Hepatitis C Link to Treatment

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Whom and how to screen.

SCREENING
Whom to Screen for HCV

Testing is recommended in select populations.

- Risk Exposures: *Needle, sharps, or mucosal exposure to HCV infected blood.*
  - 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

<table>
<thead>
<tr>
<th>Assay</th>
<th>Manufacturer</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott HCV EIA 2.0</td>
<td>Abbott Laboratories Abbott Park, IL, USA</td>
<td>EIA (manual)</td>
</tr>
<tr>
<td>Advia Centaur HCV</td>
<td>Siemens Healthcare Malvern, PA, USA</td>
<td>CIA (automated)</td>
</tr>
<tr>
<td>Architect Anti-HCV</td>
<td>Abbott Laboratories Abbott Park, IL, USA</td>
<td>CMIA (automated)</td>
</tr>
<tr>
<td>AxSYM Anti-HCV</td>
<td>Abbott Laboratories Abbott Park, IL, USA</td>
<td>MEIA (automated)</td>
</tr>
<tr>
<td>OraQuick HCV Rapid Antibody Test</td>
<td>OraSure Technologies, Inc. Bethlehem, PA, USA</td>
<td>Immunochromatographic (manual)</td>
</tr>
<tr>
<td>Ortho HCV Version 3.0 ELISA Test System</td>
<td>Ortho-Clinical Diagnostics, Inc. Raritan, NJ, USA</td>
<td>EIA (manual)</td>
</tr>
<tr>
<td>VITROS Anti-HCV</td>
<td>Ortho-Clinical Diagnostics, Inc. Raritan, NJ, USA</td>
<td>CIA (automated)</td>
</tr>
</tbody>
</table>

1. EIA: enzyme immunoassay
2. CIA: chemiluminescent immunoassay
3. CMIA: chemiluminescent microparticle immunoassay
4. 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.

HCV exposure: HCV antibody (+)

Current infection: HCV RNA (+)

Treatment Referral:
- HCV genotyping
- Fibrosis assessment
- Treatment decision

Confirm Treatment Success:
HCV RNA (–) at 12 weeks

Complete Treatment

Start Treatment:
Medication Teaching

Prior Authorization
Large Copays
Treatment Denials
No Shows

Provider Access

Post-Rx Monitoring
Adherence
On-Rx Monitoring

No Shows
Treatment Prescription → Benefits Investigation & Prior Authorization

- **Commercial**
  - Copay Ok
  - Copay $$$
  - Copay Cards

- **Medicare**
  - Copay Ok
  - Copay $$$
  - Private Grant

- **Medicaid**
  - Drug Screening
  - 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
Notably PA form wants:

1. Liver fibrosis ≥ F2.
2. Proven patient compliance.
4. Prescriber to work in or consultation with gastroenterology, hepatology, infectious disease.

### Iowa Medicaid Prior Authorization

### SECTION 2 – SUPPORTING DOCUMENTATION

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

<table>
<thead>
<tr>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pretreatment viral load (attach results): Date Obtained:</td>
</tr>
<tr>
<td>2. Documentation of advanced liver disease (attach results): Date Obtained:</td>
</tr>
</tbody>
</table>

- Liver biopsy confirming a Metavir score ≥ F2
- Transient elastography (FibroScan) score ≥ 7.5kPa
- FibroSURE (FibroTest) score ≥ 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 ☐

4. [If yes] submit chart notes documenting the steps taken to correct or address the non-compliance (attach chart notes)

5. Is the patient receiving dialysis? Yes ☐ No ☐

6. [Is the patient's creatinine clearance < 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 »

https://panfoundation.org
Assistance Program Application

Example of the most common HCV PAP application form.

APPLICATION FOR MAVYRET™ (glecaprevir/pibrentasvir)

1. PATIENT INFORMATION
   - Check if shipping to Prescriber’s office (cannot ship to a PO Box)
   - Name: [Patient's Name]
   - DOB: [Date of Birth]
   - Sex: [Male/Female]
   - Shipping Address (No PO Box):
   - Mailing Address:
   - Primary Phone: [Primary Phone Number]
   - Alternate Phone: [Alternate Phone Number]
   - Annual Household Income: [Income]
   - Number in Household (Including Self): [Number in Household]

2. PATIENT INSURANCE
   - No Insurance
   - Medicare
   - Private/Commercial
   - Other: [Other Insurance]
   - Insurance Name: [Insurance Company Name]
   - PBM Name: [PBM Name]
   - PBM Phone #: [PBM Phone Number]
   - Policyholder Name: [Policyholder Name]
   - Policyholder DOB: [Policyholder Date of Birth]

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 certifies that I have read, understood, and agreed to the HIPAA Authorization in Section 8.
   - Patient Signature / Legal Representative: [Signature]
   - Date: [Date]

4. PATIENT HISTORY & DIAGNOSIS
   - HCV Genotype:
   - Fibrosis (F) Score:
   - Diagnosis (EGV-16 Codes):
   - Treatment History:
   - Medication History:
   - Other Medications:
   - Allergies:

5. PRESCRIBER INFORMATION
   - Prescriber Name: [Prescriber Name]
   - Prescriber NPI or STN: [NPI or STN]
   - Facility Name: [Facility Name]
   - Facility Phone: [Facility Phone Number]
   - Address: [Address]
   - City/State/Zip: [City/State/Zip]
   - Contact Name: [Contact Name]
   - Contact Phone: [Contact Phone Number]
   - Contact Fax: [Contact Fax Number]

6. PRESCRIPTION
   - Must fax directly from Prescriber office
   - Please check refill number and send adverse:
     - Medication Dose/Strength:
     - DIRECTIONS:
     - QTY:
     - REFS:

7. PRESCRIBER SIGNATURE
   - Substitution Permitted
   - Dispense as Written: [Dispense as Written]
   - Date: [Date]

New York Prescribers: Please submit prescription to NY state law restrictions.
For all other states, if not faxed, must be on state specific blank if applicable.

Preparers must manually sign. Rubber stamps, signature by office personnel or computer generated images are not allowed.

uihc.org
Navigating HCV Treatment:
Their work facilitates acquisition and successful completion of HCV treatment.

Heidi Wood
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Kristy Lowenberg
Pharmacy Revenue Cycle Representative
Benefits Investigation / Prior Authorizations

Tony Huynh
PharmD, BCACP

Kelly Bredfield
Social Work
Pharmaceutical Assistance Program Applications