

## Initiation of Hepatitis C Virus (HCV) Treatment: Protocol for Prioritization

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In keeping with VA's mission and Integrity, Commitment, Advocacy, Respect, and Excellence (I CARE) core values and characteristics, this protocol for treatment prioritization is the basis for **consistent, fair, and transparent** decision making regarding initiation of antiviral therapy in patients with confirmed HCV who are eligible for medical benefits under 38 C.F.R. 17.38 and other legal authorities granted to the Veterans Health Administration (VHA). (NOTE: The process for developing this protocol included engagement of subject matter experts (SME) from VHA. A SME workgroup is being established to continue to refine the prioritization levels based on clinical criteria).

Attempts to augment resources must be ongoing and **transparent**.

The complete ethical analysis and framework that served as the basis for this protocol – and that should guide decisions regarding the need for HCV treatment in VHA – can be found on the intranet site of the VHA National Center for Ethics in Health Care [http://www.ethics.va.gov/activities/hcv\\_framework.asp](http://www.ethics.va.gov/activities/hcv_framework.asp). Please also check this link for updates to this prioritization protocol.

### 1) Clinical Priority Criteria

The clinical priority inclusion criteria are structured to enable the **sickest patients who will benefit from the treatment** to receive priority over those who are less ill. Patients with clinical indication for HCV treatment who do not have any of the exclusion criteria should be prioritized for treatment in the following order:

- A) Patients who are currently undergoing antiviral HCV therapy (i.e. their therapy should be continued, as long as it remains clinically indicated)
- B) Patients with evidence of cirrhosis or at high risk for rapid progression of disease, including:

**Any one** or more of the following criteria for cirrhosis:

- Biopsy evidence of cirrhosis (METAVIR fibrosis Stage F4 or Ishak fibrosis stage 5-6/6)
- Clinical evidence of portal hypertension related to cirrhosis (ascites, gastroesophageal varices)

- Cirrhosis diagnosis based on direct visualization of a nodular liver (surgical or laparoscopic)
- Measured portal hypertension (i.e. hepatic venous pressure gradient  $\geq 6$  mmHg)
- Liver stiffness measurement (FibroScan®)  $>15$  kPa

**Or at least 2** of the following criteria for advanced fibrosis/cirrhosis:

- Biopsy evidence of advanced fibrosis (METAVIR fibrosis Stage F3 or Ishak fibrosis stage 4/6)
- Radiographic evidence of cirrhosis (e.g. nodular liver, portal-systemic collaterals, recanalized umbilical vein or splenomegaly)
- Liver stiffness measurement (FibroScan®) between 10-15 kPa
- Fib-4 score  $> 3.25$
- Synthetic dysfunction, defined as any of the following (only one point allowed)
  - a. albumin  $<3.5$  mg/dl, OR
  - b. direct bilirubin  $>1.0$  mg/dl, OR
  - c. total bilirubin  $>2.0$  mg/dl (not explainable by another cause such as Gilbert syndrome, hemolysis, acute liver injury, biliary obstruction or atazanavir) OR
  - d. INR  $>1.2$  (not receiving warfarin)
- Platelets  $<150,000$  per ul
- AST  $>$  ALT
- HIV/HCV co-infection

**Or patients with any one** of the following criteria:

- Requiring intensive immunosuppression (e.g. status post transplantation, on chemotherapy, etc.)
- On an organ transplant list or if the transplant center requires antiviral treatment prior to listing
- Extrahepatic immune complex mediated complications of hepatitis C (e.g. cryoglobulinemia, glomerulonephritis)
- B cell lymphoma associated with HCV

C) Patients without advanced fibrosis/cirrhosis or the other conditions outlined above.

Further prioritization will be determined by a workgroup of SMEs who will provide additional clinical criteria within no more than 60 days of their charge. Those criteria will be included in a revised protocol that will be provided through the Deputy Under Secretary for Health for Operations and Management to the field.

## 2) Clinical Exclusion Criteria

Patients with any of the following clinical exclusion criteria will be determined to not need initiation of antiviral HCV therapy. This approach is based VA regulation at 38 CFR 17.38 (b). However, based on the principles of **equity** and **human dignity**, patients assessed to have an exclusion criterion should be provided all other appropriate medical care and support. HCV treatment should not be provided to patients who decline to consent to the HCV treatment (i.e. who do not want the treatment).

- Patients with confirmed presence of any advanced disease with average life expectancy of 12 months or less (e.g., severe end-stage congestive heart failure, widely metastatic carcinoma with less than 12 months average survival, or hepatocellular carcinoma with less than 12 months average survival).
- Patients with confirmed severe irreversible cognitive impairment (e.g., persistent vegetative state or advanced dementia).
- Patients with an HCV strain that is resistant to all antiviral treatments.
- Patients with a Model for End-stage Liver Disease (MELD) score >30.<sup>1</sup>

## 3) Team Structure and Process to Implement This Protocol

To ensure an **impartial** process, this protocol for making clinical decisions regarding a patient's need for care is to be implemented by HCV treatment prioritization teams that function at the highest organizational level practical, such as the VISN-level, with access to the most comprehensive data on the population of patients with HCV. The population of patients in this case includes HCV patients who have indication for treatment at the time of the team's review.

Placing the responsibility for making difficult decisions regarding clinical need on a team not only preserves the clinician's role as advocate in the clinician-patient relationship but also helps to ensure a **fair, consistent and transparent** decision making process.

HCV treatment prioritization team review should occur at least every 45 days and be based on patient information provided by clinicians. The team should consist of individuals who have knowledge of the HCV patient population, clinicians experienced in care of HCV patients, ethics experts, and other appropriate experts as needed.

To avoid decision making that is based on real or perceived conflict of interest, preferential treatment, or nepotism, the team must adhere to the protocol. Likewise, when providing information to the team, clinicians must not attempt to manipulate the exclusion or inclusion criteria to give an advantage to their patients.

#### 4) Appeals Process

Depending on the organizational level of the HCV treatment prioritization team, leadership at that organizational level or higher should also establish an appeals process to ensure **fairness** and **procedural justice** for prioritization decisions made by the team. Whether the appeal is initiated by the Veteran or by a VA clinician on the Veteran's behalf, valid appeals will generally be based on claims of the teams' failure to adhere to the established prioritization protocol, rather than an appeal for an exception to the protocol itself. Appeals for exceptions to the protocol should follow the normal clinical appeals process with input from the Office of Public Health and the National Center for Ethics in Health Care. Adjudication of appeals must not be conducted by anyone who serves on the prioritization team or by any clinician responsible for the care of the patient whose case is under appeal.

#### 5) Reference

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<sup>1</sup> MELD calculator available at  
<http://optn.transplant.hrsa.gov/converge/resources/MeldPeldCalculator.asp?index=98>