



CHANGING MEDICINE.
CHANGING LIVES.®

Hepatitis C Link to Treatment

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Reduction Summit

Whom and how to screen.

SCREENING

Whom to Screen for HCV

Testing is recommended in select populations.

- Baby Boomers: *Born 1945-1965.*
- Risk Exposures: *Needle, sharps, or mucosal exposure to HCV infected blood.*
 - Transfusion before 1987 or organ transplant before 1992.
 - Injection or intranasal substance use.
 - Unregulated tattooing / piercing.
 - Hemodialysis.
 - Incarceration.
 - Born to HCV infected mother.
- Other: *Unexplained liver disease, solid organ donor, HIV infection.*

<https://www.hcvguidelines.org/evaluate/testing-and-linkage>

Screening Tests

FDA-approved HCV-antibody Screening Assays

Assay	Manufacturer	Format
Abbott HCV EIA 2.0	Abbott Laboratories Abbott Park, IL, USA	EIA ^a (manual)
Advia Centaur HCV	Siemens Healthcare Malvern, PA, USA	CIA ^b (automated)
Architect Anti-HCV	Abbott Laboratories Abbott Park, IL, USA	CMIA ^c (automated)
AxSYM Anti-HCV	Abbott Laboratories Abbott Park, IL, USA	MEIA ^d (automated)
OraQuick HCV Rapid Antibody Test	OraSure Technologies, Inc. Bethlehem, PA, USA	Immunochromatographic (manual)
Ortho HCV Version 3.0 ELISA Test System	Ortho-Clinical Diagnostics, Inc. Raritan, NJ, USA	EIA ^a (manual)
VITROS Anti-HCV	Ortho-Clinical Diagnostics, Inc. Raritan, NJ, USA	CIA ^b (automated)
^a EIA: enzyme immunoassay ^b CIA: chemiluminescent immunoassay ^c CMIA: chemiluminescent microparticle immunoassay ^d MEIA: microparticle enzyme immunoassay Table prepared by Saleem Kamili, PhD, Centers for Disease Control and Prevention.		

Steps between HCV diagnosis and treatment completion.

LINK TO CARE

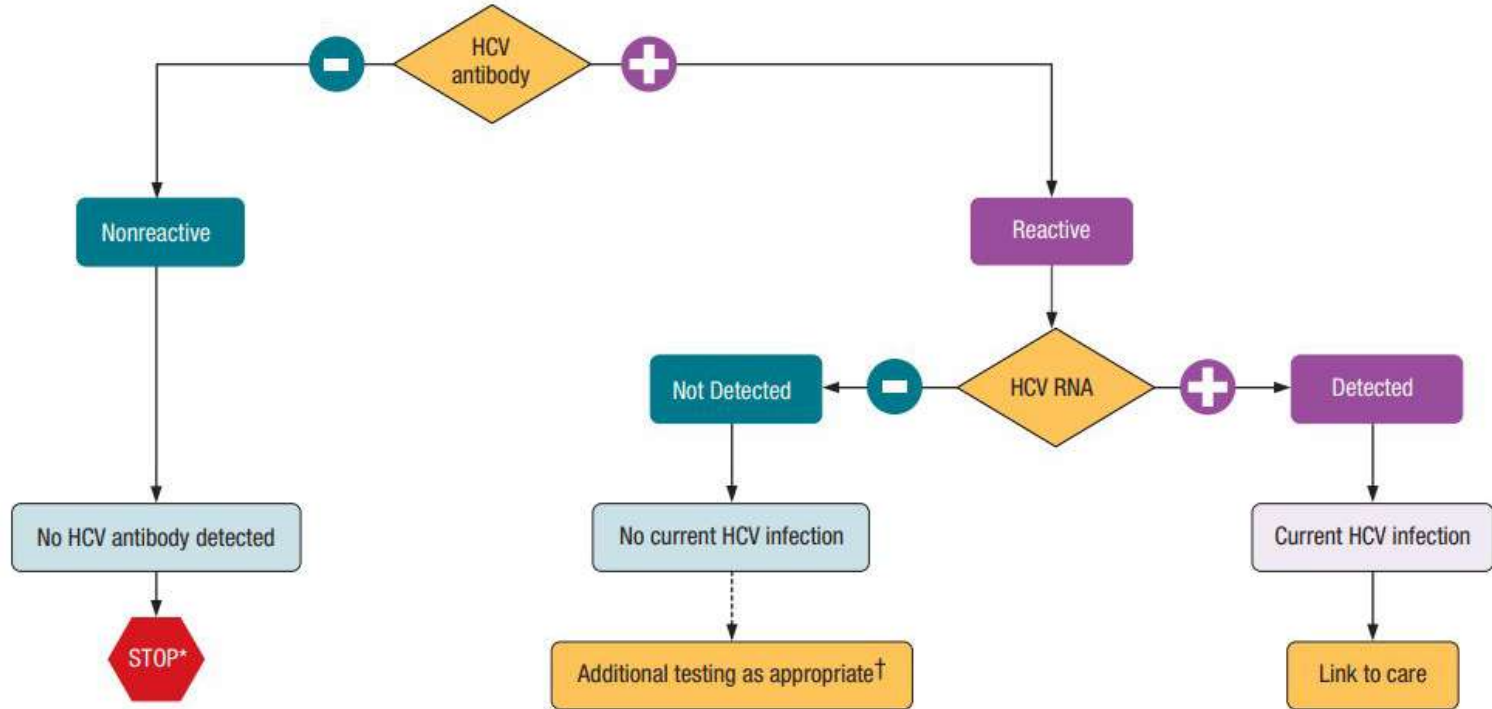
HCV Treatment

- Goal: Achieve HCV cure (SVR) and reduce
 - All-cause mortality
 - End-stage liver disease
 - Liver cancer (hepatocellular carcinoma)
 - Viral transmission
- Treatment recommended for all patients with chronic HCV except
 - Short life expectancy due to liver disease (managed by an expert).
 - Short life expectancy not improved by treatment / liver transplant.

<https://www.hcvguidelines.org/evaluate/when-whom>

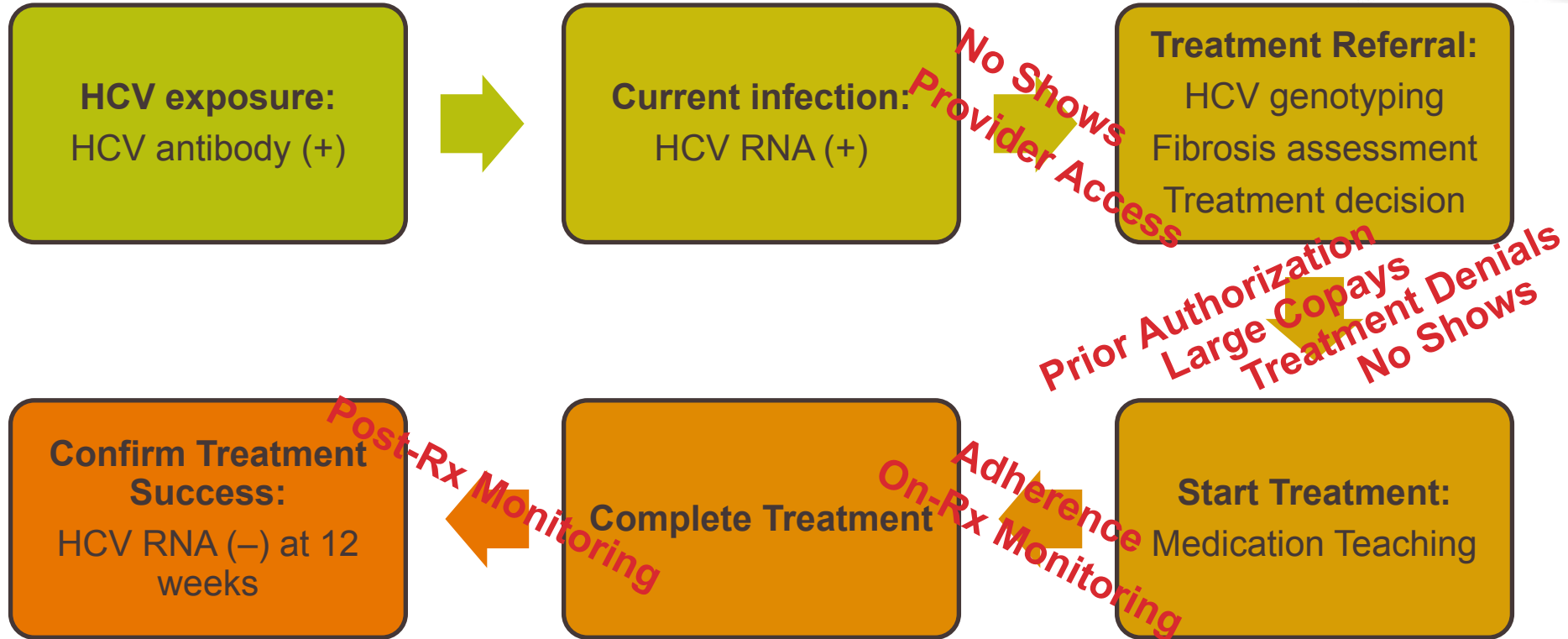
Link to Care

How to make a diagnosis of HCV infection.



Steps to Treatment Success

There are several barriers in linking HCV diagnosis to treatment success.



Treatment Prescription

Benefits Investigation & Prior Authorization

Commercial

Medicare

Medicaid

Copay Ok

Copay \$\$\$

Copay Ok

Copay \$\$\$

Drug Screening

Copay Cards

Private Grant

Fibrosis Assessment

F0-1

≥F2

Rx Denial x 2

PAP Application

Common Pathway:
1. Any denials
2. No insurer

TREATMENT

Examples of Prior Authorization, Private Grant, and Pharmaceutical Assistance Program Documentation.

EXAMPLES

Iowa Medicaid Prior Authorization

Notably PA form wants:

1. Liver fibrosis \geq F2.
2. Proven patient compliance.
3. Clean alcohol & drug screens.
4. Prescriber to work in or consultation with gastroenterology, hepatology, infectious disease.

SECTION 2 – SUPPORTING DOCUMENTATION

Review and complete each numbered item below to provide the supporting documentation for the PA request.

Diagnosis:

1. Pretreatment viral load (**attach results**): _____ Date Obtained: _____
2. Documentation of advanced liver disease (**attach results**): _____ Date Obtained: _____
 - ☐ Liver biopsy confirming a Metavir score \geq F2
 - ☐ Transient elastography (FibroScan) score \geq 7.5kPa
 - ☐ FibroSURE (FibroTest) score \geq 0.48
 - ☐ APRI score $>$ 0.7
 - ☐ Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
 - ☐ Physical findings or clinical evidence consistent with cirrhosis
 - ☐ Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

Patient History:

3. Does the patient have a history of non-compliance? ☐ Yes ☐ No
If yes, submit chart notes documenting the steps taken to correct or address the non-compliance (**attach chart notes**)
4. Documentation in provider notes (**must be submitted**) showing that member has had no abuse of alcohol and drugs for the previous 3 months. **MUST submit** urine drug screen for members with history of abuse of drugs other than alcohol. Counseling **MUST** be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
5. Is the patient receiving dialysis? ☐ Yes ☐ No
6. Is the patient's creatinine clearance \geq 30 ml/min? ☐ Yes ☐ No
7. Has patient been screened for Hepatitis B? No Yes Date: _____ Active Disease: No Yes If yes, has patient been treated or currently being treated? No Yes
8. Patient weight: _____ Date obtained: _____
9. Does patient have a limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions? ☐ Yes ☐ No

Prescriber Information:

10. Provider Practice: ☐ Digestive Disease ☐ Liver Disease ☐ Infectious Disease ☐ Other: _____
If other, note consultation with Specialist:
Consultation Date: _____ Physician Name, Phone & Specialty: _____

PAN Foundation Grants

Private grants used for copay assistance.

Assistance Amount

\$7,000 per year. Patients may apply for a second grant during their eligibility period subject to availability of funding.

Eligibility Criteria

1. The patient must be getting treatment for hepatitis C.
2. The patient must have health insurance that covers his or her qualifying medication or product.
3. The patient's medication or product must be listed on PAN's list of covered medications.
4. The patient's income must fall at or below 500% of the Federal Poverty Level.
5. The patient must reside and receive treatment in the United States or U.S. territories. (U.S. citizenship is not a requirement.)

[Calculate Your Federal Poverty Level Percentage Here »](#)

Assistance Program Application

Example of the most common HCV PAP application form.



Fax To: 1-855-886-2481
Phone: 1-855-687-7503
PO Box 4280, Gaithersburg, MD 20885

APPLICATION FOR MAVIRET™ (glecaprevir/pibrentasvir)

1 PATIENT INFORMATION

☐ Check if shipping to Prescriber's office (cannot ship to a PO Box)

Patient's Name: _____ DOB: _____ Last 4 SSN: _____ ☐ Male ☐ Female
Shipping Address (No PO Box): _____ Shipping City/State/Zip: _____
Mailing Address: _____ Mailing City/State/Zip: _____
Primary Phone: _____ Alternate Phone: _____ Language: ☐ English ☐ Spanish ☐

Annual Household Income: \$ _____

Number in Household (including self): _____

Please include financial documentation for everyone in the household. A copy of your current federal tax return is preferred.

2 PATIENT INSURANCE

☐ No Insurance ☐ Medicaid ☐ Medicare ☐ Private/Commercial ☐ Other: _____

Insurance Name: _____ Phone #: _____ PBM Name: _____ PBM Phone #: _____
Policy #: _____ Group #: _____ PBM BIN #: _____ PBM Group #: _____
Policyholder Name: _____ Policyholder DOB: _____ Please also include a front and back copy of prescription and insurance cards.

3 PATIENT CONSENT PLEASE REVIEW PRIVACY NOTICE AND PROGRAM TERMS IN SECTION 8 TO UNDERSTAND HOW WE USE YOUR PERSONAL DATA

I acknowledge that I have provided accurate and complete information and have read the Patient Terms of Participation in Section 8. My signature below certifies that I have read, understood and agreed to the HIPAA Authorization in Section 8.

PLEASE SIGN AND DATE: _____
PATIENT SIGNATURE / LEGAL REPRESENTATIVE (indicate relationship) _____ DATE _____

4 PATIENT HISTORY • DIAGNOSIS

HCV Genotype: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 Fibrosis (F) Score: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Diagnosis (ICD-10 Code): ☐ B18.2 Chronic Viral Hepatitis C ☐ B19.20 Unspecified Viral Hepatitis C without Hepatic Coma
Treatment History: ☐ Treatment - Naïve ☐ Treatment - Experienced ☐ Direct-Acting Antiviral ☐ Other HCV Medications
Medical History: ☐ Renal Insufficiency CKD Stage: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Compensated Cirrhosis (Child-Pugh A) Hep B Vaccine: ☐ No ☐ Yes Year: _____
Medications (List): _____ Allergies (List): _____

5 PRESCRIBER INFORMATION

Prescriber Name: _____ NPI or SLN: _____ ☐ Hepatology ☐ Gastro ☐ ID ☐ Other: _____
Facility Name: _____ Facility Phone: _____
Address: _____ City/State/Zip: _____
Contact Name: _____ Contact Phone: _____ Contact Fax: _____

6 PRESCRIPTION • MUST FAX DIRECTLY FROM PRESCRIBER OFFICE

(PLEASE CHECK REFILL NUMBER AND SIGN/DATE)

	MEDICATION DOSE/STRENGTH	DIRECTIONS	QTY	REFILLS
MAVIRET	glecaprevir 100 mg; pibrentasvir 40 mg fixed-dose combination tablets	1 daily dose pack (3 tablets) by mouth once daily with food	28-day supply	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Other: _____

NEW YORK PRESCRIBERS: PLEASE SUBMIT PRESCRIPTION PER NY STATE LAW RESTRICTIONS.
FOR ALL OTHER STATES, IF NOT FAXED, MUST BE ON STATE SPECIFIC BLANK IF APPLICABLE.

7 PRESCRIBER SIGNATURE

Substitution Permitted Dispense as Written Date

PRESCRIBER MUST MANUALLY SIGN. RUBBER STAMPS, SIGNATURE BY OTHER OFFICE PERSONNEL OR COMPUTER GENERATED IMAGES ARE NOT ALLOWED
I verify that the information provided is current, complete and accurate to the best of my knowledge. myAbbVie Assist reserves the right to request additional information if needed and to change or discontinue the program at any time, without notice. I shall not seek reimbursement for any medication dispensed hereunder from any government program or third party, including patient, nor will I sell, trade or distribute any such medication. I also understand that the applicant's acceptance into the program should not influence treatment decisions. By signing this form, I authorize the program and its representatives to transmit this prescription form electronically, by facsimile, or by mail to a pharmacy designated by the program for the dispensing of the medication called for herein. I understand that I may not delegate signature authority. I certify that treatment with this medication is medically necessary.

Navigating HCV Treatment:

Their work facilitates acquisition and successful completion of HCV treatment.



Heidi Wood
PharmD, BCPS

Kristy Lowenberg
Pharmacy Revenue Cycle Representative
Benefits Investigation / Prior Authorizations



Tony Huynh
PharmD, BCACP

Kelly Bredfield
Social Work
Pharmaceutical Assistance Program Applications