

EVALUATION AND MANAGEMENT OF HEPATITIS C VIRUS (HCV) INFECTION

**Federal Bureau of Prisons
Clinical Guidance**

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(Corrected Version)

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WHAT'S NEW IN BOP GUIDANCE FOR HCV INFECTION

This version of the guidance contains the following **major revisions**, based on the January 2021 guidance from the American Association for the Study of Liver Diseases (AASLD):

- **A simplified approach to evaluation and treatment of HCV** is recommended for patients with no past treatment, or current or past history, of decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, HBV or HIV coinfection, or significant drug-drug interactions.
→ See [Sections 1 and 3](#)
- HCV genotype testing is no longer recommended or required in patients eligible for the simplified approach. This is now used only in determining appropriate treatment regimens for patients with prior treatment failure, relapse, or the conditions listed above.
→ See Laboratory Tests under [Baseline Evaluation](#)
- Recommended treatment regimens
→ See [Section 6, Recommended Treatment Regimens](#)
- Only **five** co-formulated direct-acting antiviral (DAA) regimens are now recommended:
 - Elbasvir/grazoprevir (Zepatier®)
 - Glecaprevir/pibrentasvir (Mavyret®)
 - Ledipasvir/sofosbuvir (Harvoni®)
 - Sofosbuvir/velpatasvir (Epclusa®)
 - Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)
- Regimens **no longer** recommended:
 - Paritaprevir/ritonavir/ombitasvir with or without dasabuvir
 - Daclatasvir+sofosbuvir
 - Simeprevir
 - Interferon is no longer recommended for **any** regimen.
- **Treatment of acute HCV infection is now recommended**, rather than monitoring for 6 -12 months and observing for spontaneous resolution.
- **Quantitative HCV RNA viral load is recommended** pre-treatment and 12 weeks after the completion of treatment. It is **not** recommended at 4 weeks or at the completion of treatment.

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1. PURPOSE AND OVERVIEW

The Federal Bureau of Prisons (BOP) Clinical Guidance on the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection provides the most current BOP recommendations for the treatment of HCV infection in the federal inmate population.

The current HCV guidance from the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) states that the goal of treatment for HCV-infected persons is to:

- ✓ Reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.

The AASLD/IDSA HCV guidance is updated as new data become available. BOP Health Services Division clinical staff will continue to monitor this guidance and provide updates as necessary. Institution clinical staff are encouraged to review the most recent recommendations by AASLD/IDSA as well as BOP Clinical Guidance to ensure treatment decisions are based on the most current available data.

- Consult the **BOP Health Management Resources** website to determine the date of the most recent update to this document:
http://www.bop.gov/resources/health_care_mngmt.jsp.
- The **AASLD/IDSA guidance** is available at <https://www.hcvguidelines.org>. See the [References](#) section in this document for a complete citation.

➤ Simplified Treatment Approach

The AASLD/IDSA HCV guidance **recommends a simplified approach for treatment-naïve patients** with no cirrhosis or with compensated cirrhosis. The BOP HCV guidance has adapted this into three basic steps – **test, evaluate, treat**.

- With the availability of pangenotypic regimens (i.e. a medication regimen that is effective for all HCV genotypes), a simplified approach takes many of the medication selection factors into consideration to get to a treatment decision quickly in certain treatment-naïve patients.
- In such cases, the pre-treatment assessment can be included as part of Step 2 and a simplified regimen may be selected in Step 3 for eligible patients.
(<https://www.hcvguidelines.org/treatment-naive/simplified-treatment>; also <https://www.hcvguidelines.org/treatment-naive/simplified-treatment-compensated-cirrhosis>).
- After completing the evaluation summarized below, treatment-naïve inmates with HCV infection may be approved for treatment with an 8-week course of glecaprevir/pibrentasvir if there are no drug-drug interactions, and the patient does not have any of the following conditions: decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, end-stage renal disease with compensated cirrhosis, or coinfection with HBV and/or HIV.

➤ Test, Evaluate, Treat

STEP 1. Test for HCV infection with HCV Ab test.

→ [Section 2](#), *Screening for HCV Infection*

- Diagnostic evaluation of other conditions
- All inmates screened at least once
- Prenatal testing for each pregnancy
- Periodic risk-based testing related to potential HCV exposure
- On inmate request

STEP 2. Evaluate inmates who are HCV Ab positive.

→ [Section 3](#), *Evaluation of HCV Ab Positive Inmates*.

- Problem-focused history and physical exam
- **Lab tests**—CBC, PT/INR, liver panel, serum creatinine and eGFR, hepatitis B serology (HBsAg, anti-HBs, anti-HBc total), HIV serology, quantitative HCV RNA viral load.
 - HCV genotype testing is not routinely required in treatment-naïve cases with no decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, chronic hepatitis B virus infection (HBV), or HIV infection.
- **Assess for hepatic cirrhosis/compensation**—Calculate APRI score if no obvious cirrhosis; Calculate Child-Turcotte-Pugh (CTP) score if cirrhosis is known or suspected.
→ [Section 4](#), *Assess for Hepatic Cirrhosis and Decompensation*
- If HCV RNA is detectable, determine eligibility for treatment.
- **Provide patient education** and preventive health care for patients with HCV infection and with cirrhosis.

STEP 3. Treat eligible patients with an approved direct-acting antiviral (DAA) regimen.

- Pre-treatment interventions
 - Obtain a pregnancy test prior to starting treatment.
 - Repeat CBC, PT/INR, liver panel, serum creatinine and eGFR if previous results were obtained more than 6 months ago.
→ [Appendix 4](#)
- Determine the most appropriate DAA regimen, including an assessment for drug-drug interactions:
 - With the availability of pangenotypic regimens, a simplified approach takes many of the medication selection factors into consideration to get to a treatment decision quickly in certain patients.
 - Following the AASLD/IDSA simplified algorithm, treatment-naïve inmates with HCV infection may be approved for treatment with an 8-week course of glecaprevir/pibrentasvir if there are no drug-drug interactions, and the patient does not have any of the following conditions – decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, end-stage renal disease with compensated cirrhosis, or co-infection with HBV and/or HIV.

- **Refer to** AASLD HCV guidance, DHHS antiretroviral guidelines, University of Liverpool HEP Drug Interactions, and manufacturers' prescribing information for specific drug interactions
→ [References](#)
- **Submit Nonformulary Request (NFR)** for hepatitis C Treatment Algorithm Request; if approved, submit NFR(s) for specific DAA medication(s)
→ [Appendix 8](#)
- **Start treatment and follow monitoring schedule**
→ [Section 4](#) and [Appendix 3](#)

2. SCREENING FOR HCV INFECTION

➤ Inmate history and patient education

A health history should be obtained from all newly incarcerated BOP inmates. In addition, these inmates should be provided with educational information regarding prevention and transmission, risk factors, testing, and medical management of HCV infection, in accordance with BOP policy. Health education efforts may include use of the BOP peer-oriented video on infectious diseases, *Staying Alive*, which may be found on the HSD Infection Control Sallyport webpage. Using the page resource link for A-Z Topics, search under "A" for Admission and Orientation (A&O) Videos.

➤ Testing Criteria and Method

Testing for HCV infection is recommended:

- as a screening test for all inmates,
- as part of a diagnostic evaluation of inmates with certain clinical conditions (e.g., elevated liver enzymes of uncertain etiology), and
- prenatal testing for each pregnancy
- periodic risk-based testing related to potential HCV exposure
- for all inmates who request testing.

The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as **HCV Ab** ("anti-HCV" in the AASLD Guidance). The presence of these antibodies only indicates a history of exposure to the HCV virus, but does not distinguish between active and resolved infection.

Initial testing with an **HCV RNA** test is recommended for cases with a known prior positive HCV Ab if they are at risk for reinfection or suspected of reinfection, and if they previously cleared the HCV spontaneously or achieved a sustained virologic response (SVR) with treatment.

An "opt-out" strategy of voluntary testing for HCV infection is recommended for all inmates, regardless of sentencing status, including new intakes and those already in population who have not been previously tested.

An "opt-out" approach involves an informed refusal of testing, rather than informed consent (or "opt in") for testing. After informing a patient of the indications and plan for testing, the particular test is ordered and performed—unless the patient declines it. Testing is considered voluntary and is good clinical practice, but is not required by policy or law. Testing is recommended as soon as practical upon entry into the BOP as well as for inmates already in population who have not been tested previously.

➤ Risk Factors for HCV Infection

The AASLD, CDC, and USPSTF recommend risk factor-based and birth cohort screening for HCV infection. The incarcerated population is reported to have higher prevalence rates of HCV than the general population and is identified by the AASLD and USPSTF as a risk factor for which screening is recommended.

Other well-described risk factors, either for acquiring a new infection or already having HCV infection, which should be considered when recommending HCV testing to inmates, include:

- Has ever injected illegal drugs or shared equipment, including intranasal use of illicit drugs
- Received tattoos or body piercings while in jail or prison, or from any unregulated source
- High-risk sexual activity, especially HIV-infected men who have sex with men
- HIV or chronic hepatitis B virus (HBV) infection
- Received a blood transfusion or an organ transplant before 1992, received clotting factor transfusion prior to 1987, or received blood from a donor who later tested positive for HCV infection
- History of percutaneous exposure to blood (See [BOP Clinical Guidance on Medical Management of Exposures](#))
- Has ever received hemodialysis [Order alanine aminotransferase (ALT) monthly and HCV Ab semiannually for inmates on chronic hemodialysis]
- Born to a mother who had HCV infection at the time of delivery
- Born between 1945 and 1965
- Current pregnancy

➤ Clinical Conditions for Testing

HCV testing is recommended for all inmates with the following clinical conditions:

- A reported history of HCV infection without prior medical records to confirm the diagnosis
- Cirrhosis
- Elevated liver enzyme alanine aminotransferase test (ALT) levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis.

➤ Refusal of Testing

Inmates who decline testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits. A **treatment refusal form** is recommended for every testing and treatment refusal.

3. EVALUATION OF INMATES TESTING POSITIVE FOR HCV Ab

Initial evaluation of HCV Ab positive inmates includes: (a) a baseline history and physical examination and (b) baseline lab tests. The inmate should also (c) be assessed regarding the need for preventive health interventions such as vaccines and screenings for other conditions, as well as (d) counseled with information on HCV infection.

Ideally, this evaluation is performed in a timely manner after a positive HCV Ab test result is reported and combines the baseline/initial evaluation and the pre-treatment evaluation into one step.

- A **simplified approach** is recommended, especially for HCV treatment-naïve cases. These cases may then proceed directly to treatment with **an 8-week course of glecaprevir/pibrentasvir** if there are no drug-drug interactions, and the patient does not have decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, or HBV and/or HIV coinfection.
- If **cirrhosis** is present, see [Section 4](#), *Assess for Hepatic Cirrhosis and Decompensation*, to determine whether the liver disease is compensated or decompensated.

➤ Baseline Evaluation

A baseline clinician evaluation should be conducted for all inmates who are HCV Ab positive. At minimum, this evaluation should include the following elements in the **problem-focused history and physical exam**:

- **Evaluate** for signs and symptoms of liver disease, as well as for evidence of HCV sequelae (e.g. cryoglobulinemia, vasculitis).
- **Obtain** a past medical history to include co-occurring medical / mental health conditions and current medications, as well as other pertinent aspects of the patient's medical history.
- **Quantify** prior alcohol consumption, and determine risk behaviors for acquiring HCV infection (See the section on risk factors under [Screening Criteria](#) (above). Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped, e.g., the time period in which the inmate engaged in injection drug use.
 - **Referral for evaluation and treatment of substance use disorder** is recommended for inmates with evidence for ongoing high-risk behaviors related to drug and alcohol use, e.g., incident reports and sanctions related to drug use during their incarceration.
- **Inquire** about prior treatment for HCV infection, specific medications used, dosages and duration of treatment and outcomes, if known.

➤ Laboratory Tests

Recommended baseline laboratory tests are listed in [Appendix 3](#) and include the following:

- Complete blood count (CBC); prothrombin time (PT) with International Normalization Ratio (INR); comprehensive metabolic panel (CMP)
 - CMP includes liver panel (albumin, total and direct bilirubin, serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST), and alkaline phosphatase); serum creatinine and calculated glomerular filtration rate (GFR).
 - Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated, to determine the underlying cause, e.g., low hemoglobin/platelet count or GFR.

- Serology for hepatitis A (anti-HAV total), hepatitis B (HBsAg, anti-HBs, and anti-HBc total), and HIV (anti-HIV).
 - Refer to the relevant BOP Clinical Guidance for management of a positive HBsAg or HIV test. These tests may need to be repeated prior to starting HCV treatment if risk factors for transmission have occurred since their last test.
- Quantitative HCV RNA viral load testing, sensitive to ≤ 25 IU/ml, to determine if the inmate has active HCV infection.
 - Undetectable levels of HCV RNA indicate **resolved infection or a false positive** HCV Ab test. Such cases **do not** require ongoing follow-up or monitoring in a chronic care clinic.
- **HCV genotype testing is no longer routinely recommended** for HCV treatment-naïve cases because many of them will be eligible for a pangenotypic regimen.
 - A genotype does need to be obtained when considering SOF/VEL in a patient with cirrhosis as well as in situations where a non-pangenotypic regimen may be required, including: prior HCV treatment failures, decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, HBV and/or HIV coinfection, or drug-drug interactions.
- Consider other possible causes of liver disease, especially alcoholism, nonalcoholic steatohepatitis (NASH), iron overload, and autoimmune hepatitis, as clinically indicated. Unless otherwise clinically indicated, testing for other causes of liver disease—e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin—are not routinely ordered in the evaluation of a positive HCV Ab test.
- A urine drug screen is recommended only if ongoing substance use is suspected or if it is otherwise clinically indicated.

➤ Preventive Health Measures

All inmates who are HCV Ab positive should be evaluated to assess the need for the preventive health interventions. Patients with liver disease should receive standard immunizations that are applicable to an otherwise healthy population, including the following:

- **Hepatitis B vaccine:** Indicated for susceptible inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination. (Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.)
- **Hepatitis A vaccine:** Indicated for susceptible inmates with chronic HCV.
- **Influenza vaccine:** Offer to all HCV-infected inmates annually. (Inmates with cirrhosis are high priority for influenza vaccine.)

Pneumococcal vaccine: Recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) for use in adults with chronic liver disease, including cirrhosis, regardless of age. Evidence for its use in chronic HCV infection without cirrhosis is limited. (Refer to [BOP Clinical Guidance on Immunizations](#) for specific recommendations).

➤ Patient Education

Inmates diagnosed with chronic HCV infection should be counseled by a health care provider regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting HCV infection to others, both during incarceration and on release.

4. HEPATIC CIRRHOSIS AND DECOMPENSATION

Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement with fibrotic scar tissue. The natural history of HCV is such that 50–80% of HCV infections become chronic.

Progression of chronic HCV infection to fibrosis and cirrhosis may take years in some patients and decades in others—or, in some cases, may not occur at all. Most complications from HCV infection occur in people with cirrhosis.

- Patients with advanced hepatic fibrosis (primarily stage 3) have a 10% per year rate of progressing to cirrhosis (stage 4).
- Those with cirrhosis have a 4% per year rate of developing decompensated cirrhosis, and a 3% per year rate of developing hepatocellular carcinoma.

➤ Assessing for Advanced Fibrosis and Cirrhosis

Assessment is recommended for all inmates with HCV infection in order to select the most appropriate treatment regimen, prioritize inmates for treatment of HCV, and determine the need for additional health care interventions.

Cirrhosis may be diagnosed in several ways:

- **Symptoms and signs** that support the diagnosis of cirrhosis may include: Low albumin or platelets, elevated bilirubin or INR, ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.
- **The AST-Platelet Ratio Index (APRI) is the BOP-preferred method** for non-invasive assessment of hepatic fibrosis and cirrhosis.
 - The APRI score, a calculation based on results from two blood tests—the AST (aspartate aminotransferase) and the platelet count—is a less invasive and less expensive means of assessing fibrosis than a liver biopsy.
 - The formula for calculating the APRI score is:
$$\frac{[(AST/AST\ ULN) \times 100] / \text{platelet count } (10^9/L)}{1}$$
 - ➔ A calculator is available at: <http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>
 - **An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis.** At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see [abdominal imaging studies](#) bullet below in this list).
 - Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.
 - The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4). Using a cutoff of ≥ 0.7 , the sensitivity is 77% and specificity is 72% for significant fibrosis.
 - The APRI score may be invalidated in cases of splenectomy. An alternative non-invasive test (e.g., Fibrosure) may be appropriate. If a person is known to have cirrhosis, the APRI is irrelevant and unnecessary.

- **Liver biopsy is not required** unless otherwise clinically indicated or if there is uncertainty about the stage of fibrosis, based on results from non-invasive testing or other clinical indicators. However, the **presence of cirrhosis on a prior liver biopsy** may be used to meet the BOP criteria for HCV treatment.
- Although a combination of direct biomarkers and transient elastography is emerging as an accurate non-invasive assessment of fibrosis, the data is insufficient at this time to establish it as the new standard over validated indirect biomarkers such as the APRI score.
- **Abdominal ultrasound** is routinely performed in cases of known or suspected cirrhosis, and as clinically indicated on a case-by-case basis. **Abdominal imaging studies** such as ultrasound or CT scan may identify findings consistent with or suggestive of the following:
 - **cirrhosis** (nodular contour of the liver)
 - **portal hypertension** (ascites, splenomegaly, varices), or
 - **hepatocellular carcinoma**

➤ Assessing Hepatic Compensation

Assessing hepatic compensation is important for determining the most appropriate HCV treatment regimen to be used. The recommended HCV treatment regimen may differ depending on whether the cirrhosis is compensated or decompensated.

- The **CTP score** is a useful tool to help determine the severity of cirrhosis and in distinguishing between compensated and decompensated liver disease in patients with known or suspected cirrhosis. However, if the CTP score indicates compensated cirrhosis but the overall clinical picture is suggestive of decompensated cirrhosis, it may be more appropriate to choose a DAA regimen for decompensated cirrhosis.
 - ➔ CTP calculators are readily available on the Internet and are not reproduced in this document. See <http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp>.
- The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in Table 1 on the next page:

TABLE 1. USING CTP SCORES TO ASSESS HEPATIC COMPENSATION

| CTP SCORE | CTP CLASS | HEPATIC COMPENSATION |
|---|-----------|-------------------------|
| 5–6 | Class A | Compensated cirrhosis |
| 7–9 | Class B | Decompensated cirrhosis |
| ≥ 10 | Class C | |
| <ul style="list-style-type: none"> ▶ Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher. ▶ It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition. ▶ Inmates with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for Reduction in Sentence/Compassionate Release in accordance with current policy and procedures. | | |

➤ Additional Interventions for Inmates with Cirrhosis

The following recommendations apply to all inmates with cirrhosis, whether they have ongoing or resolved HCV infection.

- **Pneumococcal vaccine:** Offer to all inmates with cirrhosis.
➔ [BOP Clinical Guidance on Immunizations](#)
- **Hepatocellular carcinoma screening:** Liver ultrasound is recommended **every 6 months** for patients with cirrhosis.
- **Esophageal varices screening:** Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis.

Other healthcare interventions recommended for patients with cirrhosis may include:

- Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
- Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
- Optimized diuretic therapy for ascites
- Lactulose and rifaximin therapy for encephalopathy

In general, **NSAIDs should be avoided** in advanced liver disease/cirrhosis, and **metformin** should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of this document. Other resources should be consulted for more specific recommendations related to this condition.

5. TREATMENT CRITERIA AND PRETREATMENT INTERVENTIONS

Sustained virologic response (SVR) rates of 90% or higher can be achieved with DAA medication regimens. Eradication of HCV is associated with a number of improved outcomes, including a reduction in the following: liver inflammation and fibrosis, severity of advanced liver disease and its complications, risk of liver cancer and liver-related mortality, need for liver transplantation, and transmission of HCV infection.

➤ BOP Eligibility Criteria for HCV Treatment

All sentenced inmates with HCV infection (detectable HCV RNA) are eligible for consideration of treatment. The AASLD/IDSA guidance now recommends treatment for acute HCV infection, rather than monitoring for spontaneous resolution over 6–12 months.

Inmates being considered for treatment of HCV infection should:

- Have no contraindications to, or significant drug interactions with, any component of the treatment regimen.
- Not be pregnant, especially for any regimen that would require ribavirin.
 - Pregnant inmates may be considered for treatment on a case-by-case basis using a shared decision-making model taking into account the lack of data on DAA safety during pregnancy and the risk of transmitting HCV to the baby.

- Have sufficient time remaining on their sentence in the BOP to complete a course of treatment.
 - Inmates with a more urgent need for treatment but insufficient time remaining in BOP custody, may be considered for treatment if they will have access to medications and health care providers for continuity of care at the time of release.
 - Long-term, pre-sentence detainees in BOP custody with higher risk for disease progression or disease complications as described below may be considered for treatment if continuity of care can be reasonably assured and there is reliably sufficient time remaining in custody to complete treatment.
- Have a life expectancy greater than 18 months. Consultation with the Regional Medical Director or Central Office Physician is recommended in cases where life expectancy is uncertain.
- Inmates must demonstrate a willingness and an ability to adhere to a rigorous treatment regimen.
- **Inmates with evidence for ongoing behaviors associated with high risk of HCV transmission** (e.g., injection drug use) **are not automatically excluded** from consideration for HCV treatment.
 - Ideally, such decisions are individualized and made in the context of an integrated model of care in which there is assessment and treatment for substance use disorder, or other disorders intersecting with HCV infection.
 - Data indicate adherence may be high and reinfection rates low in some populations with ongoing risk factors. Furthermore, treatment may have the added benefit of preventing transmission from shared equipment such as needles.
 - Consultation with the Regional HCV Clinical Pharmacist, Regional Medical Director, or Central Office Physician is recommended for making treatment decisions about inmates who become reinfected as a result of ongoing high risk behavior.

Certain conditions are at **higher risk for complications or disease** progression and may require more urgent consideration for treatment, as follows:

- Advanced hepatic fibrosis
 - APRI \geq 2.0, or
 - Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, or
 - Known or suspected cirrhosis
- Liver transplant recipients
- Hepatocellular carcinoma
- Comorbid medical conditions associated with HCV, including:
 - Cryoglobulinemia with renal disease or vasculitis
 - Certain types of lymphomas or hematologic malignancies
 - Porphyria cutanea tarda
- Immunosuppressant medication for a comorbid medical condition
 - Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. Although data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting, such cases will be considered for prioritized treatment of HCV on an individual basis.

- Evidence for progressive fibrosis
 - Stage 2 fibrosis on liver biopsy, if treatment clinically indicated.
- Comorbid medical conditions associated with more rapid progression of fibrosis
 - Coinfection with HBV or HIV
 - Comorbid liver diseases [e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis (fatty liver disease)]
 - Diabetes mellitus
- Chronic kidney disease (CKD) with GFR \leq 59 mL/min per 1.73 m²
- Birth cohort 1945–1965
- Continuity of care for those already started on treatment, including inmates who are newly incarcerated in the BOP.

➤ Pre-Treatment Assessment and Interventions

A simplified approach combining Steps 2 and 3 (See [Steps](#)) into a seamless process is recommended for treatment naïve patients without current or prior history of decompensated cirrhosis, hepatocellular carcinoma, liver transplantation, end-stage renal disease (GFR < 30), HIV or HBV coinfection, or pregnancy.

Pretreatment assessment is recommended within 6 months of the projected start of treatment if there is no cirrhosis or within 3 months, if there is compensated cirrhosis.

Many aspects of the pretreatment assessment also are part of the initial evaluation and do not need to be repeated if consideration for treatment is performed within these time frames. This is an efficient way to accomplish the test-evaluate-treat approach and is recommended whenever feasible.

Pretreatment assessment and interventions include the following:

- **Laboratory tests** including CBC, PT/INR, liver panel, serum creatinine, calculated GFR.
 - Labs do not need to be repeated if obtained within 6 months in patients without cirrhosis or within 3 months in patients with compensated cirrhosis.
 - Consider retesting for HBV and HIV, if ongoing risk factors since last test result.
 - A urine drug screen is not required as part of the pretreatment evaluation, and is recommended only if ongoing substance use is suspected or if it is otherwise clinically indicated.
- Assessment for **hepatic cirrhosis and decompensation**
 - **Calculation of the APRI score** using results from the pretreatment labs. (An APRI score is not needed if there is confirmed cirrhosis.)
 - **Calculation of current CTP score** for inmates with known or suspected cirrhosis.
 - An **abdominal US** is recommended within 6 months of starting treatment for patients with cirrhosis.
- **Pregnancy testing and education** covering the potential risks of DAAs during pregnancy prior to initiating treatment in all women with childbearing potential
 - Ribavirin is contraindicated in pregnancy and in both male and female partners attempting to become pregnant.

- Assessment for significant **drug-drug interactions**
 - Resources for assessing drug interactions with DAA regimens include the AASLD HCV guidance, DHHS antiretroviral guidelines, University of Liverpool HEP Drug Interactions and manufacturers' prescribing information for specific drug interactions.
→ [References](#)
- Assessment for **current/prior medication adherence**
- Review of incident report history for **high-risk behaviors** (alcohol/drug possession/use; tattooing).
- **For ribavirin-containing regimens:**
 - A pretreatment ECG is recommended for inmates with preexisting coronary heart disease.
 - If anemia is present and has not been previously evaluated, a diagnostic evaluation is recommended prior to starting treatment.
- **Testing for NS5A resistance-associated substitutions (RASs)** is not routinely indicated, but is recommended prior to treatment with the following regimens or situations:
 - Elbasvir/grazoprevir for **HCV genotype 1a and GFR \geq 30**. If RASs are present at position 28, 30, 31, or 93, a regimen other than EBR/GZR should be used.
 - Sofosbuvir/velpatasvir for treatment-naïve **HCV genotype 3** with cirrhosis being considered for 12 weeks of treatment. If the Y93H RAS is present, RBV is added to a 12-week regimen of SOF/VEL.
 - Sofosbuvir/velpatasvir for treatment-experienced **HCV genotype 3** and no cirrhosis.
 - NS5A resistance testing may be considered when ledipasvir/sofosbuvir is an option for treatment-experienced **HCV genotype 1a** with no cirrhosis or compensated cirrhosis.
 - NS3/4A resistance testing is no longer routinely recommended.
- **Patient education**—including, but not limited to: how to take the medication, the importance of adherence, monitoring and follow up, and potential medication side effects. When ribavirin is used, specific counseling about the risks and recommendations related to pregnancy should be provided.

6. RECOMMENDED TREATMENT REGIMENS

➤ Direct Acting Antiviral Medications (DAAs)

Recommendations for **DAA treatment** regimens continue to evolve, but still depend on several factors:

- HCV genotype, except for pangenotypic regimens
- Prior HCV treatment history
- Compensated vs. decompensated liver disease
- Co-occurring medical conditions (HBV or HIV coinfection, hepatocellular carcinoma, chronic kidney disease, solid organ transplant)
- Resistance-associated substitutions (certain clinical scenarios)
- Drug-drug interactions

Special considerations: Certain conditions require special consideration when selecting an HCV treatment regimen, including decompensated cirrhosis, hepatocellular carcinoma, chronic kidney disease and compensated cirrhosis, solid organ transplant recipients, HBV or HIV coinfection, HCV infection with multiple genotypes, and pregnancy. These special considerations are addressed in [Section 8](#).

Cost: The cost of DAA regimens can vary widely. When more than one regimen is appropriate for an individual case, the most cost-effective regimen is recommended, taking into consideration all the factors listed above.

Currently, there are **three classes of HCV DAAs:** NS5A replication complex inhibitors (-asvir), NS5B polymerase inhibitors (-buvir), and NS3/4a HCV protease inhibitors (-previr). These antiviral medications for HCV infection act directly on some part of the virus, usually the replication mechanism.

- **DAAs cannot be used as monotherapy.** They must be used in combination with at least one other DAA with or without ribavirin, depending on the clinical scenario.

The most commonly recommended regimens are described briefly on the next three pages. More detailed information about the regimens and the individual medications—including indications and drug interactions—may be found in the AASLD guidance (<https://www.aasld.org/publications/practice-guidelines>), manufacturer’s prescribing information, Facts and Comparisons (available in the Bureau of Electronic Medical Records System (BEMR)), University of Liverpool HEP Drug Interactions website (<https://www.hep-druginteractions.org/checker>), and other validated resources.

Elbasvir/Grazoprevir (Zepatier®)

Formulation/Use: Co-formulation of 50 mg of elbasvir (an HCV NS5A inhibitor) and 100 mg of grazoprevir (an HCV NS3 protease inhibitor) is FDA-approved for treatment of **HCV genotypes 1 and 4**.

- In HCV genotype 1a, NS5A resistance testing is recommended prior to treatment, if GFR is ≥ 30 . If resistance is identified, selection of a different regimen is recommended.
- For treatment-experienced genotype 4 patients, consider using a different AASLD-recommended regimen.

Dosing and duration: The usual dose and duration is one tablet orally once daily, with or without food, for 12 weeks.

- No dosage adjustment is required for decreased renal function or hemodialysis, although the ribavirin dose must be adjusted for GFR < 50 .

Contraindication and uses not recommended:

- Elbasvir/grazoprevir is contraindicated in decompensated cirrhosis (CTP score ≥ 7)
- Contraindicated medications include phenytoin, carbamazepine, rifampin, efavirenz, HIV protease inhibitors (atazanavir, darunavir, lopinavir, saquinavir, and tipranavir), and cyclosporine.
- Elbasvir/grazoprevir is not recommended with moderate CYP3A inducers or with strong CYP3A inhibitors.

Warning: Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV

Glecaprevir/pibrentasvir (Mavyret®)

Formulation/use: A coformulation of 100 mg of glecaprevir and 40 mg of pibrentasvir is FDA-approved for treatment of **HCV genotypes 1, 2, 3, 4, 5, or 6**, without cirrhosis or with compensated cirrhosis (Child-Pugh A). Glecaprevir/pibrentasvir is also indicated for the treatment of adult patients with **HCV genotype 1** infection, previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Dosing and duration: The usual dose is three tablets (total daily dose: glecaprevir 300mg and pibrentasvir 120 mg) taken orally, once daily, with food. The duration of treatment is either 8, 12, or 16 weeks, as noted below:

- Treatment duration of 8 weeks is recommended for all HCV genotypes with no cirrhosis or with compensated cirrhosis if they are treatment-naïve.
- Treatment duration of 8 weeks is also recommended for genotypes 1, 2, 4, 5, or 6 with no cirrhosis if they are treatment-experienced with PEG-IFN + RBV.
- Treatment duration of 12 weeks is recommended for HCV genotype 1 in PEG-IFN + RBV + NS3/4A protease inhibitor treatment-experienced patients who are NS5A treatment-naïve with no cirrhosis or with compensated cirrhosis.
- Treatment duration of 12 weeks is recommended for HCV genotypes 1, 2, 4, 5, or 6 with compensated cirrhosis if they are treatment-experienced with PEG-IFN + RBV +/- sofosbuvir.
- Treatment duration of 16 weeks, with RBV and daily SOF added, is recommended for all genotypes with no cirrhosis or with compensated cirrhosis and prior treatment failure with GLE/PIB or SOF/VEL/VOX.
- No dosage adjustment is required for patients with any degree of renal impairment, end stage renal disease, or dialysis.

Contraindication and uses not recommended:

- Glecaprevir/pibrentasvir is not recommended for use with certain medications and herbs (e.g., carbamazepine, efavirenz, and St. John's wort).
- It is contraindicated in moderate to severe hepatic impairment (Child- Pugh B or C) or with coadministration with atazanavir and rifampin.

Warning: Risk of hepatitis B virus reactivation in patients co-infected with HCV and HBV.

Ledipasvir/sofosbuvir (Harvoni®)

Formulation/Use: A co-formulation of 90 mg of ledipasvir and 400 mg of sofosbuvir is FDA-approved for treatment of **HCV genotypes 1, 4, 5, and 6**; alone or in combination with ribavirin, without or with cirrhosis, compensated or decompensated.

Dosing and Duration: The usual dose is one tablet orally once daily, with or without food, for 12 weeks.

- AASLD recommends only an 8-week course of treatment in a subgroup of HCV-infected persons who have genotype 1a or 1b, have an HCV viral load < 6 million IU/ml, and are treatment-naïve—but are not HIV-coinfected, and do not have cirrhosis.

- A 24-week course of treatment is recommended for all genotypes with decompensated cirrhosis and either RBV ineligible, or in combination with LD-RBV for prior SOF or NS5A inhibitor based treatment failures.
- No dosage adjustment is required for patients with any degree of renal impairment, end stage renal disease, or dialysis.

Contraindications and Uses not Recommended: Ledipasvir/sofosbuvir is not recommended for use with certain anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital, or oxcarbazepine), certain rifamycin antimycobacterials (e.g., rifabutin, rifampin, or rifapentine), or the antiarrhythmic, amiodarone.

Sofosbuvir/Velpatasvir (Epclusa®)

Formulation/use: A co-formulation of 400 mg of sofosbuvir and 100 mg of velpatasvir is FDA-approved for treatment of **HCV genotypes 1, 2, 3, 4, 5, and 6**, with no cirrhosis or with compensated cirrhosis, or for decompensated cirrhosis in combination with ribavirin.

Dosing and duration: The usual dose is one tablet orally once daily, with or without food, for 12 weeks.

- In genotype 3 with a Y93H RAS, RBV is added to a 12-week regimen for patients who are treatment naïve with compensated cirrhosis or treatment experienced without cirrhosis.
- A 24-week course of treatment is recommended for all genotypes with decompensated cirrhosis and either RBV ineligible, or in combination with RBV for prior SOF or NS5A inhibitor based treatment failures.
- No dosage adjustment is required for patients with severe renal impairment, end stage renal disease, or dialysis.

Contraindications and uses not recommended:

- Sofosbuvir/velpatasvir is not recommended for use with certain anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital, or oxcarbazepine), certain rifamycin antimycobacterials (e.g., rifabutin, rifampin, or rifapentine), the antiarrhythmic amiodarone, certain antiretrovirals (efavirenz, or tipranavir/ritonavir), or proton pump inhibitors.
- If there are contraindications to ribavirin, it should not be used in combination with sofosbuvir/velpatasvir.

Warning: The risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV.

Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)

Formulation/use: A co-formulation of 400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir is FDA-approved for treatment of adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) with **HCV genotypes 1, 2, 3, 4, 5, or 6**, infections previously treated with a

regimen containing an NS5A inhibitor, or **HCV genotypes 1a or 3** infection previously treated with sofosbuvir without an NS5A inhibitor.

Dosing and duration: The usual dose is one tablet (total daily dose: 400 mg of sofosbuvir, 100nmg of velpatasvir, and 100 mg of voxilaprevir) taken orally, once daily, with food, for 12 weeks for all **HCV genotypes** and prior DAA treatment failures with SOF-based regimens, EBR/GZR, or GLE/PIB.

- RBV is added in the following scenarios: 1) compensated cirrhosis, 2) the Y93H RAS is present, or 3) treatment failure with SOF/VEL/VOX or SOF + GLE/PIB.
- A 24-week duration of treatment including RBV is recommended for treatment failures with SOF/VEL/VOX or SOF + GLE/PIB.
- No dosage adjustment is required for patients with severe renal impairment, end stage renal disease, or dialysis.
- SOF/VEL/VOX is primarily recommended for use when treatment has failed with most of the DAA regimens.

Contraindications and uses not recommended:

- Not recommended for use with P-gp inducers and/or moderate to potent CYP inducers (e.g., carbamazepine, St. John’s wort). Sofosbuvir/velpatasvir/voxilaprevir is not recommended for use with moderate or severe hepatic impairment (Child-Pugh B or C).
- This drug is contraindicated with co-administration with Rifampin.

Warning: Serious bradycardia may occur with amiodarone coadministration, particularly in patients receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. In patients without alternative viable treatment options, cardiac monitoring is recommended. There is a risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV.

Regimens not recommended

- **Monotherapy** with peginterferon, ribavirin, or any of the DAAs.
- **Dual therapy** with peginterferon and ribavirin.
- **NS3/4 HCV protease inhibitors** (boceprevir, simeprevir, or telaprevir)
- **HCV protease inhibitors for genotypes 2, 3, 5, or 6** (paritaprevir, simeprevir)

➤ **Preferred treatment regimen**

For eligible treatment-naïve cases, an 8-week course of glecaprevir/pibrentasvir is recommended, regardless of HCV genotype. Cases not eligible for this short-course, pangenotypic regimen, will need to have a genotype test if not previously performed and selection of one of the other AASLD/IDSA-preferred treatment regimens included in the following appendices:

[Appendix 1, Treatment Recommendations for Treatment Naïve HCV with No or Compensated Cirrhosis](#)

[Appendix 2, Treatment Recommendations for HCV DAA Treatment Failures](#)

➔ Refer to the AASLD/IDSA website (www.hcvguidelines.org) for any updates since March 2021.

Alternative treatment regimens: The AASLD/IDSA guidance includes recommendations for some regimens that are not specifically FDA-approved and also describe alternative treatment regimens for

situations in which a preferred regimen is not an option. These alternative regimens are not included in this BOP guidance, but can be considered on a case-by-case basis.

Submit a BEMR non-formulary request for Hepatitis C Treatment Algorithm Request with the necessary supporting documentation (see [Appendix 6](#)). If approved, submit non-formulary requests for the specific DAA medications.

➤ Potential drug interactions

In addition to the genotype, prior HCV treatment history, and status of hepatic compensation, as noted above, it is essential to review each treatment candidate for potential drug interactions prior to selecting the most appropriate regimen for HCV treatment. Adjustments of the inmate's current medications may be needed prior to starting treatment for HCV. Since information on drug-drug interactions are updated as new information becomes available, medical literature and drug interaction websites should be checked routinely. Useful resources for potential drug interactions include the AASLD/IDSA guidance, the individual manufacturers' prescribing information, University of Liverpool HEP Drug Interactions website, and the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.

7. MONITORING

➔ See [Appendix 3, Hepatitis C Treatment Monitoring Schedule](#) for a summary chart.

➤ On-treatment monitoring

Outpatient clinic visits are recommended to assess for medication adherence, side effects and symptoms of hepatic decompensation, adverse drug reactions, and drug-drug interactions. Evaluations for routine cases are suggested at 2 weeks and 4 weeks after starting therapy, and monthly thereafter. More frequent evaluations may be needed as clinically indicated, especially for more complex or severe conditions such as HBV or HIV coinfection, decompensated cirrhosis, dialysis or end-stage renal disease, or kidney or liver transplant recipients.

Lab tests are not routinely needed during treatment, except in the following situations:

- **For regimens containing ribavirin:**
 - A CBC should be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly; more frequently as clinically indicated. Ribavirin dosage adjustments may be required.
 - ➔ See [Appendix 4, Management of Hematologic Changes](#)
 - **Pregnancy testing is required** periodically during and after treatment—usually monthly during treatment and for 6 months after completion of treatment when women with childbearing potential are treated **with ribavirin-containing regimens**.
- **For regimens containing elbasvir/grazoprevir**, more frequent monitoring of ALT is necessary:
 - **For 12-week regimens**, a liver panel including ALT should be drawn at 8 weeks, and as clinically indicated. For **16-week regimens**, a liver panel including ALT should be drawn at 8 weeks and again at 12 weeks.
 - **ALT increases of less than tenfold** should be monitored approximately every 2 weeks and consideration given to discontinuation of treatment if the ALT elevations persist. Early discontinuation of HCV treatment is also recommended if ALT increases by tenfold—or if less than tenfold, but accompanied by *symptoms* such as weakness, anorexia, nausea,

vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction.

- **For patients with evidence of chronic HBV infection** (i.e., HBsAg positive) who do not meet established criteria for antiviral HBV therapy, either monitoring of HBV DNA levels or prophylactic HBV antiviral medication may be considered.
 - Monitoring with quantitative HBV DNA levels is done prior to starting HCV DAA treatment, periodically during DAA treatment (usually every four weeks), and immediately after DAA treatment. Initiate antiviral HBV treatment if the HBV DNA level increases more than 10-fold from baseline or above 1,000 IU/ml if it was previously undetectable.
 - Prophylactic HBV antiviral medication may be initiated prior to or at the same time HCV DAA treatment is started, and continued for 12 weeks after DAA treatment completion.

➤ Post-treatment monitoring

A quantitative HCV RNA viral load assessment is recommended at **12 weeks after completion** of treatment; if HCV is undetectable, it defines a sustained viral response (SVR).

If the HCV viral load is undetectable at 12 weeks after completion of treatment, the inmate may be removed from the chronic care clinic for this condition, if he or she has no cirrhosis, complications, or related comorbidities, and the HCV infection has been changed to “resolved” in the problem list.

Recurrent viremia following an SVR may be due to relapse or reinfection. To help distinguish between relapse and reinfection in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained. If the post-SVR genotype is the same as the pre-treatment genotype, it is not possible to distinguish relapse from reinfection. In addition, ask about and educate on HCV risk factors, assess readiness for retreatment, and consider referring for drug education programming and treatment if there is evidence for ongoing substance use.

➤ Ongoing monitoring

Periodic monitoring is recommended for all those with active infection, including HCV treatment failures, relapse of HCV infection or reinfection, and those with chronic HCV infection who are not yet treated.

- **For cases without advanced fibrosis, cirrhosis, or complications**, annual evaluation is appropriate. This evaluation should include a focused review of systems and patient education relevant to HCV, vital signs and a focused physical examination, and lab monitoring (CBC, PT/INR, liver panel, serum creatinine, calculated GFR, and calculation of the APRI score).

For patients with cirrhosis or significant comorbidities, even in those who achieve SVR after treatment, evaluation is recommended at least every 6 months, and more frequently when clinically indicated.

8. SPECIAL CONSIDERATIONS

➤ HCV Infection with more than one genotype

Very little data are available to guide the selection of a DAA regimen when more than one HCV genotype are present at the same time. In such cases, selection of either a pangenotypic regimen or a regimen that is effective against both of the existing genotypes is appropriate, in consultation with a BOP Hepatitis Clinical Pharmacy Consultant or Central Office Physician.

➤ HBV/HCV Coinfection

In patients coinfecting with HBV and HCV, HBV reactivation may occur during or after treatment with HCV DAAs. Testing for HBV infection—including HBsAg, anti-HBs, and anti-HBc total, as well as HBV DNA levels in those with a reactive HBsAg—is recommended for all patients being considered for treatment of HCV infection.

- **If criteria for treatment of HBV are met**, it is recommended that HBV treatment be started prior to or at the same time as HCV treatment, and monitored according to HBV treatment guidance.
- **For patients with evidence of chronic HBV infection (i.e., HBsAg positive) who do not meet established criteria for antiviral HBV therapy**, either monitoring of HBV DNA levels or prophylactic HBV antiviral medication may be considered.
 - **Monitoring with quantitative HBV DNA levels** is done prior to starting HCV DAA treatment, periodically during DAA treatment (usually every four weeks), and immediately after DAA treatment. Initiate antiviral HBV treatment if the HBV DNA level increases more than 10-fold from baseline or above 1,000 IU/ml if it was previously undetectable.
 - **Prophylactic HBV antiviral medication** may be initiated prior to or at the same time HCV DAA treatment is started, and continued for 12 weeks after DAA treatment completion.
- **For isolated anti-HBc total positive cases with negative HBsAg and anti-HBs**, monitor ALT at baseline, at the completion of HCV treatment, and again during post-treatment follow-up.

➤ HIV Coinfection

Currently recommended HCV regimens are equally effective for HCV mono-infection and coinfection with HIV. However, an alternative HCV regimen or an alternative antiretroviral medication regimen may be necessary due to potential drug interactions between the HCV DAAs and certain antiretrovirals.

The following are links to tables showing drug interactions between the HIV antiretrovirals and the HCV Direct Acting Antivirals (DAAs):

- ➔ See <https://aidsinfo.nih.gov/guidelines/htmltables/1/7363>
- ➔ See <https://www.hcvguidelines.org/unique-populations/hiv-hcv>

➤ Decompensated Cirrhosis

Treatment of HCV patients with decompensated cirrhosis should be managed in consultation with an experienced clinician/specialist, with treatment requests considered on a case-by-case basis. The regimens and other considerations listed below are for those with a current or prior history of decompensated cirrhosis. Inmates with decompensated cirrhosis and a CTP score ≥ 10 (Class C) may meet reduction in sentence criteria.

- ➔ See **Table 2** on the next page for a summary of treatment recommendations for decompensated cirrhosis.

TABLE 2. HCV TREATMENT RECOMMENDATIONS FOR DECOMPENSATED CIRRHOSIS (CURRENT OR PRIOR HISTORY)

| TREATMENT HISTORY | HCV GENOTYPES AND TREATMENT REGIMENS |
|---|---|
| RBV eligible (except TF with SOF or NS5A regimens; see below) | LDV/SOF + RBV-LD: 12 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL + RBV*: 12 wks (genotypes 1–6) |
| RBV ineligible | LDV/SOF: 24 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL: 24 wks (genotypes 1–6) |
| TF with SOF or NS5A regimens (RBV eligible) | LDV/SOF + RBV-LD: 24 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL + RBV*: 24 wks (genotypes 1–6) |
| ABBREVIATIONS: See GLOSSARY . * A full weight-based ribavirin dose may be started in cases with CTP Class B decompensated cirrhosis, while low initial dose is used in cases with CTP Class C. | |

➤ Hepatocellular carcinoma

The presence of HCC may impact both the timing of HCV treatment and the choice of DAA treatment regimen. The timing of treatment for HCV relative to the treatment of HCC is an important consideration that is impacted by the choice of treatment for HCC and the patient’s life expectancy, and is recommended to be done in collaboration with the treating oncologist.

- In the context of HCV infection, HCC usually occurs in the presence of cirrhosis. Whether cirrhosis is compensated or decompensated affects the choice of DAA medication.
- The SVR rates are lower for patients with HCC than those who don’t have HCC. Therefore, these cases are not eligible for the shorter 8-week treatment regimens. Additional data is needed to determine whether a longer duration of treatment will achieve a higher SVR rate.

➤ Transplant Recipients

Consultation with a transplant specialist is recommended before and in conjunction with treatment of HCV in liver, kidney or other solid organ transplant candidates or recipients. AASLD-recommended HCV DAA regimens for liver or kidney transplant recipients, as well as potential DAA drug interactions with anti-rejection medications, may be found at <https://www.hcvguidelines.org/unique-populations>

➤ Chronic kidney disease (CKD)

HCV is independently associated with the development of chronic kidney disease (CKD). Published studies indicate that HCV is associated with 1) a higher risk of developing proteinuria and CKD; 2) a higher risk for progression to end-stage-liver-disease (ESLD); and 3) an increased risk of mortality for dialysis patients.

- Patients with CKD, HCV and no cirrhosis may be considered for the simplified approach to treatment. Those with cirrhosis are not eligible for the simplified approach.

- **No dosage or duration adjustment is required for any degree of renal impairment when using any of the currently recommended DAAs** including elbasvir/grazoprevir (genotypes 1 or 4), glecaprevir/pibrentasvir (genotypes 1-6), ledipasvir/sofosbuvir (genotypes 1, 4, 5, or 6), or sofosbuvir/velpatasvir (genotypes 1-6).
- **Ribavirin doses must be decreased with GFRs ≤ 50 .** For GFRs 30–50, ribavirin is dosed 200 mg alternating every other day with 400 mg. For GFR < 30, including hemodialysis, the ribavirin dose is 200 mg daily. Consultation with a transplant specialist is recommended prior to and in conjunction with treatment of HCV in kidney transplant candidates or recipients.

➤ **Pregnancy Considerations**

The current AASLD/IDSA guidance recommends consideration of treatment of HCV during pregnancy or breastfeeding on an individual basis only if the benefits outweigh the potential or unknown risks.

- Testing for HCV infection is recommended as part of prenatal care for each pregnancy.
- Treatment of HCV infection is recommended before becoming pregnant to decrease the risk of maternal-infant transmission.
- **Ribavirin is contraindicated during pregnancy:**
 - **Women with childbearing potential** who are being considered for an HCV regimen that includes ribavirin should be counseled on the adverse fetal effects of ribavirin. They should be advised not to become pregnant during treatment with ribavirin—and for 6 months after the treatment has ended. They should also be advised that the same risks apply if a male sex partner is being treated with ribavirin. A negative pregnancy test should be documented before starting treatment with ribavirin, then monthly during treatment and monthly for 6 months after treatment.
 - **Men being treated with ribavirin** should also be counseled on the adverse fetal effects of ribavirin. They should be advised not to cause pregnancy in their female sex partners during treatment with ribavirin—and for 6 months after the treatment has ended.
- HCV RNA testing is recommended prior to initiating treatment in the postpartum period to determine if spontaneous resolution of HCV infection occurred during the pregnancy.

References

AASLD/IDSA. Recommendations for testing, managing, and treating hepatitis C. *AASLD/IDSA website*. <http://www.hcvguidelines.org>. Updated January 21, 2021. Accessed February 2021. Refer to this website for any updates since November 2019.

Note about the AASLD/IDSA website: To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management.

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. AIDSinfo website. <https://aidsinfo.nih.gov/guidelines>. Updated October 17, 2017. Accessed August 2018.

Glossary of Abbreviations

| MEDICATIONS | |
|---|--|
| DAA | direct acting antiviral medication |
| DCV | daclatasvir |
| DSV | dasabuvir |
| EBR | elbasvir* |
| GLE | glecaprevir* |
| GZR | grazoprevir* |
| LDV | ledipasvir* |
| OBV | ombitasvir |
| PTV | paritaprevir |
| PEG-IFN | pegylated interferon, peginterferon |
| PI | protease inhibitor |
| PIB | pibrentasvir* |
| PrO | paritaprevir/ritonavir/ombitasvir |
| PrOD | paritaprevir/ritonavir/ombitasvir/dasabuvir |
| RBV | ribavirin |
| RBV-LD | ribavirin, low initial dose |
| SOF | sofosbuvir* |
| SMV | simeprevir |
| VEL | velpatasvir* |
| VOX | voxilaprevir* |
| * Medications marked with an asterisk (*) are direct acting antiviral medications (DAAs). | |
| OTHER TERMS | |
| AASLD | American Association for the Study of Liver Diseases |
| ALT | alanine aminotransferase |
| ANA | antinuclear antibody |
| APRI | AST to Platelet Ratio Index |
| AST | aspartate aminotransferase |
| CBC | complete blood count |
| CTP score | Child-Turcotte-Pugh score |
| EGD | esophagogastroduodenoscopy |
| GFR | glomerular filtration rate |
| HBV | hepatitis B virus |
| HBsAg | hepatitis B surface antigen |
| HCC | hepatocellular carcinoma |
| HCV | hepatitis C virus |

| | |
|--------------------|--|
| HIV Ab or anti-HIV | HIV antibody |
| IDSA | Infectious Diseases Society of America |
| INR | International Normalization Ratio |
| NASH | nonalcoholic steatohepatitis |
| PT | prothrombin time |
| RAS | resistance-associated substitution |
| SVR | sustained virologic response |
| TE | treatment-experienced |
| TF | treatment failure |
| TN | treatment-naïve |
| ULN | upper limit of normal |

Appendix 1. Treatment Recommendations for Treatment Naïve HCV Infection

| DAA TREATMENT OPTIONS FOR TREATMENT NAÏVE HCV INFECTION ^{A, B, C, D} (No Cirrhosis or Compensated Cirrhosis) | | | | | |
|--|----------|---|---|---|-----|
| DAA Regimen | Genotype | | | | |
| | 1 | 2 | 3 | 4 | 5/6 |
| GLE/PIB 8 wks ^E | ✓ | ✓ | ✓ | ✓ | ✓ |
| SOF/VEL 12 wks ^E | ✓ | ✓ | ✓ | ✓ | ✓ |
| LDV/SOF 12 wks ^E | ✓ | | | ✓ | ✓ |
| EBR/GZR 12 wks ^E | ✓ | | | ✓ | |

NOTES:

A. All regimens in this Appendix are identified as RECOMMENDED in the AASLD guidance. Alternative regimens may be appropriate in some cases, but are not included in this table. Some AASLD recommended regimens are not FDA-approved, but are based on available evidence.

B Choice of regimen is determined by HCV genotype, treatment history, presence of compensated cirrhosis or no cirrhosis, and resistance-associated substitutions; it is also influenced by potential drug interactions and cost.

C. Recommendations in this table may not be appropriate in decompensated cirrhosis, hepatocellular carcinoma with compensated or decompensated cirrhosis, chronic kidney disease with GFR < 30, liver or kidney transplant recipients, HCV infection with multiple genotypes, HIV infection, or if there are NS5A RASs. Refer to the specific sections in this guidance and the AASLD/IDSA guidance for treatment of HCV in these situations.

D. Simplified approach to treatment: GLE/PIB or SOF/VEL are recommended regimens for patients without the above co-occurring conditions.

E. Exceptions to the standard treatment regimens above:

- 1) GLE/PIB:** in patients with HCV/HIV coinfection and compensated cirrhosis, a 12 week regimen is recommended for all genotypes.
- 2) SOV/VEL:** in treatment naïve genotype 3 with a Y93H RAS and compensated cirrhosis, RBV is added to the regimen.
- 3) LDV/SOF:** 8 weeks may be considered for treatment naïve HCV genotypes 1 or 4 without cirrhosis and VL < 6 million IU/ml and no HIV co-infection. Do not use LDV/SOF in subtype 6e, if known.
- 5) EBR/GZR:** in genotype 1 with an NS5A RAS, do not use EBR/GZR.

MEDICATIONS:

EBR/GZR=elbasvir/grazoprevir; **GLE/PIB** = glecaprevir/pibrentasvir (Mavyret™); **LDV/SOF** = ledipasvir/sofosbuvir (Harvoni®); **RAS**=Resistance-Associated Substitutions; **RBV** = weight-based ribavirin; **SOF** = sofosbuvir; **SOF/VEL** = sofosbuvir/velpatasvir (Epclusa®); **SOF/VEL/VOX** = sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

Appendix 2. Treatment Recommendations for DAA HCV Treatment Failures

| SPECIFIC DAA REGIMEN THAT FAILED | TREATMENT OPTIONS FOR DAA TREATMENT-EXPERIENCED HCV ^{A, B, C, D, E, F} | | | |
|--|---|---------------------------|-----------------------|---------------------------|
| | GENOTYPE 1, 2, 4, 5, OR 6 | | GENOTYPE 3 | |
| | NO CIRRHOSIS | COMPENSATED CIRRHOSIS | NO CIRRHOSIS | COMPENSATED CIRRHOSIS |
| GLE/PIB | ▶ GLE/PIB+SOF+RBV: 16 wks | | | |
| | ▶ SOF/VEL/VOX: 12 wks | ▶ SOF/VEL/VOX+RBV: 12 wks | SOF/VEL/VOX: 12 wks | ▶ SOF/VEL/VOX+RBV: 12 wks |
| EBR/GZR or SOF-based regimens (SOF + RBV + PEG-IFN or SOF + NS5Ai) | ▶ SOF/VEL/VOX: 12 wks | | ▶ SOF/VEL/VOX: 12 wks | ▶ SOF/VEL/VOX+RBV: 12 wks |
| SOF/VEL/VOX or SOF + GLE/PIB | ▶ GLE/PIB+SOF+RBV: 16 wks ^G ▶ SOF/VEL/VOX+RBV: 24 wks | | | |

Notes:

A. All regimens in this Appendix are identified as RECOMMENDED in the AASLD guidance. Alternative regimens may be appropriate in some cases, but are not included in this table. Some AASLD recommended regimens are not FDA-approved, but are based on available evidence.

B. Choice of regimen is determined by HCV genotype, treatment history, presence of compensated cirrhosis or no cirrhosis, and resistance-associated substitutions; it is also influenced by potential drug interactions and cost.

C. Recommendations in this table may not be appropriate in decompensated cirrhosis, hepatocellular carcinoma with compensated or decompensated cirrhosis, chronic kidney disease with GFR < 30, liver or kidney transplant recipients, HCV infection with multiple genotypes, HIV infection, or if there are NS5A RASs. Refer to the specific sections in this guidance and the AASLD/IDSA guidance for treatment of HCV in these situations.

D. Treatment- Experienced w/ PEG-IFN + RBV +/- NS3/4 PI. AASLD/IDSA guidance makes no treatment recommendations for treatment failures with PEG-IFN + RBV +/- NS3/4 PI based on SVR rates of current DAA regimens being similar to those of treatment naïve patients. Consultation with a BOP Regional Hepatitis Clinical Pharmacist is recommended prior to starting treatment. In general, the regimens for treatment naïve HCV infection may be followed for this treatment experienced group. However, the following modifications are recommended in the prescribing information for each specific scenario below.

- 1) GLE/PIB is recommended for 12 weeks rather than 8 weeks for genotype 1.
- 2) RBV is added to a 12 week regimen of EBR/GZR for genotypes 1a or 1b..
- 3) RBV is added to a 16 week regimen of EBR/GZR for genotype 4.
- 4) For genotypes 1, 4, 5, or 6, LDV/SOF is recommended for 24 weeks or for 12 weeks with added RBV.,

E. Treatment failures with PrO are not specifically addressed by AASLD/IDSA, but this regimen is most like GLE/PIB.

F. Treatment failures with PrOD are not specifically addressed by AASLD/IDSA, but this regimen is most like SOF/VEL/VOX.

G. Consider extending treatment to 24 weeks in genotype 3 with cirrhosis or SOF + GLE/PIB failure.

MEDICATIONS:
GLE/PIB = glecaprevir/pibrentasvir (Mavyret™); **LDV/SOF** = ledipasvir/sofosbuvir (Harvoni ©);
PEG-IFN = pegylated interferon (peginterferon); **NS3/4 PI** = protease inhibitor (boceprevir, telaprevir, simeprevir);
PrO = paritaprevir/ritonavir/ ombitasvir; **PrOD** = paritaprevir/ritonavir/ombitasvir + dasabuvir;
RBV = weight-based ribavirin; **SOF** = sofosbuvir; **SOF/VEL** = sofosbuvir/velpatasvir (Epclusa©);
SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir (Vosevi©)

Appendix 3. Hepatitis C Treatment Monitoring Schedule

| Evaluation ^{1, 2} | Baseline (HCV Ab positive) | Pretreatment (Within 180 days of Tx) | On-Treatment Monitoring (by week of treatment) | | | | | | | 12 wks Post-Tx |
|--|----------------------------|--------------------------------------|--|-------------------------------------|---|----|----|----|----|-----------------|
| | | | 2 | 4 | 8 | 12 | 16 | 20 | 24 | |
| Clinician evaluation | X | X | X | X | X | X | X | X | X | X |
| HIV Ab, HBV Serology ³ , Anti-HAV (IgG) | X | | | | | | | | | |
| Prothrombin Time/INR | X | X | | | | | | | | |
| CBC ⁴ | X | X | As clinically indicated ^{4,5} | | | | | | | |
| Serum creatinine + eGFR | X | X | | | | | | | | |
| ALT, AST, bilirubin, alkaline phosphatase, albumin ⁵ | X | X | | | | | | | | |
| APRI & CTP scores ⁶ | X | X | | | | | | | | |
| HCV RNA, quantitative ⁷ | X | | | | | | | | | X |
| HCV genotype ² | | | | | | | | | | |
| Assess for drug-drug interactions & adherence | | X | At each clinician evaluation during treatment. | | | | | | | |
| Review incident report history for high-risk behavior (alcohol/drug possession/use; tattooing) | | X | If indicated. | | | | | | | |
| Urine pregnancy test ⁸ (if childbearing potential) | | X | | Monthly while on treatment with RBV | | | | | | monthly x 6 mos |

- 1 Conduct further diagnostic evaluations as clinically warranted to identify other potential causes of the patient's liver disease such as hemochromatosis, Wilson's disease, or autoimmune hepatitis (e.g., serum iron, serum copper, ANA/ ESR). If any of these conditions are diagnosed or strongly suspected, a pre-treatment liver biopsy should be considered.
- 2 **Baseline and Pretreatment evaluations may be combined and HCV genotype testing is not routinely recommended as part of a simplified approach** to HCV treatment in treatment-naïve cases with no current or prior history of decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, chronic kidney disease with compensated cirrhosis, HBV or HIV infection, pregnancy, or significant drug interactions with glecaprevir/pibrentasvir.
- 3 **Recommended baseline testing for hepatitis B status includes HBsAg, anti-HBs, and anti-HBc total.** If either HBsAg or anti-HBc total is positive, obtain an HBV DNA viral load. If criteria for treatment of HBV are met, initiating antiviral therapy for HBV is recommended prior to or at the same time as HCV treatment. If criteria for treatment of chronic HBV infection are not met, either monthly HBV DNA viral loads or prophylactic HBV antiviral medication are recommended during treatment for HCV.
- 4 On-treatment monitoring of CBCs is indicated for RBV-containing regimens at 2 weeks, 4 weeks, then monthly while on treatment, and more frequently as clinically indicated. **RIBAVIRIN-CONTAINING REGIMENS: A pretreatment ECG is recommended for inmates with preexisting coronary heart disease.**
- 5 **More frequent monitoring of ALT is necessary in certain situations:** 1) **Regimens containing elbasvir/grazoprevir:** An ALT should be drawn at 4 weeks and again at 8 weeks, and as clinically indicated. For 16-week regimens, an ALT should also be drawn at 12 weeks; 2) **Patients with compensated cirrhosis** who are treated with paritaprevir/ritonavir/ ombitasvir, with or without dasabuvir, require more frequent monitoring of ALT; 3) **Increases in the ALT should prompt more frequent monitoring or early discontinuation.** Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks. Early discontinuation of HCV treatment is recommended if ALT increases by tenfold—or if less than tenfold, but accompanied by *symptoms* such as weakness, anorexia, nausea, vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction
- 6 A CTP score is calculated only for cases with known or suspected cirrhosis.
- 7 For treatment regimens recommended in this document, the **routine schedule of HCV RNA testing** includes baseline testing and 12 weeks after completion of therapy. If HCV RNA is undetectable 12 weeks after treatment, no further follow-up for HCV is required.
- 8 On- and post-treatment monitoring for pregnancy is recommended only for RBV-containing regimens. A pre-treatment pregnancy test is recommended for all regimens.

Appendix 4. Management of Hematologic Changes

Note: For patients prescribed a direct-acting antiviral (DAA) for HCV infection, if ribavirin must be discontinued due to hematologic changes, the DAA also may need to be discontinued. Consultation with an experienced clinician is recommended.

HEMOGLOBIN (Hgb)

| Value | Ribavirin Adjustment and Supportive Treatment | |
|-------------|--|---|
| 10–11 g/dL | <p>Ribavirin →</p> <ul style="list-style-type: none"> ▶ If no or minimal symptoms, then no dose modification. ▶ If symptomatic, decrease ribavirin by 200 mg/day. | <p>Candidates for Erythropoietin: Rule out other causes of anemia. If anemia persists at 2 weeks after reducing ribavirin—and there is no hypertension—then consider erythropoietin, especially if the patient demonstrates a virologic response. Erythropoietin should be considered primarily for patients who are cirrhotic, post-transplant, HIV/HCV coinfecting, or treated with a DAA.</p> <p>Dosage: Epoetin alfa 40,000 units subcutaneously weekly</p> <p>Goal: Hemoglobin 12 g/dL</p> <p>Note: If hemoglobin is <12 g/dL for more than 4 weeks at the reduced/adjusted dose, then discontinue ribavirin.</p> |
| 8.5–10 g/dL | <p>Ribavirin → ↓ to 600 mg daily (200 mg AM & 400 mg PM)</p> | |
| < 8.5 g/dL | <p>Ribavirin → Discontinue until resolved.</p> | |

Appendix 5. Resources—Prevention and Treatment of Viral Hepatitis

HEALTH CARE PROFESSIONALS

American Association for the Study of Liver Diseases and Infectious Disease Society of America
Hepatitis C Guidance

<http://www.hcvguidelines.org>

Centers for Disease Control and Prevention
National Center for Infectious Diseases—Hepatitis Branch

<http://www.cdc.gov/ncidod/diseases/hepatitis/>

MELD Score Calculator

<http://optn.transplant.hrsa.gov/converge/resources/MeldPeldCalculator.asp?index=98>

National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases

<http://www.niddk.nih.gov>

National Clinicians' Post-Exposure Prophylaxis PEpline: (888) 448-4911

<http://www.nccc.ucsf.edu/>

U.S. Department of Veterans Affairs National Hepatitis C Program

<http://www.hepatitis.va.gov/>

PATIENT EDUCATION

American Liver Foundation (ALF)

<http://www.liverfoundation.org>

Centers for Disease Control and Prevention (CDC)

<http://www.cdc.gov/idu/hepatitis/index.htm>

Hepatitis Foundation International (HFI)

<http://www.hepfi.org>

The National Digestive Diseases Information Clearinghouse (NDDIC)

http://www.digestive.niddk.nih.gov/diseases/pubs/hepc_ez/index.htm

U.S. Department of Veterans Affairs National Hepatitis C Program—For Veterans
and the Public

<http://www.hepatitis.va.gov/patient/index.asp>

Appendix 6. Hepatitis C Treatment Algorithm/Nonformulary Request Worksheet

The BOP *Hepatitis C Treatment Algorithm/Nonformulary Request Worksheet* is available on the next page.

U.S. DEPARTMENT OF JUSTICE FEDERAL BUREAU OF PRISONS

| | |
|---|---|
| Inmate Name: | Projected Release Date: |
| Register Number: | Weight (lb.): (within 90 days of request) |
| APRI Score: APRI Date: APRI = ([AST/ULN AST]/Plt) x 100 | HCV Genotype: 1a 1b 2 3 4 5 6 |
| CTP Score(if cirrhotic): Date: POINTS (circle): <u>1</u> <u>2</u> <u>3</u> Albumin(g/dL): >3.5 2.8-3.5 <2.8 Bilirubin(mg/dL): <2 2-3 >3 INR: <1.7 1.7-2.3 >2.3 Encephalopathy: none grade 1-2 grade 3-4 Ascites: none diuretic diuretic responsive refractory | Liver Biopsy Result (amount of fibrosis): Date Performed: <input type="checkbox"/> Not Performed <input type="checkbox"/> Portal <input type="checkbox"/> Periportal <input type="checkbox"/> Bridging <input type="checkbox"/> Cirrhosis <input type="checkbox"/> None Note: For regimens with elbasvir/grazoprevir in the treatment of HCV genotype 1a, an HCV NSSA virologic resistance test is required. |
| Prior Antiviral Treatment for HCV: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, answer the following: Drug Names and Dosages: Start Date: Stop Date: Reason stopped: Prior Treatment Response <input type="checkbox"/> SVR <input type="checkbox"/> Relapser <input type="checkbox"/> Partial Responder <input type="checkbox"/> Null Responder | |
| Requested Treatment Regimen(check all that apply): <input type="checkbox"/> Ledipasvir/sofosbuvir (Harvoni®) <input type="checkbox"/> Glecaprevir/pibrentasvir (Mavyret™) <input type="checkbox"/> Elbasvir/grazoprevir (Zepatier®) <input type="checkbox"/> Sofosbuvir/velpatasvir (Epclusa®) <input type="checkbox"/> Sofosbuvir/velpatasvir (Epclusa®) <input type="checkbox"/> Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) <input type="checkbox"/> Ribavirin <input type="checkbox"/> Other _____ | |
| Eligibility Criteria: <input type="checkbox"/> Sentenced inmate with sufficient time remaining on sentence to complete a course of treatment prior to halfway house (RRC), home confinement, or GCT/Full Term release, and Life Expectancy > 18 mo. <input type="checkbox"/> Inmate is willing and able to adhere to a rigorous treatment regimen (no documented non-adherence to prior therapy, failure to complete pretreatment evaluation process, or unwillingness to commit or consent to HCV treatment). <input type="checkbox"/> No contraindications or drug interactions with requested treatment regimen <input type="checkbox"/> No uncontrolled or unstable medical or mental health conditions. <input type="checkbox"/> No current pregnancy | |
| Health Services Staff Name / Signature / Date / Institution | |
| Documentation - include copies of the following with the BEMR non-formulary request: <input type="checkbox"/> CBC, serum creatinine and eGFR, liver panel, INR (dated within 180 days of request) <input type="checkbox"/> HCV RNA viral load (reported as IU/ml) (anytime prior to treatment) <input type="checkbox"/> HCV genotype (anytime prior to treatment)if not treatment naïve or a candidate for simplified treatment. <input type="checkbox"/> HIV Ab - if positive, include CD4 and HIV viral load (dated within 180 days of request) and current antiretroviral medication regimen <input type="checkbox"/> Hepatitis B serology (sAb, sAg, and cAb)- if HBsAg reactive, include eAg, eAb, and HBV DNA viral load <input type="checkbox"/> Liver biopsy report (if performed, but not required unless clinically indicated) <input type="checkbox"/> If cirrhosis or APRI ≥ 2(defined by pathology or clinical findings), include abdominal US or CT <input type="checkbox"/> Pregnancy test if woman with child-bearing potential (dated within 90 days of request) | |
| PROCEDURE FOR SUBMITTING HCV TREATMENT REQUEST - Generate a BEMR non-formulary request (NFR) for Hepatitis C Treatment Algorithm. - Include all information and attach all required documentation from above. - May scan and attach Hepatitis C Treatment Algorithm Nonformulary Request Worksheet to NFR. | |