AETC AIDS Education & Training Center Program Midwest

Hepatitis C Treatment in Primary Care

Part 1: The Basis for Treatment in Primary Care

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MEDICAL SCHOOL
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Disclaimer

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Disclosure

- No disclosures

Epidemiology: Scope and Impact of Chronic Hepatitis C (CHC) Infections

2.7 million Americans estimated to be living with Hepatitis C

1.7 million unaware of their HCV positive status (63%)

30,500 Annual incidence of Hepatitis C infections in the US

432,000 have begun treatment for HCV infection

Kattakuzhy, et al. 2017. Ann Int Med

Yoo, et al. 2017. Journal of Clinical and Translational Hepatology

Impact:

- Hepatitis C induced cirrhosis (+/- HCC) is the leading indication for liver transplantation in the US adult population[1]
- Financial Impact:
  - Annual medicaid healthcare costs were $17,879 greater for patients with chronic HCV compared to controls without HCV[2]
- Morbidity/Mortality:
  - Estimated mortality of ~10,000 deaths per year in the US secondary to HCV-related end-stage liver disease[2]

Yoo, et al. 2017. Journal of Clinical and Translational Hepatology

Risk factors for hepatitis C

Transmission

- Sharing drug equipment
- Birth
- Healthcare exposures
- Sex with an infected person
- Unregulated tattoos or piercings
- Sharing personal items
- Blood transfusions and organ transplants

Higher risk

- Injection and intranasal drug use
- Men who have sex with men
- Persons on long-term hemodialysis (ever)
- Prior recipients of a transfusion or organ transplant, including persons who:
    a. Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
    b. Received clotting factor concentrates produced before 1987
- Persons who were ever incarcerated

History of Treatment for Hepatitis C

Interferon-Based Regimens (Pegylated interferon + ribavirin)

- Dates: (*** - 2011)
- Less than ideal treatment option in numerous ways:
  - Poor sustained viral response (SVR or “cure”) rate = ~50%[2]
  - Long duration of treatment (~48 weeks)
  - Lots of side effects: Flu-like symptoms, fatigue, depression, etc
  - High rate of patients failing to complete treatment course
- Managed by specialists due to complexity of regimens

DAA (Direct-Acting Antiviral) Agents

- Release Date: 2012
- Significant improvement on interferon based regimens:
  - Improved SVR Rate: ~92%[2]
  - Decreased side effects
  - Shorter duration of treatment (~12 weeks)
- Cons: $$$$$

Past/Current Barriers to Receiving DAA therapy

1. Knowledge of infection ~63% of patients unaware of HCV+ status
2. Cost "...Published wholesale acquisition cost of sofosbuvir was $1000 per day in 2014 (or $84,000 for a 12-week course)" - Lu et al; 2019[3]
3. Past MN Medicaid policies requiring the following for DAA treatment:
    a. Patients remain sober >6 months
    b. Specialty referral to GI/hepatology

Addressing the Barriers to DAA Treatment

Barrier 1: Knowledge of infection

New CDC recs for broader HCV screening

Population	Recommendation	Grade
Adults aged 18 to 79 years	The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.	B

What's new?	This recommendation expands the population that should be screened. The USPSTF now recommends that all adults aged 18 to 79 years be screened. Previously, it recommended screening adults born between 1945 and 1965 and others at high risk.
How often?	One-time screening for most adults. Periodically screen persons with continued risk for HCV infection (eg, persons with past or current injection drug use). There is limited evidence to determine how often to screen persons at increased risk.

Barrier 2: Cost of Medication

Medicaid treats more for Hepatitis C as cost drops

The costs of treating Hepatitis C on Minnesota Medicaid have fallen 35 percent and are expected to continue dropping. Patient advocates say the state insurance program should rescind treatment restrictions to limit the spread of the disease.

Patients **Cost Per Patient**

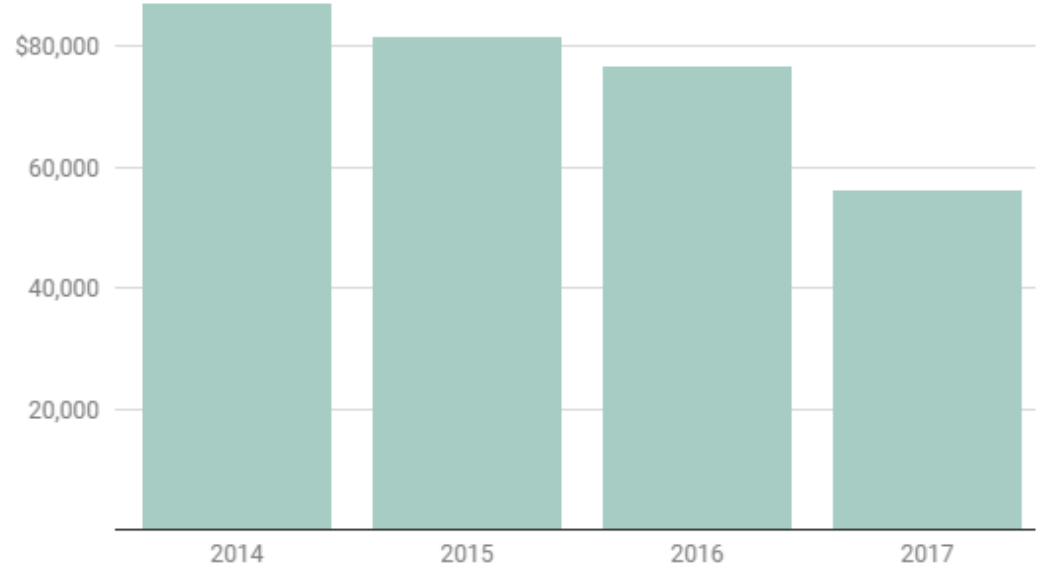

Chart: Jim Foster, Star Tribune • Source: Minnesota Department of Human Services • Get the data

Price Drop in DAA Therapy

1. Development of new DAA's and increased pharmaceutical competition over recent years has led to significantly improved costs for patients
    a. "List prices for DAAs themselves have declined drastically, from nearly $100,000 per treatment course in 2014 to as low as $24,000 per treatment course today." - Roebuck et al, 2019[2]
    b. "Supplemental rebates have risen from about 22% off list price in 2014 to as high as 60% in ensuing years." - Roebuck et al, 2019[2]

Barrier 3: Minnesota Medicaid Policies

LOCAL

With advisory panel's vote, Minnesota takes a step toward broader hepatitis treatment

The state could remove limits to getting effective drug under Medicaid.

By Glenn Howatt Star Tribune | JUNE 13, 2019 — 8:12PM

The state's Medicaid formulary committee, an advisory group that helps set policy on prescription drugs, voted Wednesday night to remove a restriction which said the drug could be prescribed only by medical specialists, such as gastroenterologists. That move will allow primary care doctors to treat their patients in most cases.

The committee also agreed to remove rules that required patients to be sober for at least six months before becoming eligible for the medications. But the committee expressed some concern that patients should be making progress toward addiction recovery, and will vote in a future meeting on how to enact that into a written policy.

Effective January 1st, 2020 in Minnesota...

1. PCPs can treat Hepatitis C in select patients
2. There is no longer sobriety requirements for treatment

The Basis for Treating Hep C in Primary Care

Annals of Internal Medicine

ORIGINAL RESEARCH

Expansion of Treatment for Hepatitis C Virus Infection by Task Shifting to Community-Based Nonspecialist Providers

A Nonrandomized Clinical Trial

Sarah Kattakuzhy, MD; Chloe Gross, RN; Benjamin Emmanuel, MPH; Gebeyehu Teferi, MD; Veronica Jenkins, MD; Rachel Silk, RN, MPH; Elizabeth Akoth, RN, MS; Aurielle Thomas, BA; Charisse Ahmed, BS; Michelle Espinosa; Angie Price, CRNP; Elana Rosenthal, MD; Lydia Tang, MD; Eleanor Wilson, MD, MS; Soren Bentzen, PhD; Henry Masur, MD; Shyam Kottilil, MD, PhD; and the ASCEND Providers*

Results: 516 patients achieved SVR, a response rate of 86% (95% CI, 83.0% to 88.7%), with no major safety signals. Response rates were consistent across the 3 provider types: NPs, 89.3% (CI, 83.3% to 93.8%); PCPs, 86.9% (CI, 80.6% to 91.7%); and specialists, 83.8% (CI, 79.0% to 87.8%). Patient loss to follow-up was the major cause of non-SVR.

After a 3 hour training session, there was no difference in SVR between PCPs and specialists in a real world setting (86%)

High “No-Show” Rate with HCV Specialty Referral

1. Studies have shown poor rate of follow-up with HCV specialists after referral, particularly for patients from marginalized communities:
    a. “Overall, 36% of patients with a scheduled [HCV specialty] appointment did not complete medical evaluation.” Zuckerman et al
    b. “Patients with medicaid were 79% less likely to complete an evaluation as those without Medicaid, even when controlling for other factors.” Zuckerman et al

Potential Reasons for High Specialty “No-Show” Rate

1. Fear of stigma/bias with unfamiliar medical provider
2. Health literacy / difficulty navigating healthcare system
3. Transportation issues
4. Finances / Insurance issues

In summary...

- **Similar Efficacy:** With only 3-hours of training, PCP's/NP's have shown equal rates of achieving SVR when compared to specialists.
- **Increased Accessibility:** Requiring a specialty referral to receive treatment for chronic HCV introduces an additional barrier to care, particularly for marginalized communities.
- **Wide-Scale Impact:** Increasing access to DAA treatment for HCV would result in reductions in morbidity/mortality, HCV transmission, and annual healthcare costs (i.e. cost of DAA treatment would be offset by annual healthcare savings after only 16 months).

References

1. Yoo, Eric R., et al. "Expanding treatment access for chronic hepatitis C with task-shifting in the era of direct-acting antivirals." *Journal of Clinical and Translational Hepatology* 5.2 (2017): 130.
2. Roebuck, M. Christopher, and Joshua N. Liberman. "Assessing the Burden of Illness of Chronic Hepatitis C and Impact of Direct-Acting Antiviral Use on Healthcare Costs in Medicaid." *The American journal of managed care* 25.8 (2019): S131-S139.
3. Lu, Christine Y., et al. "Cost burden of hepatitis C virus treatment in commercially insured patients." *The American journal of managed care* 25.12 (2019): e379-e387.
4. Zuckerman, Autumn, et al. "Increasing success and evolving barriers in the hepatitis C cascade of care during the direct acting antiviral era." *PloS one* 13.6 (2018): e0199174.

AETC AIDS Education & Training Center Program
Midwest

Hepatitis C Treatment in Primary Care

Part 2: How it Works in 5 Steps

Ryan Kelly
Community-University Health Care Center

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Step 1: Establish a diagnosis of chronic hepatitis C
Step 2: Determine if the patient is eligible for treatment in the primary care setting
Step 3: Prescribe treatment
Step 4: Monitoring during treatment
Step 5: Post-treatment follow up

Case

MS is a 34 year old male with PMH significant for 14 year history of IV drug use (heroin, cocaine, methamphetamine), DVT/PE on warfarin, and bipolar disorder who presents to your primary care clinic for establish care/suboxone/forms visit after discharge from the hospital for S. aureus bacteremia secondary to right upper extremity cellulitis. In the hospital, he was found to have mild transaminitis and positive Hepatitis C antibody screen. He was started on Suboxone by the hospitalist team and is interested in chemical dependency treatment. His current medications include warfarin (for DVT/PE dx 4 months ago), abilify 5 mg daily, sertraline 100 mg daily, cefazolin 500 mg QID, buprenorphine 8 mg/naloxone 2 mg daily. He states he has never been told that he has hepatitis C before, but is interested in treatment if indicated.

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1. What further workup is needed for his possible chronic hepatitis C?
2. Does his hepatitis C require referral to specialist care for treatment?
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Step 1: Establish a diagnosis of chronic hepatitis C

How do I know my patient has chronic HCV?

Screening for HCV

- Screen all adults at least once in their lifetime
- Screen children at increased risk
- Screen those at ongoing risk for HCV infection periodically
- Screen with a **hepatitis C screen with reflex to HCV RNA quantification and HCV genotype**

Positive screen

- If HCV antibodies present (on screen), need to confirm presence of HCV RNA (HCV RNA quant)
- *Prove persistence of HCV for 6 months: Look for past records of positive screen, if none, repeat tests in 6 months. Alternatively, if exposure timing is known, can base on that.*

Evidence of chronic HCV

- Assess patient interest in treatment
- Start treatment workup to determine if they have any factors that would preclude them from treatment in primary care

Step 2: Determine if the patient is eligible for treatment in the primary care setting

Who is eligible for treatment in primary care?

Who Is Eligible for Simplified Treatment

Adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment

Who Is *NOT* Eligible for Simplified Treatment

Patients who have any of the following characteristics:

- Prior hepatitis C treatment
- Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
- HIV or HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Initial labs

- Quantitative HCV RNA (HCV viral load) -- you may have this as a reflex
- HCV genotype and subtype -- you may have this as a reflex
- CBC, CMP
- UPT
- HIV screen
- Hepatitis B screen: Hepatitis B surface antigen, hepatitis B surface antibody, hepatitis B core antibody
- Not needed, but consider:
  - **INR**
  - **Hepatitis A screen: Hepatitis A IgG antibody**

Lab timeline

Per HCV guidelines (unfortunately different insurances have different thoughts). Hence, best to have all done within 6 months)

Pretreatment laboratory testing

Within 6 months of initiating treatment:

- Complete blood count (CBC)
- Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
- Calculated glomerular filtration rate (eGFR)

Any time prior to starting antiviral therapy:

- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen

Before initiating antiviral therapy:

- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

Cirrhosis evaluation

A fibrosis-4 (FIB-4) score is usually all you need

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST (U/L)}}{\text{Platelet Count } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$$

If the FIB-4 is <1.45 and platelet count and albumin are normal, you don't need to worry about cirrhosis and can move forward with treatment. If the FIB-4 is >3.25, they most likely have cirrhosis and should be referred to a specialist. If the score is in between, obtain a FibroScan to better characterize whether or not they have cirrhosis (can still treat in primary care if < 3.25, but cirrhosis means life long HCC screening.

Step 3: Prescribe treatment

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg)
taken with food for a duration of 8 weeks

Shorter duration of treatment and preferred for MN Medicaid

Sofosbuvir (400 mg) / velpatasvir (100 mg)
for a duration of 12 weeks

Pill not actual size

Side effects

- Common
  - Fatigue
  - Headache
- Rare
  - Elevated liver enzymes
  - Liver failure

Common medication interactions

- Stop all statins while on treatment
- Monitor warfarin closely (weekly), may become subtherapeutic
- Advise diabetic patients to monitor for hypoglycemia

Missed dose

From glecaprevir/pibrentasvir product insert:

- Less than 18 hours from the usual time glecaprevir/pibrentasvir taken:
  - take the missed dose as soon as possible
  - then take the next dose at the usual time
- More than 18 hours from the usual time that glecaprevir/pibrentasvir taken:
  - do not to take the missed dose
  - take the next dose at the usual time

Practical steps

- No data on treatment in pregnancy, so check a pregnancy test first and provide counseling (currently wait until after delivery)
- Medication reconciliation is important - work with pharmacy to assess for drug-drug interactions
- Initial drug choice is the same regardless of HCV genotype in patients without cirrhosis (glecaprevir/pibrentasvir)
- Educate about proper administration of medications, adherence, and prevention of reinfection → employ harm reduction strategies when applicable
- **Prior authorization form must be complete and sent to specialty pharmacy**
- **Be aware of which specialty pharmacies that can fill these medications are available to your patients (usually this is dependent on patient insurance as well)**
- For your individual clinic, have a plan for how that medication will be dispensed and how you will have ongoing follow up to optimize adherence (i.e. Will the drug be sent to the clinic for the first dose? Will it be mailed to the patient and you have a telephone discussion?)

Drug-drug interactions can be assessed using:
AASLD/IDSA guidance:
University of Liverpool drug interaction checker: https://www.hep-druginteractions.org/checker

Harm reduction syringe exchange information: https://www.health.state.mn.us/people/syringe/

PATIENT INFORMATION (Please type or print clearly)

Patient Name			DOB		Gender	
Address						
City		State		Zip Code		Phone Number

MEDICAL ASSESSMENT

Please include a copy of relevant chart notes, labs, HBV screening results, current medication list, and drug allergies

Diagnosis: ❑ B18.2 HCV (chronic) Genotype: 1a 1b 2 3 4 5 6

Treatment Experience: ❑ Naïve ❑ Experienced Previous medications used: _____

HCV RNA Result: _____ Draw Date: ____/20__

Fibrosis Score: _____ Cirrhosis ❑ No ❑ Yes If yes please circle: compensated or decompensated

Does the patient have any of the following : ❑ HIV Co-Infection ❑ HCC ❑ Liver Transplant

For Fee-for-Service Medicaid and Managed Medicaid Patients

If the patient has a substance use disorder or IV drug use, the patient must:

Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request

OR

Be counseled about measures to reduce the risk of HCV transmission to others;
and evidence of counseling is provided at time of request

AND

Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:

Condom distribution -
Access to sterile syringes -
Naloxone training and distribution -
Medication-assisted treatment options

OR

Not be candidate for ANY of the harm reduction services above;
and provider provides the reason the patient is not a candidate for each of the harm reduction service above

PRESCRIPTION INFORMATION

❑ **Epclusa™ (velpatasvir/sofosbuvir 100mg/400mg tablet)**
1 tablet once daily.
Qty: 28 tablets Refill #____

❑ **Harvoni ™ (ledipasvir/sofosbuvir 90mg /400mg tablet)**
1 tablet once daily.
Qty: 28 tablets Refill #____

❑ **Mavyret™ (glecaprevir/pibrentasvir 100mg /40mg tablet)**
3 tablets once daily.
Qty: 84 tablets Refill #____

❑ **Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir (400mg/100mg/100mg) tablet)**
1 tablet once daily.
Qty: 28 tablets Refill #____

❑ **Zepatier™ (elbasvir/grazoprevir 50mg/100mg tablet)**
1 tablet once daily.
Qty: 28 tablets Refill #____

❑ **Ribavirin 200mg**
❑1200 mg – (3 QAM /3QPM) Qty 168
❑ Other – (__QAM/__QPM) Qty ____ Refill #____

❑ **Condoms**
Use as directed for sexual activity
Qty: 12 Condoms Refill #____

❑ **Syringes** ***Sharps container will be included with order***
Length: ❑½" ❑1" Volume: ❑½cc ❑1cc Gauge 29g
Use as directed
Qty: _____ syringes Refill #____

❑ **Naloxone 4mg/0.1 ml Nasal Spray**

Insert the tip or the nozzle into one nostril and firmly press plunger to give one dose for suspected opioid overdose. Call 911. Open second pack and repeat every 2-3 minutes if needed.

Qty: 1 package Refill#____

PROVIDER INFORMATION

Prescriber's Name (Print)	DEA:	NPI:
Signature:	Date:	Prescriber's Phone:
Form Faxed by/telephone #:		Clinic Contact & Phone:

UNIVERSITY OF MINNESOTA | **Protocol (###)**

Community-University Health Care Center (CUHCC)

Hepatitis C Treatment Protocol

Related Policy Name & #:	
Effective Date:	
Responsible:	Clinical Teams
Accountable (CUHCC Owner):	Chief Clinical Officer
Consulted:	Medical, Pharmacy, Nursing
Informed:	
CUHCC Author(s):	Medical Providers, Director of Pharmacy

If you have questions about this protocol, please contact your supervisor or CUHCC Compliance Officer.

Instruction
(include: roles/responsibility and refer to any other needed instructions/forms)

Purpose: provide appropriate and successful completion of hepatitis C treatment

See Appendix A for visit flow

Provider Role
- Medical providers conduct appropriate screening, history, and physical exam.
- Medical providers review prior liver imaging, labs, and arrange for ultrasound of liver (ie FibroScan) as indicated.
- Discuss risks/benefits of treatment options and select medication appropriate for patient's treatment. Complete prior authorization as needed.
- Monitor side effects, lab parameters (CMP, viral load), and adherence during treatment
- Post-treatment evaluation at 12 weeks, 6 month US if needed, and strategies to avoid re-infection.

Pharmacist Role
- Comprehensive medication management initial visit to start treatment, including reviewing drug interactions
- Provide patient education about course of treatment including indication, effectiveness, safety, adherence, and follow up expectations for successful completion of treatment.

Medical Assistant (MA)/Licensed Practical Nurse (LPN) Role
- Order or activate labs as discussed during pre-visit planning
- Call/Send letter to patients for follow up on results as directed by providers.

Referral & HIM Teams Role
- Receive and arrange for liver imaging as ordered by medical provider
- Obtain prior or current liver imaging records and/or enter into electronic health record for provider review

Specialty pharmacies

Insurance	Preferred Medications	Preferred Pharmacy
Hennepin Health	Glecaprevir/ pibrentasvir	**Lumicera Pharmacy** 310 Integrity Drive Madison, WI 53717 Phone: 855-847-3554 Fax: 855-847-3558
Medica	Unsure	**Accredo Pharmacy** (mail order pharmacy)
BCBS MN UCare	Glecaprevir/ pibrentasvir	**Fairview Specialty Pharmacy** 711 Kasota Ave. SE Minneapolis, MN 55414 Phone: 612-672-5260 Toll-free: 800-595-7140 Fax: 866-347-4939
Health Partners	sofosbuvir / velpatasvir?	**CVS Caremark Specialty Pharmacy** Fax Referral To: 1-877-552-2907 Phone: 1-888-345-1678 See online form from CVS website

Step 4: Monitoring during treatment

Labs: 4 weeks into treatment (NOT needed)

- HCV RNA (HCV viral load)
  - If detectable at treatment week 4, repeat quantitative HCV RNA viral load after 2 additional weeks of treatment (treatment week 6)
- Could consider creatinine and hepatic panel - this is not standardized
- https://www.hcvguidelines.org/treatment-naive/simplified-treatment
- If Hep B Surface Antigen positive, recommend monthly HBV DNA
- If Hep B Core Antibody positive, consider monthly Hep B S Ag / HBV DNA

You don't necessarily have to get labs at 4 weeks--you could just do a test for cure after treatment. At BFM, they do not get mid-treatment labs. This is our procedure at CUHCC because patients will be coming at 4 weeks for more medication anyway, and may not come for a cure visit due to multiple factors

Step 5: Post-treatment follow up

Test for cure and labs 12 weeks or later after completion of therapy

- HCV RNA (HCV viral load) and hepatic panel (if previously elevated)
  - Undetectable HCV RNA ≥12 weeks after treatment completion are deemed to have achieved sustained virologic response (SVR12)
- If SVR
  - If noncirrhotic, no further specific hepatic follow up needed
  - Remind patients that HCV antibody testing will likely remain positive
  - If ongoing risk for HCV infection, monitor for reinfection annually with viral load
- If no SVR
  - Refer to specialist for evaluation for retreatment

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Q&A and Evaluation

- Please type your questions in the chat box or unmute yourself to speak
- While Dr. Kelly is answering questions, please complete our grant-required evaluation

Learn more

AASLD/IDSA HCV guidelines

AASLD/IDSA treatment algorithm for simplified chronic HCV treatment without cirrhosis

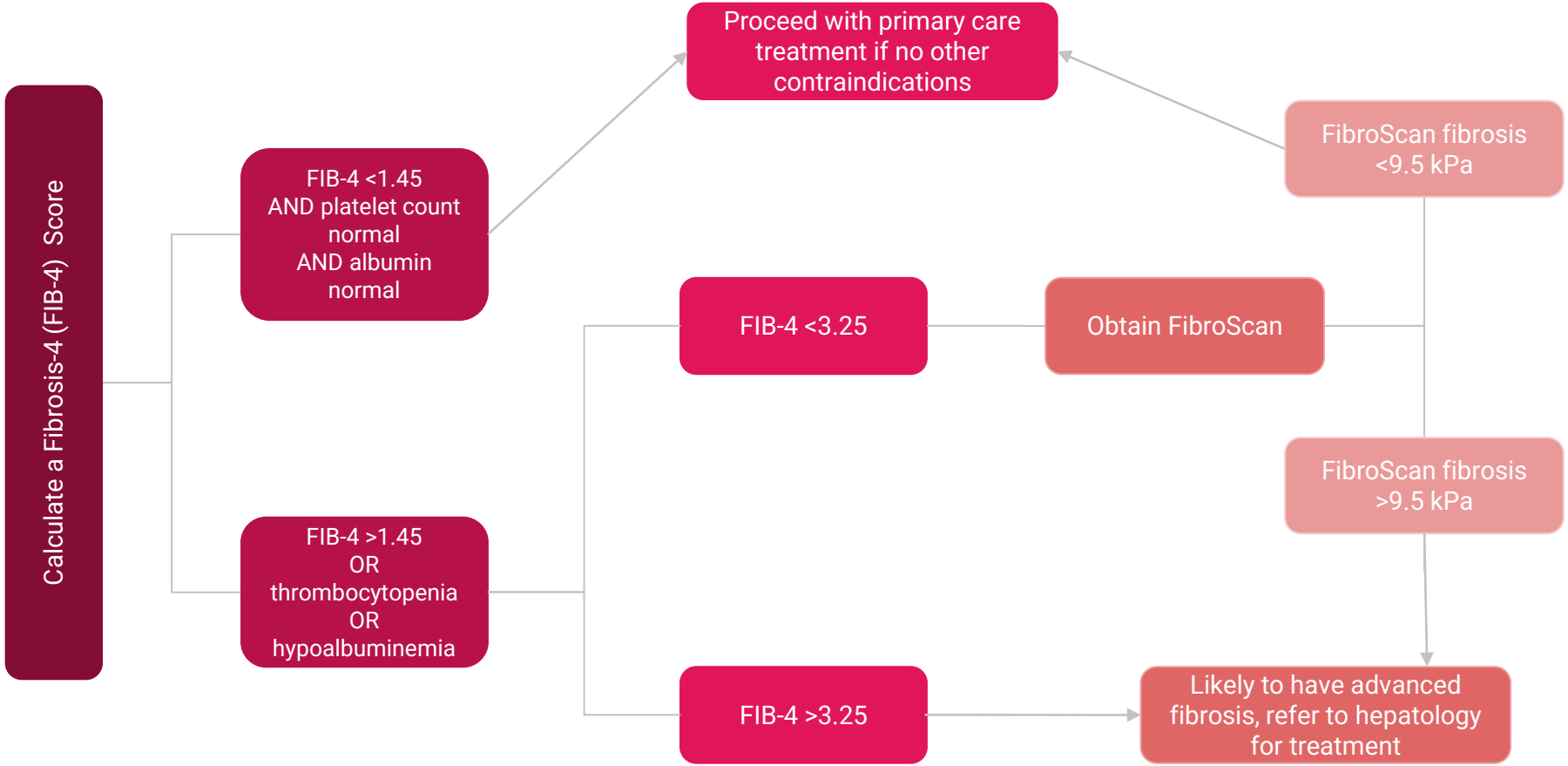
The Curbsiders Internal Medicine Podcast #66 Hepatitis C: Workup and Treatment in Primary Care

University of Liverpool drug interaction checker

Minnesota Medicaid treatment criteria and preferred drug list

Hennepin Healthcare ECHO resources for in depth hepatitis C topics and conversations, case presentations

AETC National HIV-HCV Curriculum https://aidsetc.org/hivhcv


Calculate a Fibrosis-4 (FIB-4) Score
FIB-4 <1.45 AND platelet count normal AND albumin normal
Proceed with primary care treatment if no other contraindications
FibroScan fibrosis <9.5 kPa
FIB-4 <3.25
Obtain FibroScan
FIB-4 >1.45 OR thrombocytopenia OR hypoalbuminemia
FibroScan fibrosis >9.5 kPa
FIB-4 >3.25
Likely to have advanced fibrosis, refer to hepatology for treatment

Please reach out

Paul Stadem, MD stad0107@umn.edu -- Family Medicine resident at Broadway Family Medicine Clinic who started a Hepatitis C treatment program at his primary care clinic

Ryan Kelly, MD kelly847@umn.edu -- Internal Medicine-Pediatrics doctor at Community University Health Care Center (CUHCC) who advocated for changes in Minnesota to make hepatitis C treatment more accessible for all patients and is treating patients for hepatitis C in the primary care setting

Sign up for the Hennepin Healthcare Viral Hepatitis Echo: Join hepatology and infectious disease experts and primary care physicians from across MN in Hepatitis C treatment topics and case discussions. Bring your cases to discuss! Sessions are 1st and 3rd Tuesday of the month from 12:05-1:05 pm.