HEPATITIS C PROVIDER POCKET GUIDE

THIS GUIDE IS BROUGHT TO YOU BY:

swope HEALTH

Swope Health implemented a Hepatitis C treatment program in 2019 after witnessing a significant need in the community it serves. They continue to be dedicated to helping all persons have access to this life saving treatment.

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IN COLLABORATION WITH:

Mid-America (HHS Region 7) ATTC
Addiction Technology Transfer Center Network
Funded by Substance Abuse and Mental Health Services Administration

Missouri DHSS Department of Health and Senior Services

MoHealthNet

NVHR National Viral Hepatitis Roundtable

NATIONAL HEALTH CARE for the HOMELESS COUNCIL

Screening and Treatment Guideline References

CDC. Testing Recommendations for Hepatitis C Virus Infection. http://www.cdc.gov/hepatitis/hcv/guidelinesc.htm

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org.

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This guide is dedicated to
all who have lost their lives to Hepatitis C
without access to treatment.
It is time for a change.
Together, we can eliminate Hepatitis C.
-Rachel Melson

TEST

UNIVERSAL SCREENING

- At least once in a lifetime for all adults aged 18 years and older
- All pregnant women during each pregnancy
- One-time screening regardless of age among people with recognized conditions or exposures:
  - HIV positive
  - History of injection drug use and shared needles, syringes, or other drug preparation equipment
  - People who ever received maintenance hemodialysis
  - People with persistently abnormal ALT levels
  - Prior recipients of transfusions or organ transplants before 1992
  - Healthcare, emergency, and public safety personnel after exposures to HCV-positive blood
  - Children born to mothers with HCV infection

ROUTINE PERIODIC TESTING

- For people with ongoing risk factors, while risk factors persist:
  - People who currently inject drugs and share needles, syringes, or other drug preparation equipment
  - People who ever received maintenance hemodialysis
- Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons may be reluctant to disclose stigmatizing risks.

HCV TEST ORDERS

- HCV antibody with reflex to RNA
  - HCV antibody testing should not be tested without reflexive RNA unless it is for rapid testing
- Rapid/point of care antibody test
  - If positive, order a HCV RNA to verify if the patient requires treatment

TEST INTERPRETATION

ANTIBODY	RNA	TREATMENT
NEGATIVE	NEGATIVE	NOT INDICATED, ROUTINE PERIODIC SCREENING, REPEAT IN 6 MO IF CONCERN FOR RECENT EXPOSURE
POSITIVE	NEGATIVE	
POSITIVE	**POSITIVE**	**TREATMENT INDICATED**

EVALUATE

DIAGNOSTIC STUDIES

GENERAL LABS

REQUIRED

CBC w/ PLT
CMP
HIV Screening
Pregnancy Test

ENCOURAGED

AFP, Tumor Marker
PT/INR
TSH, Reflex to T4
Iron/TIBC

HEPATITIS SPECIFIC STUDIES

REQUIRED

RNA Quantitative
HCV Genotyping *
*only required for insurances
Fibrosis Evaluation (1 of the following):

- FibroSURE (LabCorp) or FibroTEST (Quest)
- FibroScan
- FIB-4 & APRI Calculations

Hepatitis B Surface Ab & Core Ab
Hepatitis B Antigen
Hepatitis A IgM

$$\frac{\text{AGE} \times \text{AST}}{\text{PLT} \times \sqrt{\text{ALT}}} = \textbf{FIB - 4}$$

> 3.25 is predicative of advanced cirrhosis

$$\frac{\frac{\text{AST}}{40}}{\text{PLT}} \times 100 = \textbf{APRI}$$

> 1.0 is predicative of cirrhosis

CTP Scoring

Points	1	2	3
Encephalopathy	NONE	Grade 1-2	Grade 3-4
Ascites	NONE	Mild-Mod	Severe
Bilirubin	<2	2-3	>3
Albumin	>3.5	2.8-3.5	<2.8
PT or INR	<4 <1.7	4-6 1.7-2.3	>6 >2.3

CTP Class

A = 5-6 points Least Severe
B = 7-9 points Moderately Severe
C = 10-15 points Most Severe

Cirrhosis Severity

ULTRASOUND INDICATIONS

CONCERN FOR HEPATOCELLULAR CARCINOMA OR CIRRHOSIS

- Low PLT (< 150)
- Elevated AFP
- Discordant results
- Elevated Fibrosis:
  - Stage F3 or F4
  - FIB-4 > 3.25 or APRI > 1.0

SURVEILLANCE FOR HEPATOCELLULAR CARCINOMA

With elevated fibrosis stages (F3 & F4):
Ultrasounds should be checked **every 6 months** to screen for Hepatocellular Carcinoma and advanced liver disease

TREAT

VACCINE RECOMMENDATIONS

ALL PERSONS WITHOUT IMMUNITY TO HEP A & B:

Hepatitis A

- Harvix: 2 dose schedule (0 and 6-12 months) -or-
- Vaqta: 2 dose schedule (0 and 6-18 months)

Hepatitis B

- Engerix-B: 3 dose schedule (0, 1, and 6-12 months) -or-
- Recombivax HB: 3 dose schedule (0, 1, and 6-12 months) -or-
- Heplisav-B: 2 dose schedule (0, and 1 month)

Hepatitis A/B Combination

- Twinrix: 3 dose schedule (0, 1, and 6-12 months)

ALL PERSONS WITH CHRONIC LIVER DISEASE:

PPSV23

- Age 19-64: 1 dose
- Age > 65: 1 dose at least 1 year after the PCV13 and at least 5 years after any prior dose

PCV13

- Age > 65: 1 dose

Continue all other Routine Adult Vaccinations per schedule

TREATMENT CONSIDERATIONS

Consider referring to higher level of care when:

- Co-Infection is present (Hepatitis B and/or HIV)
- History of organ transplant
- Cirrhosis is highly suspected
  - Fibrosis stage 4
  - Low PLT and two noninvasive tests are discordant
- Pregnancy

Treatment is contraindicated when:

- Life expectancy is short and cannot be improved by HCV treatment, liver transplant, or other measures
- Patient is a child under age 3

PATIENT ENCOUNTERS

Consultation: review lab work, conduct physical exam, vaccinate Hep A/B as indicated, order U/S for elevated fibrosis, discuss treatment & medication
Medication Start: medication education, may be in-person or telehealth
4-Week Follow-up: lab monitoring as applicable, assess compliance
End of Treatment: lab monitoring as applicable, discuss SVR follow-up labs

TREAT

MEDICATION CONSIDERATIONS

REVIEW MEDICATION LIST PRIOR TO TREATMENT FOR:

- **Statins or other cholesterol lowering agents**
  - May lead to an increased risk of rhabdomyolysis
- **Certain vitamins**
  - Excess iron intake without deficiency can promote hepatic injury
  - St. John's Wort should be avoided
- **Certain seizure medications**
  - Including carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- **GERD/Acid suppressing medications**
  - Suppressing GI acidity can lead to DAAs being less effective
- **Warfarin**
  - Monitor INR for subtherapeutic anticoagulation
- **Diabetic Medications**
  - Monitor for hypoglycemia
- **Ethinyl Estradiol**
  - May lead to hepatotoxicity
- **Antiarrhythmics**
  - Amiodarone may lead to toxicity and bradycardia
- **Certain HIV medications**

These are not all of the potential interactions and do not indicate that treatment is contraindicated with these medications. For more information visit:
www.hep-druginteractions.org

DIRECT ACTING ANTIVIRALS

Mavyret
Glecaprevir (300 mg) - Pibrentasvir (120 mg)

100mg / 40mg tablets
3 tablets once daily for 8 weeks

Epclusa
Sofosbuvir (400 mg) - Velpatasvir (100 mg)

400 mg / 100 mg tablets
once daily for 12 weeks

Harvoni
Ledipasvir (90mg) - Sofosbuvir (400 mg)

90 mg / 400 mg tablets
once daily for 12 weeks

Zepatier
Elbasvir (50 mg) - Grazoprevir (100 mg)

50 mg / 100mg tablet
once daily for 12 weeks

Vosevi
Sofosbuvir (400 mg) - Velpatasvir (100 mg) - Voxilaprevir (100 mg)

400 mg /100mg /100 mg
once daily for 12 weeks

There is no prior authorization required for Mavyret for patients with Missouri Medicaid

TREAT

TREATMENT GUIDELINES

For up-to-date guidelines: https://www.hcvguidelines.org

Treatment-Naïve Adults Without Cirrhosis

Mavyret
Glecaprevir (300 mg) - Pibrentasvir (120 mg)
for 8 weeks

OR

Epclusa:
Sofosbuvir (400 mg) - Velpatasvir (100 mg)
for 12 weeks

Treatment-Naïve Adults With Compensated Cirrhosis

Mavyret
Glecaprevir (300 mg) - Pibrentasvir (120 mg) for 8 weeks

Epclusa is an option, however resistance testing is necessary for genotype 3.

TREATMENT MONITORING

After 4 weeks and at end of treatment: PLT, AST/ALT, HCV RNA
Assess for worsening of liver function and decrease in HCV RNA

Any patient with a **10-fold or greater increase in ALT levels** or with **symptoms suggestive of acute hepatic injury** and increases in ALT that are less than 10-fold should **discontinue therapy** with close monitoring and follow up for improvement.

12 Weeks Post-Treatment
Lab Work: HCV RNA (PLT, AST/ALT if previously abnormal)
Vaccines: Finish Hep A/B or B series
Ultrasounds: Ordered every 6 months for elevated fibrosis scores
Education: Re-exposure risk reduction, lifetime Hep C antibody presence, SVR/cure significance, HCC surveillance

CURE = SVR
Sustained Virologic Response is an undetectable HCV RNA 12 weeks or later after the completion of DAA HCV treatment

TREAT

TREATMENT INTERRUPTIONS

During First 28 days of DAA Treatment

- **Missed < 7 days:** restart DAA immediately and complete treatment
- **Missed > 8 days:** restart DAA immediately and check RNA
  - Negative RNA: complete treatment course as planned*****
  - Positive RNA or unable to obtain: extend DAA treatment by 4 additional weeks

After 28 days of DAA Therapy

- **Missed < 7 days:** restart DAA immediately and complete treatment
- **Missed 8-20 consecutive days:** restart DAA immediately and check RNA
  - Negative RNA: complete treatment course as planned*****
  - Positive RNA or unable to obtain: extend DAA treatment by 4 additional weeks
- **Missed >21 consecutive days:** Stop DAA treatment and assess SVR in 12 weeks; retreat if RNA is positive

*******Extend DAA for 4 weeks in genotype 3*

RETREATMENT INDICATIONS

Sofosbuvir-Based Treatment Failure

Vosevi
Sofosbuvir (400 mg) -Velpatasvir (100 mg) -Voxilaprevir (100 mg)
400 mg /100mg /100 mg once daily for 12 weeks

Glecaprevir/Pibrentasvir Treatment Failure
Without Compensated Cirrhosis

Vosevi
Sofosbuvir (400 mg) -Velpatasvir (100 mg) -Voxilaprevir (100 mg)
400 mg /100mg /100 mg once daily for 12 weeks

With Compensated Cirrhosis
Vosevi + weight-based ribavirin for 12 weeks

REINFECTION is rare.
However, it requires **re-treatment**.
Unless there is suspicion for previous treatment failure,
patient should be retreated as if they are treatment-naïve and based on their current lab and physical exam findings.

TREAT

PROVIDER SUPPORT

HEPATITIS C ONLINE
www.hepatitisc.uw.edu

- Education on HCV diagnosis, monitoring, and management
- Includes information on HCV biology and medications
- Clinical Calculators/Tools: CTP, FIB-4, APRI; CAGE, AUDIT-C
- CE/CME available

MO VIRAL HEPATITIS ECHO
www.showmeecho.org/clinics/hepatitis-c

- Provides collaboration, support and ongoing learning with HCV experts
- Sessions include didactic education and participant case studies/questions
- CE/CME available

NATIONAL CLINICIAN CONSULTATION CENTER
www.nccc.ucsf.edu/clinician-consultation/hepatitis-c-management

- Consultation for treatment decision-making and management of co-morbidities, complications, and special populations
- Warm-line: (844) 437-4636
- Monday – Friday, 9 a.m. – 8 p.m. ET

PROJECT HEP CURE
www.dss.mo.gov/mhd/hepc

- Information about treating MO HealthNet participants for HCV

MO DEPARTMENT OF HEALTH & SENIOR SERVICES
www.health.mo.gov/living/healthconditions/diseases/communicable/hepatitisc

- Recommendations and resources for screening and treating HCV
- Viral hepatitis epidemiologic profile & fact sheets

ADDICTION TECHNOLOGY TRANSFER NETWORK
https://attcnetwork.org/centers/global-attc/hcv-current-initiative

- Resources for integrating HCV treatment in Opioid Treatment Programs or treating persons with HCV and substance use disorders

NATIONAL VIRAL HEPATITIS ROUNDTABLE
https://nvhr.org/resources/

- Resources for navigating treatment access barriers, provider and patient toolkits, and advocacy efforts

UNINSURED ASSISTANCE

AbbVie: myAbbVie Assist
Medication: Mavyret
www.abbvie.com/patients/patient-assistance/program-qualification/mavyret-program-selection.html#myabbvie

Gilead: Support Path
Medications: Epclusa, Vosevi, Harvoni, Solvadi
www.mysupportpath.com

TREAT

PRIOR AUTHORIZATIONS

Missouri Medicaid:

- No PA needed for Mavyret and may pick up all 8 weeks at once
- PA required for alternatives

Medicare & Other Insurances

- All will require a PA
- Most will require genotyping

Information for other state Medicaid requirements and their grades can be found at:
www.stateofhepc.org

State grades are based on:

- Liver damage restrictions
- Sobriety restrictions
- Prescriber restrictions

CO-PAY & PREMIUM ASSISTANCE

My Good Days
Insurance Type**:** Medicare or Military
Amount: up to $15,000
Income: Below 500% FPL
www.mygooddays.org

HealthWell Foundation
Insurance Type: Any
Amount: up to $30,000
Income: 400 - 500% FPL
www.healthwellfoundation.org

Patient Access Network
Insurance Type**:** Any
Amount: up to $6,800
Income: Below 500% FPL
www.panfoundation.org

Patient Advocate Foundation
Insurance Type: Any
Amount: up to $15,000
Income: Below 400% FPL
www.patientadvocate.org

CO-PAY COUPONS

Epclusa
Coverage: $5 per monthly prescription
Max of 25% of catalog price
www.epclusa.com/sign-up-eligibility

Vosevi
Coverage: $5 per monthly prescription
Max of 25% of catalog price
www.vosevi.com/co-pay-coupon-registration

Mavyret
Coverage: $5 per monthly prescription
www.mavyret.com/savings-card

Harvoni
Coverage: $5 per monthly prescription
Max of 25% of catalog price
www.harvoni.com/support-and-savings/co-pay-coupon-registration

PREVENT

HARM REDUCTION

Harm reduction is an evidenced-based approach that aims to:

- Reduce the negative health, social, and economic consequences related to drug use and other "at risk" behaviors
- Promote public health, human rights, and social justice

Examples: medication assisted treatment (MAT), syringe exchange programs & sharps disposal, drug checking programs (fentanyl test strips), safer sex & drug use supplies, overdose prevention & naloxone distribution

Naloxone/Narcan Candidate Screening Questions*

- Have you ever experienced an overdose?
- In the last year, have you used an illegal drug or a prescription medication for non-medical reasons or that was not prescribed to you?
- Are you taking a prescribed opioid or benzodiazepine?
- Have you recently left prison/correctional facility or a detox/rehab facility?
- Have you ever witnessed an overdose?
- Does someone in your home or care use illegal drugs or have a substance use disorder?

Provider Considerations

- If the patient has not used in the last year, when was the last time? Is there a concern for relapse?
- Is the opioid high dose (> 50 MME/day)?
- Is the patient at risk for returning to using a high dose of a substance they are no longer tolerant to?

***A yes to any of these questions warrants a naloxone prescription**

RESOURCES

NATIONAL HARM REDUCTION COALITION
www.harmreduction.org

- Resources on overdose prevention, syringe access, harm reduction trainings and implementation guides
- Hepatitis C and harm reduction intersection information

PROVIDERS CLINICAL SUPPORT SYSTEM
www.pcssnow.org

- Trainings for primary care providers in evidence-based prevention and treatment of opioid use disorders and chronic pain
- DEA X-Waiver training for healthcare providers

NOTES

This Pocket Guide is not a replacement for clinical judgement and the guidelines represented are reviewed and updated frequently. We urge you to review the living document at **www.hcvguidelines.org** for the latest recommendations.