

# Hepatitis C Virus (HCV): Packet for Clinicians



Dear Clinician,

Enclosed you will find information regarding the identification of patients at-risk of HCV, prescribing information for HCV, and information regarding billing and payment methods for HCV. These materials include:

- Dear Clinician Letter
- Action Items for Primary Care Providers
- HCV Genotype I Treatment Algorithm
- HCV Testing Recommendations
- HCV Testing Algorithm
- HCV Results Interpretation
- Billing and Coding Guide for Screening, Diagnosis and Referral of Patients with HCV
- Reporting Guidelines for Hepatitis
- Pharmaceutical Company Patient Assistance and Cost-sharing Assistance Programs: Hepatitis
- LAHHUB Patient Facing Materials Order Form
- State Contact List
- HCV Brochure

Louisiana Dept. of Health, Office of Public Health  
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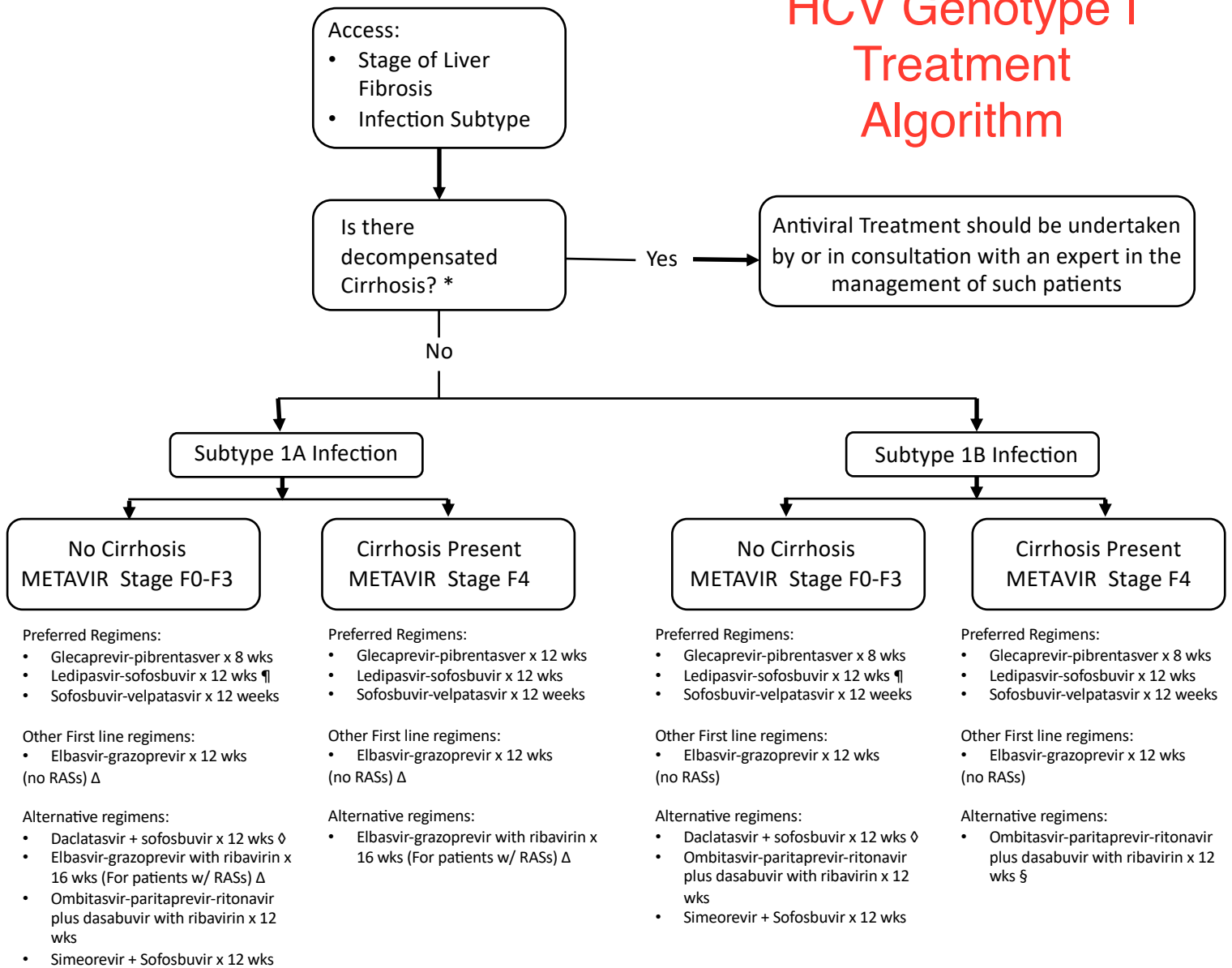
## Action Items for Primary Care Clinicians



It is estimated that approximately 1.6% to 2.6% of the Louisiana population, or 74,000-121,000 people, are currently living with chronic HCV infection. 50% are unaware of their status. Hepatitis C can be treated and cured in almost all patients in 12 weeks, which can prevent liver disease progression, cancer and premature death. Hepatitis C can be prevented through harm reduction and substance use services and proper infection control in health care.

1. **Get trained to prescribe DAA curative treatment**, by visiting Hepatitis C Online, a free education website from the University of Washington at <https://www.hepatitisc.uw.edu/>. Continuing Medical/ Nursing Education (CME/ CNE) available. Also visit <https://aetc.online/resources/hcv/> for additional resources.
2. **Screen all people at risk for hepatitis C infection**, including baby boomers and anyone with history of blood exposure (e.g., medical exposures) or intranasal or injection drug use.
3. **Conduct RNA confirmatory testing and/or implement reflex RNA testing** on all people who screen hepatitis C antibody positive. Automatic confirmatory reflex testing is available from all major laboratories. Call your lab for specific ordering and specimen requirements.
4. **Link to care**. People who are found to be infected with hepatitis C should be linked to care immediately. For help finding referrals for your patients, visit the Louisiana Health Hub at <https://www.louisianahealthhub.org/hep-directory>
5. **Develop hepatitis C clinical care capacity**. Review the American Association for the Study of Liver Diseases (AASLD) guidelines at <https://www.aasld.org/publications/practice-guidelines-0>
6. **Evaluate and treat hepatitis C in all infected patients**, including people who use drugs.
7. **Screen cirrhotic patients for liver cancer** according to AASLD guidelines, even after they have been cured of hepatitis C.
8. **Provide reinfection prevention education and support**. Request patient educational materials and visit <https://www.louisianahealthhub.org/hep-c-testing> to connect people to reinfection prevention services such as harm reduction and syringe exchange programs. Also see <https://aetc.online/resources/hcv/> for provider resources.

# HCV Genotype I Treatment Algorithm



- The preferred and first-line regimen options listed for each patient population are likely of comparably high efficacy. The choice between them is based on potential drug interactions, local availability, and individual financial or insurance limitations. Overall, we favor glecaprevir-pibrentasvir, ledipasvir-sofosbuvir, or sofosbuvir-velpatasvir for their simplicity of administration (once-daily dosing without the need to evaluate for baseline polymorphisms), and extensive data to support their use. Drug interactions are generally manageable but should be evaluated prior to initiation, particularly with NS3/4A protease inhibitor-containing regimens (such as glecaprevir-pibrentasvir).
- Doses of direct-acting antivirals are standard. Daclatasvir dose adjustment is warranted with concomitant use of P450 inducers and inhibitors. If ribavirin is used, dosing is weight based: 1000 mg daily if <75 kg and 1200 mg daily if ≥75 kg.
- This algorithm does not apply to patients with estimated glomerular filtration rate <30 mL/min per 1.73 m<sup>2</sup> (or on dialysis). Refer to guidelines on HCV treatment in patients with renal impairment for more details.

HCV: hepatitis C virus; RASs: resistance-associated substitutions; HIV: human immunodeficiency virus.

\* Ascites, hepatic encephalopathy, prolonged prothrombin time, decreased serum albumin, and/or hyperbilirubinemia.

¶ Treatment with ledipasvir-sofosbuvir for 8 instead of 12 weeks is a highly effective option for treatment-naïve patients without cirrhosis who have a baseline viral level <6 million international units/mL. However, if such patients have negative traditional predictors of treatment response (ie, male gender, obesity, black race) or HIV infection, we favor treating for 12 weeks if possible.

Δ For subtype 1a-infected patients in whom elbasvir is being considered, testing for NS5A RASs should be performed. RASs that confer reduced susceptibility to elbasvir-grazoprevir include polymorphisms at M28, Q30, L31, and Y93. If these are present, the recommended regimen is elbasvir-grazoprevir with ribavirin for 16 weeks.

◇ In the United States, daclatasvir plus sofosbuvir is not approved by the Food and Drug Administration for genotype 1 infection, so it may not be a feasible option for most patients.

§ If ombitasvir-paritaprevir-ritonavir plus dasabuvir is used in patients with cirrhosis, close monitoring for hepatic decompensation is warranted. This regimen is contraindicated in patients with Child-Pugh classes B and C cirrhosis.

# Testing Recommendations



CDC's Testing Recommendations for hepatitis C virus infection are outlined below. Testing should be initiated with anti-HCV. For those with reactive test results, the anti-HCV test should be followed with an HCV RNA.

## Persons for Whom HCV Testing Is Recommended

- [Adults born from 1945 through 1965](#) should be tested once (without prior ascertainment of HCV risk factors)
- HCV testing is recommended for those who:
  - Currently injecting drugs
  - Ever injected drugs, including those who injected once or a few times many years ago
  - Have certain medical conditions, including persons:
    - who received clotting factor concentrates produced before 1987
    - who were ever on long-term hemodialysis
    - with persistently abnormal alanine aminotransferase levels (ALT)
    - who have HIV infection
  - Were prior recipients of transfusions or organ transplants, including persons who:
    - were notified that they received blood from a donor who later tested positive for HCV infection
    - received a transfusion of blood, blood components, or an organ transplant before July 1992
- HCV- testing based on a **recognized exposure** is recommended for:
  - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
  - Children born to HCV-positive women

Note: For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

### **Persons for Whom Routine HCV Testing Is of Uncertain Need**

- Recipients of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm)
- Intranasal cocaine and other non-injecting illegal drug users
- Persons with a history of tattooing or body piercing
- Persons with a history of multiple sex partners or sexually transmitted diseases
- Long-term steady sex partners of HCV-positive persons

### **Persons for Whom Routine HCV Testing Is Not Recommended**

(unless they have risk factors for infection):

- Health-care, emergency medical, and public safety workers
- Pregnant women
- Household (nonsexual) contacts of HCV-positive persons
- General population

Source: <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>

# Perinatal Hepatitis C



## Testing Timeline:

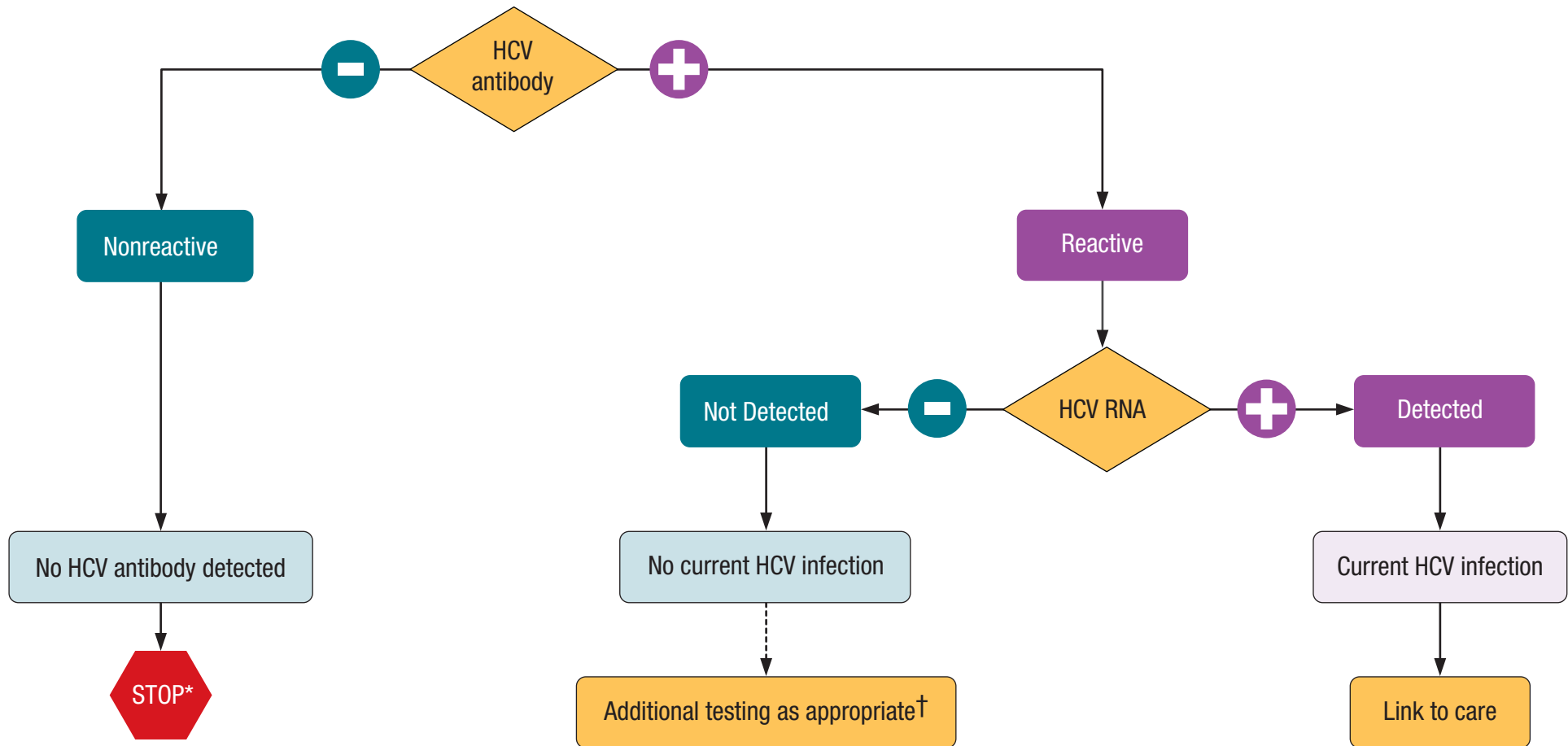
<b>Either</b>	
<b>After 18 months</b>	Test for hepatitis C Antibody- if the test is positive, follow up with hepatitis C RNA (viral load) confirmatory test
<b>After 2 months</b>	<b>OR</b> Test for hepatitis C RNA confirmatory test, and again after 12 months
<b>After 12 months</b>	Test one more time for hepatitis C RNA confirmatory test

Testing for hepatitis C antibodies if the baby is less than 18 months old is not recommended, as the antibodies are still maternal antibodies that were passed down by the mother.

# Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention



\* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

# Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
<b>HCV antibody nonreactive</b>	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required.  If recent exposure in person tested is suspected, test for HCV RNA.*
<b>HCV antibody reactive</b>	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
<b>HCV antibody reactive, HCV RNA detected</b>	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
<b>HCV antibody reactive, HCV RNA not detected</b>	No current HCV infection	No further action required in most cases.  If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay.  In certain situations,‡ follow up with HCV RNA testing and appropriate counseling.

\* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

‡ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.



<b>CPT® Code</b>	<b>Description</b>
<b>Hepatitis Screening Tests</b>	
86708	Hepatitis A antibody (HAAb); total
86704	Hepatitis B core antibody (HBcAb); total
86705	Hepatitis B core antibody (HbcAb); IgM
86706	Hepatitis B surface antibody (HbsAb)
87340	Hepatitis B surface antigen (HBsAg) detection
86803	Hepatitis C antibody (for OraQuick® testing, use 92 modifier code or QW with Medicare)
<b>Hepatitis C Diagnosis Tests</b>	
87520	Hepatitis C RNA; direct probe technique
87521	Hepatitis C RNA; amplified probe technique
87522	Hepatitis C RNA; quantification
87902	Hepatitis C virus genotype analysis
<b>Hepatitis Vaccination</b>	
90632	Hepatitis A vaccine, adult, for IM use. Ex. Havrix (GlaxoSmithKline)
90636	Hepatitis A and Hepatitis B vaccine (HepA-HepB), adult, for IM use. Ex. Twinrx (GlaxoSmithKline)
90746	Hepatitis B vaccine, adult (3 dose schedule), for IM use. Ex. Engerix (GlaxoSmithKline)
<b>Evaluation and Management (E &amp; M) – Clinical Visits</b>	
99201 (10min) 99202 (20min) 99203 (30min)	Office or other outpatient visit for the evaluation and management of a new patient.
99211 (5min) 99212 (10min) 99213 (15min)	Office or other outpatient visit for the evaluation and management of an established patient.
99401 (15min) 99402 (30min)	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual.
<b>Venipuncture</b>	
36415	Collection of venous blood by venipuncture
<b>Immunization Administration</b>	
90471	Immunization administration (includes percutaneous, intra-dermal, subcutaneous, intramuscular and jet injections, on single or combination vaccine/toxoid)
90472	Each additional vaccine (single or combination vaccine); List separately in addition to the code for primary procedure.

ICD-9	ICD-9 HCV Disease Diagnosis	ICD-10	ICD-10 HCV Disease Diagnosis
<b>Hepatitis Screening Codes</b>			
V 70.0	Routine medical examination		
V73.89	Screening for other specified viral disease		
V01.79	Contact or exposure to other viral diseases	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
V02.60	Carrier or suspected carrier of viral hepatitis unspecified		
V02.62	Carrier or suspected carrier of hepatitis C		
<b>Hepatitis Diagnosis Codes</b>			
<b>Hepatitis B</b>			
070.3	Chronic hepatitis B without mention of hepatic coma		
<b>Hepatitis C</b>			
070.41	Acute hepatitis C w/hepatic coma	B17.11	Acute hepatitis C w/out hepatic coma
070.51	Acute hepatitis C w/out hepatic coma	B17.10	Acute hepatitis C w/out hepatic coma
070.44	Chronic hepatitis C w/hepatic coma		
070.54	Chronic hepatitis C w/out hepatic coma	B18.2	Chronic hepatitis C w/out hepatic coma
070.70	Unspecified hepatitis C w/out hepatic coma	B19.2	Unspecified hepatitis C w/out hepatic coma
070.71	Unspecific hepatitis C w/hepatic coma	B19.21	Unspecific hepatitis C w/hepatic coma
573.3	Hepatitis unspecified		
V12.09	History of hepatitis C		
<b>Risk Factors for Hepatitis Screening</b>			
305.90	Other, mixed or unspecified drug abuse, unspecified use		
305.91 305.92 305.93	Nondependent other, mixed or unspecified drug abuse <ul style="list-style-type: none"> <li>• Continuous use</li> <li>• Episodic use</li> <li>• In remission</li> </ul>		
V69.2	High-risk sexual behavior	Z72.5	High-risk sexual behavior
V01.6	Contact with or exposure to venereal disease		
709.09	Tattooing		
042	HIV Screening		
V73.89	Screening examination for viral disease		
V69.8	Other problems related to lifestyle		
<b>Liver Disease</b>			
571.8	Other chronic nonalcoholic liver disease	K76.0	Fatty liver, not elsewhere classified
571.9	Unspecified chronic liver disease w/out alcohol	K76.9	Liver disease, unspecified
790.4	Nonspecific elevation of levels of transaminase or LDH		
<b>Vaccination</b>			
V05.3	Needed for prophylactic vaccination and inoculation against viral hepatitis	Z23	Encounter for immunization
<b>Screening for Alcohol</b>			
V79.1	Screening for alcohol		

# Reporting Guidelines for Hepatitis



## Louisiana Sanitary Code, LAC: 51:11.105

*Per Louisiana Law, **all clinicians** must report the following infections to the Office of Public Health within the specified time, **regardless** of independent, automatic reporting by laboratories.*

### **Class B Diseases, Reportable within 1 business day**

- Hepatitis A (acute illness)
- Hepatitis B (acute, perinatal, or during pregnancy)
- Hepatitis E

### **Class C Diseases, Reportable within 5 business days**

- Hepatitis C (acute)

### **Reporting Instructions:**

To report any of the above conditions, please fax lab and relevant case information within the specified timeframe, to the Infectious Disease Epidemiology Confidential Fax: 504-568-8290 or call Infectious Disease Epidemiology: 504-568-8313 or 1-800-256-2748 if outside regular business hours.

**Please note:** the conditions and classifications are current as of October 2018. Revisions to the sanitary code will: 1) Move Hepatitis C from Class C to Class B; 2) Add Perinatal Hepatitis C as a Class B condition.



# Pharmaceutical Company Patient Assistance and Cost-sharing Assistance Programs: Hepatitis

June 19, 2018

## What is a Patient Assistance Program (PAP)?

A patient assistance program (PAP) is a program run through pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare or AIDS Drug Assistance Programs (ADAPs). Each individual company has different eligibility criteria for application and enrollment in their patient assistance program.

## What is a Cost-sharing Assistance Program (CAP)?

A cost-sharing assistance program (CAP) is a program run through pharmaceutical companies to offer cost-sharing assistance (including deductibles, co-payments and co-insurance) to people with private health insurance to obtain viral hepatitis drugs at the pharmacy.

## Pharmaceutical Company Patient Assistance Programs

Company	Contact Information	Drugs Covered	Financial Eligibility
<b>For Hepatitis B Virus (HBV)</b>			
Bristol-Myers Squibb	855-898-0267 <a href="http://www.baraclude.bmscustomerconnect.com/">http://www.baraclude.bmscustomerconnect.com/</a>	Baraclude	300% FPL
Gilead Sciences	800-226-2056 <a href="https://www.gileadadvancingaccess.com/">https://www.gileadadvancingaccess.com/</a>	Hepsera, Vemlidy, and Viread	500% FPL
GlaxoSmithKline <sup>1</sup>	866-728-4368 <a href="http://www.gskforyou.com">www.gskforyou.com</a>	Epivir	250% FPL
<b>For Hepatitis C Virus (HCV)</b>			
AbbVie	855-687-7503 <a href="http://www.viekirahcp.com/">http://www.viekirahcp.com/</a>	Mavyret and Viekira XR	500% FPL or <\$100,000 annual household income
Bristol-Myers Squibb	800-736-0003 <a href="http://www.bmspaf.org/">http://www.bmspaf.org/</a>	Daklinza	300% FPL
Gilead Sciences <sup>2</sup>	855-769-7284 <a href="http://www.mysupportpath.com">www.mysupportpath.com</a>	Epclusa, Harvoni, Sovaldi, and Vosevi	500% FPL or <\$100,000 annual household income
Merck and Co. <sup>3</sup>	866-251-6013 <a href="http://www.merckhelps.com">www.merckhelps.com</a>	Zepatier	500% FPL

<sup>1</sup> If seeking Epivir for the treatment of HIV (not hepatitis B), contact ViiVConnect to enroll in their PAP.

<sup>2</sup> Effective July 1, 2015, patients who are insured and who do not meet their payer’s coverage criteria will no longer be eligible for support via Gilead’s patient assistance program. This includes clients whose insurer has limited access based on: fibrosis score; step-therapy; or clinical criteria (e.g., drug and alcohol testing).

<sup>3</sup> Effective May 18, 2016, patients who are insured and who do not meet their payer’s coverage criteria will no longer be eligible for support via Merck’s patient assistance program. This includes clients whose insurer has limited access based on: fibrosis score; step-therapy; or clinical criteria (e.g., drug and alcohol testing).

## Pharmaceutical Company Cost-sharing Assistance Programs

Company	Contact Information	Drugs Covered	Assistance	Renewal
<b>For Hepatitis B Virus (HBV)</b>				
Bristol-Myers Squibb	855-898-0267 <a href="http://www.baraclude.com">www.baraclude.com</a>	Baraclude	Program participants are given a co-payment assistance card that provides up to \$400 per month for eligible patients with commercial health insurance. Card expires at the end of each calendar year.	Automatic renewal each year for enrolled patients.
Gilead Sciences <sup>4</sup>	800-226-2056 <a href="http://www.gilead.com/us/advancing_access">www.gilead.com/us/advancing_access</a>	Vemlidy	The co-payment coupon program will cover out-of-pocket prescription costs up to \$3,600 per year for patients with commercial insurance. Coupon can be used for 60- and 90-day prescriptions.	Automatic renewal each year for enrolled patients.
<b>For Hepatitis C Virus (HCV)</b>				
AbbVie	844-277-6233 or 844-865-8725 <a href="http://www.viekira.com/">www.viekira.com/</a> <a href="http://www.mavyret.com/">www.mavyret.com/</a>	Mavyret and Viekira XR	Individuals cannot have federally-funded prescription coverage. Individuals pay the first \$5 and then receive up to a maximum of 25% of the catalog price for their medication prescription.	Card expires 12 months after initial use. Reapply if additional prescriptions are needed.
Bristol-Myers Squibb	844-442-6663 <a href="http://www.patientsupportconnect.com/">www.patientsupportconnect.com/</a>	Daklinza	The program provides participants with a co-payment card that covers costs up to \$5,000 per 28-day supply of 30mg or 60mg Daklinza or up to \$10,000 per 28-day supply of 90mg Daklinza for people who have private insurance.	Card expires at the end of each calendar year. Automatic renewal for patients with an active Daklinza prescription.
Gilead Sciences	855-769-7284	Epclusa, Harvoni,	The co-payment coupon program covers up to a maximum of 25% of the catalog price of a 12-week regimen of a Gilead HCV medication (Epclusa, Harvonia, Sovaldi, & Vosevi) after the	Reapply if another regimen is later needed.

<sup>4</sup> As of June 7, 2018, Gilead no longer offers co-payment assistance for Viread that is prescribed to treat hepatitis B, due to the release of a generic alternative.

	<a href="http://www.epclusa.com">www.epclusa.com</a> <a href="http://www.harvoni.com">www.harvoni.com</a> <a href="http://www.sovaldi.com">www.sovaldi.com</a> <a href="http://www.vosevi.com">www.vosevi.com</a>	Sovaldi, and Vosevi	payment of first \$5 per prescription fill. Offer is valid for 6 months from the time of first redemption.	
Merck and Co.	866-251-6013 <a href="http://www.zepatier.com">www.zepatier.com</a>	Zepatier	Participants must pay the first \$5 and then receive savings of up to 25% of the catalog price of Zepatier per prescription, on up to four prescriptions of 28 tablets each.	New coupon must be obtained for every four prescriptions.

## Foundations Providing Access to Care Assistance for People Living with HBV and/or HCV

### [Chronic Disease Fund](#)

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The [Chronic Disease Fund's](#) co-payment and medication assistance program provides financial assistance to eligible individuals.

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### [HealthWell Foundation](#)

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The [HealthWell Foundation's](#) co-payment assistance program provides up to \$15,000 in financial assistance to eligible individuals for HCV treatment. Eligible patients include those who are insured and have an annual household income of up to 500% of the federal poverty level (FPL).

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### [Needy Meds](#)

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[Needy Meds](#) offers resources that are helpful to uninsured and underinsured patients including an MRI/CAT scan discount program and medical bill mediation.

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### [Patient Access Network Foundation](#)

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The [Patient Access Network \(PAN\) Foundation](#) offers help and hope to people with chronic or life-threatening illnesses, including HIV and hepatitis, for whom cost limits access to medical treatments.

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### [Patient Advocate Foundation Co-Pay Relief Program](#)

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The [Patient Advocate Foundation \(PAF\) Co-Pay Relief Program \(CPR\)](#) provides direct financial support to insured patients, including Medicare Part D beneficiaries, who financially and medically need assistance paying prescription medication co-payments, co-insurance and deductibles relative to their diagnosis.

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### [RxOutreach](#)

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[RxOutreach](#) is a mail order pharmacy for people with little to no health insurance coverage.

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### [Wells Specialty Pharmacy](#)

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[Wells Specialty Pharmacy](#) is a mail order pharmacy that provides specialty medications for HCV at affordable prices. They also offer a PAP, CAP, and can connect patients to manufacturer discount programs.

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## Additional Resources

The following resources may be of interest to individuals living with viral hepatitis.

### [Clinical Trials](#)

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A service of the U.S. National Institutes of Health, [ClinicalTrials.gov](https://clinicaltrials.gov) is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

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### [Fair Pricing Coalition \(FPC\)](#)

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As part of their advocacy work, the [Fair Pricing Coalition \(FPC\)](#) negotiates with companies to ensure that PAPs are adequately generous and easy to apply for.

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### [Health Insurance Marketplace](#)

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The official site of the Health Insurance Marketplace, [Healthcare.gov](https://healthcare.gov) allows individuals and families to sign-up for insurance coverage through the Affordable Care Act.

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### [Help-4-Hep](#)

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[Help-4-Hep](#) is a non-profit toll-free helpline for those with concerns about HCV. Help-4-Hep can also help individuals access lower-cost testing for HCV.

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### [Patient Advocate Foundation](#)

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The [Patient Advocate Foundation](#) hosts a “Hepatitis C CareLine” devoted to all aspects of access to care, insurance denials, etc. for patients and providers. The hotline may be reached by calling 800-532-5274.

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### [Treatment Action Group](#)

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[Treatment Action Group](#) collaborates with activists, community members, scientists, governments, and drug companies to make safer, more effective and less toxic treatment for viral hepatitis available.

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## State Contact List



### **Viral Hepatitis Surveillance and Case Reporting**

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