow-up appointment (either telemedicine or in person)

LABORATORY AND RADIOLOGY FACTORS

- Understand patient’s access to laboratory and radiology services
  - Need to make sure patients can get the needed labs to undergo HCV evaluation and start treatment. Providers and patients need to understand the impact in time delays for getting those labs and staging complete. With certain populations in person visits may be needed to facilitate needed lab work
  - Need to make it clear to patients that certain labs and radiology are required to better understand their degree of liver disease from HCV and to start HCV treatment

WHEN TELEMEDICINE MAY NOT BE APPROPRIATE

- Decompensated liver disease (bleeding, ascites, encephalopathy, jaundice)
- Consideration of referral for a liver transplant
- Emergent or urgent medical/psychiatric conditions
Subjective:

@NAME@ is here for HCV.

HPI

@NAME@ has been feeling

Possible risk factor for HCV:
Possible time of exposure:
Previous heavy EtOH:
Current EtOH:
Previous drug use:
Psychiatric issues
Current drug use:
Previous HCV treatment:

No evidence of ascites, jaundice, confusion or gastrointestinal bleeding.

Objective:

@PHYEXAMBYAGE@

@RESUFAST(WBC,HGB,HCT,PLT,ALT,AST,NA,K,CL,CREATININE,BUN,CO2,INR,GLU)@
@RESUFAST(LABPROT,LABALBU)@

HCV staging (Fibroscan, APRI, FIB-4, Fibrosure):

Abdominal imaging:

Hep A and B immune status:
Hep A IgG
HepBs Ab

HIV status:
HIV Ab

Hep Bs Ag status:
HepBsAg
HepBc IgG total
Assessment/Plan:

@DIAGX@
@NAME@ is a @AGE@ @SEX@ with chronic HCV infection. Patient would benefit from treatment.

HCV
- Educated patient on HCV and risk factors for transmission
- Educated about importance of HCV staging/fibrosis determination
- Will proceed with HCV treatment, generic Epclusa for 12 weeks
- Patient was counseled on the importance of medication compliance for the full 12 weeks; advised to contact me if 7 days missed
- Educated patient on most common side effects (headache, fatigue, insomnia, nausea, diarrhea)
- Educated patient while on medication to avoid acid suppressing medications or notify MD if they are needed
- Basic drug interactions reviewed (PPIs, statins, cardiac, seizure meds) and the med changes are as follows:
  - Needs hepatic function at 4 weeks on treatment if isolated HBcAb IgG+; otherwise no monitoring needed on treatment
  - Check hepatic function and HCV viral load 12 weeks after treatment complete
  - Counseled patient on risk of heavy drinking
  - Advised against alcohol use while on treatment
  - Based on staging will decide if long term follow up is needed; if needed will refer to hepatology clinic
  - If cirrhotic will get US and AFP every 6 months until patient can be seen by specialist
  - Will vaccinate for hep A and B as needed

RTC in 6 months, around 12 weeks post-treatment
References

questions that may arise. Any medications used. Questions or concerns from providers can be directed to the HCV Prescriber Warm Line for any clinical recommendations regarding hepatitis, management, and treating hepatitis C. Retreatment

31. AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. When and in whom to initiate HCV therapy. [AASLD-IDSA Hepatitis C Guidance]


31. AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. Retreatment of persons in whom prior therapy failed. [AASLD-IDSA Hepatitis C Guidance]

67. Advisory Committee on Immunization Practices. Recommended Immunization Schedule for Adults Aged 19 Years or Older by Medical Conditions and Other Indications, United States, 2018 [ACIP]


77. AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. HCV testing and linkage to care. [AASLD-IDSA Hepatitis C Guidance]


FOR REFERENCE PURPOSES ONLY: It is the prescriber’s responsibility to remain up to date with the latest guidelines and recommendations regarding hepatitis, screening for hepatitides, treatment recommendations, and prescriber information for any medications used. Questions or concerns from providers can be directed to the HCV Prescriber Warm Line for any clinical questions that may arise.

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