

# **Clinical Decision Support (CDS) Content and Health Level 7 (HL7)- Compliant Knowledge Artifacts (KNARTs)**

## **Gastroenterology: Hepatitis C Clinical Content White Paper**

**Department of Veterans Affairs (VA)**



**Knowledge Based Systems (KBS)  
Office of Informatics and Information Governance (OIIG)  
Clinical Decision Support (CDS)**

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# **Clinical Decision Support (CDS) Content and Health Level 7 (HL7)-Compliant Knowledge Artifacts (KNARTs): Gastroenterology: Hepatitis C Clinical Content White Paper**

by Department of Veterans Affairs (VA)

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**Table 1. Relevant KNART Information: Gastroenterology: Hepatitis C**

<b>KNART Name</b>	<b>Associated CLIN</b>
Hepatitis C- Consult Request/Documentation Template	CLIN0005AD
Hepatitis C- Elbasvir/Grazoprevir- Order Set	CLIN0004AC
Hepatitis C- Ledipasvir/Sofobuvir- Order Set	CLIN0004AC
Hepatitis C- Glecaprevir/Pibrentavir- Order Set	CLIN0004AC
Hepatitis C- Composite/Consult Request	N/A

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# Introduction

The VA is committed to improving the ability of clinicians to provide care for patients while increasing quality, safety, and efficiency. Recognizing the importance of standardizing clinical knowledge in support of this goal, VA is implementing the HL7 Knowledge Artifact Specification for a wide range of VA clinical use cases. Knowledge Artifacts, referred to as KNARTs, enable the structuring and encoding of clinical knowledge so the knowledge can be integrated with electronic health records to enable clinical decision support.

The purpose of this Clinical Content White Paper is to capture the clinical context and intent of KNART use cases in sufficient detail to provide the KNART authoring team with the clinical source material to construct the corresponding knowledge artifacts using the HL7 Knowledge Artifact Specification. This paper has been developed using material from a variety of sources: VA artifacts, clinical practice guidelines, evidence in the body of medical literature, and clinical expertise. After reviewing these sources, the material has been synthesized and harmonized under the guidance of VA subject matter experts to reflect clinical intent of this use case for this use case.

Unless otherwise noted, items within this white paper (e.g., documentation template fields, orderable items, etc.) are chosen to reflect the clinical intent at the time of creation. To provide an exhaustive list of all possible items and their variations is beyond the scope of this work.

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# Conventions Used

Conventions used within the knowledge artifact descriptions include:

<obtain>: Indicates a prompt to obtain the information listed

- If possible, the requested information should be obtained from the underlying system(s). Otherwise, prompting the user for information may be required
- Default Values: Unless otherwise noted, <obtain> indicates to obtain the most recent observation. It is recognized that this default time-frame value may be altered by future implementations

[...]: Square brackets enclose explanatory text that indicates some action on the part of the clinical user, or general guidance to the clinical or technical teams. Examples include, but are not limited to:

[Begin ...], [End ...]: Indicates the start and end of specific areas to clearly delineate them for technical purposes.

[Activate ...]: Initiates another knowledge artifact or knowledge artifact section.

[Section Prompt: ...]: If this section is applicable, then the following prompt should be displayed to the user.

[Section Behavior: ...]: Indicates technical constraints or considerations for the selection of items outlined in the section prompt.

[Attach: ...]: Indicates that the specified item (e.g. procedure or result interpretation) should be attached to the documentation template if available.

[Link: ...]: Indicates that rather than attaching an item (e.g. image), a link should be included in the documentation template.

[Clinical Comment: ...]: Indicates technical considerations or notes to be utilized for KNART authoring and at time of implementation planning.

[Technical Note: ...]: Indicates technical considerations or notes to be utilized for KNART authoring and at time of implementation planning.

[If ...]: Indicates the beginning of a conditional section.

[Else, ...]: Indicates the beginning of the alternative branch of a conditional section.

[End if ...]: Indicates the end of a conditional section.

☐ [Check box]: Indicates items that should be selected based upon the section selection behavior.



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# Chapter 1. Gastroenterology: Hepatitis C

## 1. Clinical Context

[Begin Clinical Context.]

Intended to identify patients for whom hepatitis C treatment is recommended; facilitate discussion between the primary care provider and the patient regarding test results, precautions to prevent further liver damage and disease transmission, potential barriers to care, and patient treatment preferences and goals; support documentation related to the discussion and pretreatment assessment; and promote decision-making and appropriate ordering based on patient- and disease-specific factors.

**Table 1.1. Clinical Context Domains**

Target User	Primary Care Physicians, Gastroenterologists
Patient	Adult outpatients with chronic Hepatitis C infection
Priority	Routine
Specialty	Primary Care, Gastroenterologists
Location	Outpatient

[End Clinical Context.]

## 2. Knowledge Artifacts

[Begin Knowledge Artifacts.]

This section describes the CDS KNARTs that are part of the GI Hepatitis C group, and include:

- Composite/Consult Request: Gastroenterology: Hepatitis C KNART
  - High-level, encompassing artifact meant to communicate the request for gastroenterology consultation
  - Relies upon the documentation template and order set artifacts
- Consult Request/Documentation Template: Gastroenterology: Hepatitis C KNART
  - Documents information provided either by a provider referring to gastroenterology for management of hepatitis C, or by a provider managing a hepatitis C patient himself or herself
  - Includes logic for appropriate display of documentation sections
- Order Sets: Gastroenterology: Hepatitis C KNART
  - Orderable items associated with the management of hepatitis C
  - Includes logic for appropriate display of the order set

[End Knowledge Artifacts.]

---

# Chapter 2. Composite: Hepatitis C Consult Request

[Begin Composite.]

## 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

Hepatitis C is a pervasive, and usually silent, disease with serious implications for morbidity and mortality. With the availability of a host of efficacious but expensive new drugs, it is imperative that patients be screened and treated for hepatitis C according to evidence-based guidelines. Examples include the use of ledipasvir/sofosbuvir for hepatitis C genotypes 1, 4, 5, and 6; elbasvir/grazoprevir for hepatitis C genotypes 1 and 4; and glecaprevir/pibrentasvir for all hepatitis C genotypes (VA October 2017; AASLD/IDSA 2017). In addition to matching the appropriate drug combinations to the appropriate genotypes, accounting for decompensated liver disease, prior treatments, comorbid conditions, and potential drug–drug interactions further complicates rational prescribing. Operationalizing such evidence—thus making the right thing to do also the easy thing to do—within the VA is particularly important because the complexity of the viral nomenclature and indications for pharmacologic therapy can easily overwhelm non-hepatologists.

[Technical Note: Users should revise the information provided in the documentation template—consult request form as needed during the evaluation.]

[End Knowledge Narrative.]

## 2. Consult Request

[Begin Consult Request.]

Reason for Consult: Treatment recommendation for patient with Chronic Hepatitis C

[Section Prompt: Goal of Consult.]

[Section Selection Behavior: Required. Select one.]

- ☐ Return to primary care provider (PCP) for therapy
- ☐ Start treatment and return to PCP for follow up and maintenance
- ☐ Start treatment, monitor for effect and when on stable therapy return to PCP
- ☐ Treat as long as necessary (or indefinitely)

Consult Specialty: Gastroenterology

Priority: Routine

<obtain> Referring Physician

<obtain> Referring Physician Contact Information

<obtain> Patient Identification

<obtain> Patient Demographics

<obtain> Information required by receiving facility

[End Consult Request.]

[End Composite.]

---

# Chapter 3. Consult Request/Documentation Template: Hepatitis C

[Begin Consult Request/Documentation Template.]

[Technical Note: Users should enter information into the documentation template—consult request form as needed during the evaluation.]

## 1. Demographics

[Begin Demographics.]

[Technical Note: Pre-populate the Age and Race/Ethnicity.]

<obtain> Age (Years)

<obtain> Race/Ethnicity

[End Demographics.]

## 2. Problem List

[Begin Problem List.]

[Technical Note: Pre-populate the Problem List, providing capability to edit the list.]

<obtain> Problem List

[End Problem List.]

## 3. Body Mass Index (BMI)

[Begin Body Mass Index.]

[Technical Note: Pre-populate the BMI, providing capability to edit.]

<obtain> Body Mass Index (BMI) (kg/m<sup>2</sup>)

<obtain> Date BMI determined

[End Body Mass Index.]

## 4. Medication List

[Begin Medication List.]

[Technical Note: Pre-populate the Medication List, providing capability to edit the list.]

<obtain> Medication List (Including Over-the-Counter Medications and Supplements)

[End Medication List.]

## 5. History of Present Illness

[Begin History of Present Illness.]

[Section Prompt: Prior Treatment.]

[Section Selection Behavior: Select all that apply.]

[Technical Note: Prior Treatment to be auto-populated when data is available.]

- ☐ NS3 Protease Inhibitor plus Peginterferon Alfa/Ribavirin
- ☐ NS5A Protease Inhibitor
- ☐ Peginterferon Alfa/Ribavirin
- ☐ Simeprevir/Sofosbuvir
- ☐ Sofosbuvir
- ☐ Sofosbuvir/Ribavirin with or without Peginterferon Alfa/Ribavirin
- ☐ Other medications or treatments

<obtain> Details and results of other medications or treatments

[Section Prompt: Liver Complications or Extrahepatic Manifestations.]

[Section Selection Behavior: Select all that apply.]

- ☐ Ascites due to liver failure
- ☐ Cirrhosis

[Technical Note: If cirrhosis is selected, calculate Child Turcotte Pugh Class (CTP) automatically and pre-select A, B or C. Mechanism should be provided for the user to override the pre-selected class. Default is A. Class C requires at least one of the following: 1) total bilirubin > 3 mg/dL; or 2) serum albumin < 2.8 g/dL; or 3) international normalized ratio > 2.30; or 4) moderate to severe ascites; or 5) grade III to IV or refractory hepatic encephalopathy. Class B does not have any of the criteria for class C and requires at least one of the following: 1) total bilirubin 2-3 mg/dL; or 2) serum albumin 2.8 to 3.5 g/dL; or 3) international normalized ratio 1.71 to 2.30; or 4) mild ascites; or 5) grade I to II encephalopathy or encephalopathy that is suppressed with medications. Class A requires all of the following: 1) total bilirubin < 2 mg/dL; and 2) serum albumin > 3.5 g/dL; and 3) international normalized ratio ≤ 1.70; and 4) no ascites; and 5) no encephalopathy. Provide link to <https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp>]

[Section Prompt: Child Turcotte Pugh Class for this patient.]

- ☐ A
- ☐ B
- ☐ C

[Technical Note: Encephalopathy should be automatically selected if data is available.]

- ☐ Encephalopathy

[Technical Note: Hepatocellular Carcinoma should be automatically selected if data is available.]

- ☐ Hepatocellular Carcinoma
- ☐ Liver Transplant

<obtain> Date

<obtain> Hepatitis C Infection status of the allograft

☐ Other Liver Complications or Extrahepatic Manifestations

<obtain> Details

[End History of Present Illness.]

## 6. Labs

[Begin Labs.]

[Technical Note: Please auto populate data in this section if it is available.]

[Technical Note: If auto populated, please provide the most recent lab result.]

[Technical Note: Please prompt provider to order a new Complete Blood Count if this there are no results or the date is not within 1 year.]

[Section Prompt: Prior lab results:]

☐ Complete Blood Count

<obtain> Date

Results

<obtain> White Blood Cell Count (K/microliter)

<obtain> Mean Cell Volume (femtoliters)

<obtain> Hemoglobin (g/dL)

<obtain> Platelet Count (K/microliter)

[Technical Note: Please prompt provider to order a new Hepatic Function Panel if there are no results or the date is not within 1 year.]

☐ Hepatic Function Panel

<obtain> Date

Results

<obtain> Albumin (d/dL)

<obtain> Total Bilirubin (mg/dL)

<obtain> Alanine Aminotransferase (U/L)

<obtain> Aspartate Aminotransferase (U/L)

<obtain> Alkaline Phosphatase (U/L)

[Technical Note: Please prompt provider to order a new International Normalized Ratio (INR) if this test has no results or the date is not within 1 year.]

☐ International Normalized Ratio

<obtain> Date

<obtain> Results

[Technical Note: Please prompt provider to order a new Glomerular Filtration Rate if there are no results or the date is not within 1 year.]

☐ Estimated Glomerular Filtration Rate

<obtain> Date

<obtain> Results (mL/min per 1.73 m<sup>2</sup>)

[Technical Note: Please prompt provider to order a new Creatinine if there are no results or the date is not within 1 year.]

☐ Creatinine

<obtain> Date

<obtain> Results (mg/dL)

[Technical Note: Please prompt provider to order a new Hepatitis C Virus (HCV) Viral Load if there are no results or the date is not within 1 year.]

☐ HCV Viral Load [Quantitative HCV Ribonucleic Acid (RNA)]

<obtain> Date

<obtain> Results (IU/L)

[Technical Note: Please prompt provider to order a new HCV Genotype if there are no results.]

☐ HCV Genotype

<obtain> Date

<obtain> Results

[Technical Note: Please prompt provider to order a new Human Immunodeficiency Virus (HIV) test if there are no results or if the results are negative and the date is not within 5 years.]

☐ HIV Test

<obtain> Date

<obtain> Results

[Technical Note: Please prompt provider to order a new Hepatitis B Screen if there are no results or the date is not within 10 years.]

☐ Hepatitis B Screen

<obtain> Date

Results

<obtain> HBsAg

<obtain> Anti-HBs

<obtain> Anti-HBc

[End Labs.]

## 7. Imaging

[Begin Imaging.]

[Technical Note: Corresponding links to the images should be attached automatically if text is provided for an interpretation field in this section. If no results are found, indicate this to the user.]

<obtain> Liver Ultrasound Interpretation

[Technical Note: Link to full Report and Images]

<obtain> Liver Computed Tomography (CT) Interpretation

[Technical Note: Link to full Report and Images]

<obtain> Liver Magnetic Resonance Imaging (MRI) Interpretation

[Technical Note: Link to full Report and Images]

<obtain> Fibroscan Interpretation

[Technical Note: Link to full Report and Images]

[End Imaging.]

[End Consult Request/Documentation Template.]



---

# Chapter 4. Order Set: Hepatitis C

## Elbasvir/Grazoprevir

[Begin Order Set: Hepatitis C - Elbasvir/Grazoprevir.]

### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[End Knowledge Narrative.]

### 2. Medications

[Begin Medications.]

[Technical Note: This section should be available to any provider who is treating a patient with hepatitis C.]

[Technical Note: Subsections in this section should be made available according to the subpopulation criteria identified in the subheadings, based on automated data evaluation and on data entered into the hepatitis C documentation template.]

[Section Prompt: Elbasvir/grazoprevir is contraindicated in patients with decompensated cirrhosis.]

[Section Prompt: Elbasvir/grazoprevir should not be used in combination with 1) strong CYP3A inducers; or 2) OATP1B1/3 inhibitors; or 3) efavirenz.]

[Section Prompt: Providers should check <http://www.hep-druginteractions.org>, <https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp>, and/or a pharmacist for additional drug interactions or contraindications before starting elbasvir/grazoprevir.]

[Section Prompt: Qualifications for the following treatment include: Genotype 1a, Treatment-Naïve or Treatment-Experienced (PEG/RBV), No NS5A Polymorphisms at Position 28, 30, 31, or 93, without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1a, Treatment-Naïve, with NS5A Polymorphisms at Position 28, 30, 31, or 93, without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 3 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1a, Treatment-Experienced (First Generation Protease Inhibitor Plus PEG/RBV), No NS5A Polymorphisms at Position 28, 30, 31, or 93, without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) daily

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food  
168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1a, Treatment-Experienced (PEG/RBV or First Generation Protease Inhibitor Plus PEG/RBV), with NS5A Polymorphisms at Position 28, 30, 31, or 93, without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 3 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food  
140 capsules 3 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food  
168 capsules 3 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1b, Treatment-Naïve or Treatment-Experienced (PEG/RBV), without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1b, Treatment-Experienced (First Generation Protease Inhibitor Plus PEG/RBV), without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food  
140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food  
168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 4, Treatment-Naïve, without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 4, Treatment-Experienced (PEG/RBV), without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Elbasvir/grazoprevir (50 mg/100 mg) 1 tablet oral, daily, 28 tablets 3 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food  
140 capsules 3 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food  
168 capsules 3 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Reduced-Dose Ribavirin for Patients with Renal Impairment (Creatinine Clearance 30–50 mL/min/1.73 m<sup>2</sup>).]

☐ Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 3 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Reduced-Dose Ribavirin for Patients with Renal Impairment (Creatinine Clearance < 30 mL/min/1.73 m<sup>2</sup>).]

☐ Ribavirin 200 mg capsule oral, take 1 capsule daily with food 28 capsules 2 refills (routine)

- ☐ Ribavirin 200 mg capsule oral, take 1 capsule daily with food 28 capsules 3 refills (routine)

[End Medications.]

### 3. Laboratory Tests

[Begin Laboratory Tests.]

[Technical Note: This section should be available to users in gastroenterology settings and for primary care providers who are managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

- ☐ Complete blood count 1 time (routine)
- ☐ Hepatic function panel 1 time (routine)
- ☐ International normalized ratio 1 time (routine)
- ☐ Basic metabolic panel 1 time (routine)
- ☐ Glomerular filtration rate 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 5 years.]

- ☐ HCV genotype 1 time (routine)

[Section Prompt: The following labs are recommended if not performed within the previous 10 years.]

- ☐ Hepatitis B surface antigen (HBsAg) 1 time (routine)
- ☐ Hepatitis B core antibody (HBcAb) 1 time (routine)
- ☐ Hepatitis B surface antibody (HBsAb) 1 time (routine)
- ☐ Hepatitis A antibody (HAVAb) 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 6 months.]

- ☐ HCV viral load (quantitative HCV RNA) 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 5 years]

- ☐ Resistance-associated substitutions 1 time (routine)
- ☐ HIV test 1 time (routine)

[Technical Note: The following order for qualitative human chorionic gonadotropin (HCG) should be available for female patients of reproductive age only.]

[Section Prompt: The following lab is recommended if not performed within the previous 2 weeks.]

- ☐ Qualitative human chorionic gonadotropin 1 time (routine)

[End Laboratory Tests.]

### 4. Patient and Caregiver Education

[Begin Patient and Caregiver Education.]

[Technical Note: This section should be available to users in gastroenterology settings and for primary care providers who are managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

“Hepatitis C Information for Veterans” available at <https://www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf>

“Chronic Hepatitis C and Alcohol Use” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-alcohol-brochure.asp>

“What to Expect Before Your Treatment for Hepatitis C Virus” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-pretreatment.asp>

“Ribavirin: Information for Patients” available at <https://www.hepatitis.va.gov/pdf/patient-ribavirin.pdf>

“Taking Your Hepatitis C Therapy: Zepatier(TM) with or without Ribavirin” available at <https://www.hepatitis.va.gov/pdf/patient-zepatier.pdf>

“Managing Side Effects of Zepatier(TM)” available at <https://www.hepatitis.va.gov/pdf/side-effects-zepatier.pdf>

“Managing Side Effects of Zepatier(TM) + Ribavirin” available at <https://www.hepatitis.va.gov/pdf/side-effects-zepatier-ribavirin.pdf>

“Tracking My Hepatitis C Treatment Results” available at <https://www.hepatitis.va.gov/products/patient/tracking-chart.asp>

[End Patient and Caregiver Education.]

[End Order Set: Hepatitis C - Elbasvir/Grazoprevir.]

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# Chapter 5. Order Set: Hepatitis C

## Ledipasvir/Sofosbuvir

[Begin Order Set: Hepatitis C - Ledipasvir/Sofosbuvir.]

### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[End Knowledge Narrative.]

### 2. Medications

[Begin Medications.]

[Technical Note: This section should be available to any provider who is treating a patient with hepatitis C.]

[Technical Note: Subsections in this section should be made available according to the subpopulation criteria identified in the subheadings, based on data pulled automatically or entered into the hepatitis C documentation template.]

[Section Prompt: Ledipasvir/sofosbuvir should not be used in patients with severe renal impairment (eGFR<30mL/min/1.73 m<sup>2</sup>), with end-stage-renal disease, or on hemodialysis.]

[Section Prompt: Ledipasvir/sofosbuvir should not be used in combination with amiodarone, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, rosuvastatin, St. John's wort, elvitegravir/cobicistat/emtricitabine/tenofovir, tipranavir/ritonavir, or simeprevir.]

[Section Prompt: Ledipasvir/sofosbuvir should not be used in patients who require twice-daily proton pump inhibitor therapy for esophageal disease.]

[Section Prompt: Providers should check <http://www.hep-druginteractions.org>, <https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp>, and/or a pharmacist for additional drug interactions or contraindications before starting ledipasvir/sofosbuvir.]

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Naïve, without Cirrhosis, HCV RNA < 6 Million IU/mL.]

[Section Prompt: An 8-week duration of therapy should be used in non-African American patients only; a 12-week duration of therapy should be used in patients who are African American.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 1 refill (routine)

[Technical Note: The following order should be available for patients who are African American.]

[Section Prompt: For patients who are African American:]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Naïve, without Cirrhosis, HCV RNA ≥ 6 Million IU/mL.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Naïve, without Cirrhosis, with HIV Coinfection.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Naïve, with Compensated Cirrhosis.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), without Cirrhosis.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), with Compensated Cirrhosis (CTP A).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), Ribavirin Intolerant, with Compensated Cirrhosis (CTP A).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1 with Decompensated Cirrhosis (CTP B or C).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Ribavirin Intolerant, with Decompensated Cirrhosis (CTP B or C).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Pre- or Post-Liver Transplant (Including CTP A, B, or C or Suitable Candidate with Hepatocellular Carcinoma).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 4, 5, or 6 without Cirrhosis or with Compensated Cirrhosis (CTP A).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 4, 5, or 6 with Decompensated Cirrhosis (CTP B or C).]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 4, Post-Liver Transplant.]

☐ Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

☐ Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Reduced-Dose Ribavirin for Patients with Renal Impairment (Creatinine Clearance 30–50 mL/min/1.73 m<sup>2</sup>).]

☐ Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 2 refills (routine)

[End Medications.]

### 3. Laboratory Tests

[Begin Laboratory Tests.]

[Technical Note: This section should be available to users in gastroenterology settings and for primary care providers who are managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

☐ Complete blood count 1 time (routine)

☐ Hepatic function panel 1 time (routine)

☐ International normalized ratio 1 time (routine)

☐ Basic metabolic panel 1 time (routine)

☐ Glomerular Filtration rate 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 5 years.]

☐ HCV genotype 1 time (routine)

[Section Prompt: The following labs are recommended if not performed within the previous 10 years.]

☐ Hepatitis B surface antigen (HBsAg) 1 time (routine)

☐ Hepatitis B core antibody (HBcAb) 1 time (routine)

☐ Hepatitis B surface antibody (HBsAb) 1 time (routine)

☐ Hepatitis A antibody (HAVAb) 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 6 months.]

☐ HCV viral load (quantitative HCV RNA) 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 5 years.]

☐ HIV test 1 time (routine)

[Technical Note: The following order for qualitative human chorionic gonadotropin (HCG) should be available for female patients of reproductive age only.]

[Section Prompt: The following lab is recommended if not performed within the previous 2 weeks.]

☐ Qualitative human chorionic gonadotropin 1 time (routine)

[End Laboratory Tests.]

## 4. Patient and Caregiver Education

[Begin Patient and Caregiver Education.]

[This section should be available to users in gastroenterology settings and for primary care providers who are managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

- “Hepatitis C Information for Veterans” available at <https://www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf>
- “Chronic Hepatitis C and Alcohol Use” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-alcohol-brochure.asp>
- “What to Expect Before Your Treatment for Hepatitis C Virus” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-pretreatment.asp>
- “Ribavirin: Information for Patients” available at <https://www.hepatitis.va.gov/pdf/patient-ribavirin.pdf>
- “Taking Your Hepatitis C Therapy: Harvoni(R) with or without Ribavirin” available at <https://www.hepatitis.va.gov/pdf/patient-harvoni.pdf>
- “Managing Side Effects of Harvoni(R)” available at <https://www.hepatitis.va.gov/products/patient/side-effects-handouts.asp>
- “Managing Side Effects of Harvoni(R) and Ribavirin” available at <https://www.hepatitis.va.gov/pdf/side-effects-harvoni-ribavirin.pdf>
- “Tracking My Hepatitis C Treatment Results” available at <https://www.hepatitis.va.gov/products/patient/tracking-chart.asp>
- [End Patient and Caregiver Education.]

[End Order Set: Hepatitis C - Ledipasvir/Sofosbuvir.]



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# Chapter 6. Order Set: Hepatitis C

## Glecaprevir/Pibrentasvir

[Begin Order Set: Hepatitis C - Glecaprevir/Pibrentasvir.]

### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[End Knowledge Narrative.]

### 2. Medications

[Begin Medications.]

[Technical Note: This section should be available to any provider who is treating a patient with hepatitis C.]

[Technical Note: Subsections in this section should be made available according to the subpopulation criteria identified in the subheadings, based on data pulled automatically or on data that is entered into the hepatitis C documentation template.]

[Section Prompt: Glecaprevir/pibrentasvir should not be used in patients with decompensated cirrhosis (CTP B or C).]

[Section Prompt: Glecaprevir/pibrentasvir should not be used in combination with atazanavir or rifampin.]

[Section Prompt: Providers should check <http://www.hep-druginteractions.org>, <https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp>, and/or a pharmacist for additional drug interactions or contraindications before starting glecaprevir/pibrentasvir.]

[Section Prompt: Qualifications for the following treatment include: Genotype 1, 2, 3, 4, 5, or 6, Treatment-Naïve, without Cirrhosis.]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 1 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, 2, 3, 4, 5, or 6, Treatment-Naïve, with Compensated Cirrhosis (CTP A).]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (NS5A Protease Inhibitor without Prior NS3/4A Protease Inhibitor), without Cirrhosis.]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, 2, 4, 5, or 6, Treatment-Experienced (Interferon, Pegylated Interferon, Ribavirin, and/or Sofosbuvir), without Cirrhosis.]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 1 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 3, Treatment-Experienced (Interferon, Pegylated Interferon, Ribavirin, and/or Sofosbuvir), without Cirrhosis.]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 3 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (NS5A Protease Inhibitor without Prior NS3/4A Protease Inhibitor), with Compensated Cirrhosis (CTP A).]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 3 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, Treatment-Experienced (NS3/4A Protease Inhibitor without Prior NS5A Protease Inhibitor), with Compensated Cirrhosis (CTP A).]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 1, 2, 4, 5, or 6, Treatment-Experienced (Interferon, Pegylated Interferon, Ribavirin, and/or Sofosbuvir), with Compensated Cirrhosis (CTP A).]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 2 refills (routine)

[Section Prompt: Qualifications for the following treatment include: Genotype 3, Treatment-Experienced (Interferon, Pegylated Interferon, Ribavirin, and/or Sofosbuvir), with Compensated Cirrhosis (CTP A).]

☐ Glecaprevir/pibrentasvir (100 mg/40 mg) 3 tablets oral, daily, 84 tablets 2 refills (routine)

[End Medications.]

### 3. Laboratory Tests

[Begin Laboratory Tests.]

[Technical Note: This section should be available to users in gastroenterology settings and for primary care providers managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

☐ Complete blood count 1 time (routine)

☐ Hepatic function panel 1 time (routine)

☐ International normalized ratio 1 time (routine)

☐ Basic metabolic panel 1 time (routine)

☐ Glomerular filtration rate 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 5 years.]

☐ HCV genotype 1 time (routine)

[Section Prompt: The following labs are recommended if not performed within the previous 10 years.]

☐ Hepatitis B surface antigen (HBsAg) 1 time (routine)

☐ Hepatitis B core antibody (HBcAB) 1 time (routine)

☐ Hepatitis B surface antibody (HBsAb) 1 time (routine)

☐ Hepatitis A antibody (HAVAb) 1 time (routine)

[Section Prompt: The following lab is recommended if not performed within the previous 6 months.]

☐ HCV viral load (quantitative HCV RNA) 1 time (routine)

☐ HIV test 1 time (routine)

[Technical Note: The following order for qualitative human chorionic gonadotropin (HCG) should be available for female patients of reproductive age only.]

[Section Prompt: The following lab is recommended if not performed within the previous 2 weeks.]

☐ Qualitative human chorionic gonadotropin 1 time (routine)

[End Laboratory Tests.]

## 4. Patient and Caregiver Education

[Begin Patient and Caregiver Education.]

[This section should be available to users in gastroenterology settings and for primary care providers who are managing hepatitis C patients themselves or referring a patient to gastroenterology for management of hepatitis C.]

- “Hepatitis C Information for Veterans” available at <https://www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf>
- “Chronic Hepatitis C and Alcohol Use” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-alcohol-brochure.asp>
- “What to Expect Before Your Treatment for Hepatitis C Virus” available at <https://www.hepatitis.va.gov/products/patient/hepatitisC-pretreatment.asp>
- “Taking Your Hepatitis C Therapy: Mavyret(TM)” available at <https://www.hepatitis.va.gov/pdf/patient-mavyret.pdf>
- “Managing Side Effects of Mavyret(TM)” available at <https://www.hepatitis.va.gov/pdf/side-effects-mavyret.pdf>
- “Tracking My Hepatitis C Treatment Results” available at <https://www.hepatitis.va.gov/products/patient/tracking-chart.asp>

[End Patient and Caregiver Education.]

[End Order Set: Hepatitis C - Glecaprevir/Pibrentasvir.]

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# Appendix A. Existing Sample VA Artifacts

Figures A.1 through A.8 for the Hepatitis C - Elbasvir/Grazoprevir - Order Set are from the Portland VAMC.

**Figure A.1. Hepatitis C Treatment**

The screenshot shows a web-based form titled "Hepatitis C Treatment" with a "Done" button in the top right corner. The form is divided into two main sections. The first section, titled "Prescribers", contains a paragraph stating: "The following information is needed to complete the request for sofosbuvir in compliance with VISN 20 formulary guidelines." Below this paragraph is a list of required information items: "HCV genotype", "Ascites information (for CP Score)", "Hepatic Encephalopathy information (for CP Score)", and "MELD/CHILD PUGH will need to be calculated (links to the calculators and lab data is provided)". The second section is a large, empty text area, preceded by a tab-like header labeled "<< Hepatitis C Treatment Medications >>".

**Hepatitis C Treatment** Done

**Prescribers**

The following information is needed to complete the request for sofosbuvir in compliance with VISN 20 formulary guidelines.

- HCV genotype
- Ascites information (for CP Score)
- Hepatic Encephalopathy information (for CP Score)
- MELD/CHILD PUGH will need to be calculated (links to the calculators and lab data is provided)

<< Hepatitis C Treatment Medications >>

**Figure A.2. Template: Formulary Exception- Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 1 of 5)**

The screenshot shows a web-based form titled "Template: Formulary Exception - HCV Outpt PADR". The form is designed for healthcare providers to request a formulary exception for Hepatitis C Virus (HCV) treatment. It includes several sections for data entry and decision-making.

**Header:** A link "<- CLICK HERE TO START \*\*\*\*\* HCV Treatment \*\*\*\*\*" is located at the top left.

**Verification:** A statement "I verify that I am a provider in conjunction with the liver clinic authorized to prescribe this medication:" is followed by a radio button labeled "Yes".

**Test Results:** Fields for "HCV Genotype:", "HCV Viral Load:", and "FIB 4:" are provided, each with a text input field. A link "Fibrosis-4 (FIB-4) Calculator" is next to the FIB 4 field.

**History and Testing:** There are checkboxes for "Treatment History:", "Resistance Testing:" (with radio buttons for "No" and "Yes"), and "Is the patient cirrhotic?".

**Imaging and Biopsy:** Fields for "Fibroscan (if applicable):", "Liver Biopsy (if applicable):", and "Imaging (if applicable):" are included.

**Special Conditions:** A checkbox "Does the patient have any of the following special conditions?" is followed by a list of conditions with checkboxes: "HIV", "Liver Transplant", "CKD (CrCl < 30 or HD)", and "None".

**HCV Regimen Requested:** Two links are provided: "Hep C Treatment Regimen - Patients WITH Cirrhosis" and "Hep C Treatment Regimen - Patients WITHOUT Cirrhosis".

**Regimen Selection:** A list of treatment regimens is shown, each with a radio button: "Harvoni, 1 tablet daily", "Zepatier, 1 tablet daily", "Viekira, use as directed, following package instructions", "Sofosbuvir, 1 tablet daily", "Simeprevir, 1 tablet daily", "Epclusa, 1 tablet daily", and "Daclatasvir, 1 tablet daily".

**Footer:** At the bottom, there are buttons for "All", "None", "Preview", "OK", and "Cancel". A note "\* Indicates a Required Field" is also present.

**Figure A.3. Template: Formulary Exception- Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 2 of 5)**

Template: Formulary Exception - HCV Outpt PADR

☐ HIV  
☐ Liver Transplant  
☐ CKD (CrCl < 30 or HD)  
☐ None

HCV Regimen Requested:  
[Hep C Treatment Regimen - Patients WITH Cirrhosis](#)  
[Hep C Treatment Regimen - Patients WITHOUT Cirrhosis](#)

☒ Harvoni, 1 tablet daily  
☐ Zepatier, 1 tablet daily  
☐ Viekira, use as directed, following package instructions  
☐ Sofosbuvir, 1 tablet daily  
☐ Simeprevir, 1 tablet daily  
☐ Epclusa, 1 tablet daily  
☐ Daclatasvir, 1 tablet daily

Expected duration of treatment: \*  weeks.

☐ Is Ribavirin needed?  
☐ Special Request(s):

Labs:

CHEM 7 PANEL 03/06/2017 10:12  
UREA NITROGEN 132

No CBC in the past 1Y

LIVER FUNCTION PANEL 03/06/2017 13:38  
PROTEIN, TOTAL 120

No HEPATITIS B SURFACE ANTIGEN in the last 1Y  
No HEPATITIS B CORE ANTIBODY TOTAL in the last 1Y

All None \* Indicates a Required Field Preview OK Cancel

**Figure A.4. Template: Formulary Exception- Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 3 of 5)**

Template: Formulary Exception - HCV Outpt PADR

☒ <- CLICK HERE TO START \*\*\*\*\* HCV Treatment \*\*\*\*\*

I verify that I am a provider in conjunction with the liver clinic authorized to prescribe this medication: ☒ Yes

HCV Genotype: \*test  
HCV Viral Load: \*test  
FIB 4: \*test [Fibrosis-4 \(FIB-4\) Calculator](#)

☒ Treatment History:

☐ Naive  
☒ Experienced  
Previous treatment(s):  
\*  
Response: \*  
☒ Relapsed  
☐ Breakthrough  
☐ Non-responder  
☐ Unable to tolerate

☒ Resistance Testing: ☐ No ☒ Yes

☒ Is the patient cirrhotic?

Fibroscan (if applicable):  
Liver Biopsy (if applicable):  
Imaging (if applicable):

☐ No  
☒ Yes

Child Pugh Scoring Tool (information only):

	1 point	2 points	3 Points
Ascites:	Never had ascites	Completely managed on diuretics	Not responsive to diuretics
Hepatic	Never had	Controlled w/	Recurrent

All None \* Indicates a Required Field Preview OK Cancel



**Figure A.5. Template: Formulary Exception- Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 4 of 5)**

Template: Formulary Exception - HCV Outpt PADR

Child Pugh Scoring Tool (information only):

	1 point	2 points	3 Points
Ascites:	Never had ascites	Completely managed on diuretics	Not responsive to diuretics
Hepatic Encephalopathy:	Never had encephalopathy	Controlled w/ meds	Recurrent encephalopathy
Total Bilirubin:	Less than 2.0	2.0 to 3.0	Over 3.0
INR:	Less than 1.7	1.7 to 2.2	Over 2.2
Albumin:	Over 3.5	2.8 to 3.5	Less than 2.8

Child Pugh

Ascites Score: \* ☐ 1 ☐ 2 ☐ 3

Hepatic Encephalopathy Score: \* ☐ 1 ☐ 2 ☐ 3

Total Bilirubin Score: \* ☐ 1 ☐ 2 ☐ 3

INR Score: \* ☐ 1 ☐ 2 ☐ 3

Albumin Score: \* ☐ 1 ☐ 2 ☐ 3

TOTAL Child Pugh Score (from above): \* ☐ A ☐ B ☐ C

Child-Pugh Scoring: 5-6 = A; 7-9 = B; 10-15 = C

☐ Further work-up

☒ Does the patient have any of the following special conditions?

- ☐ HIV
- ☐ Liver Transplant
- ☐ CKD (CrCl < 30 or HD)
- ☐ None

HCV Regimen Requested:

[Hep C Treatment Regimen - Patients WITH Cirrhosis](#)

[Hep C Treatment Regimen - Patients WITHOUT Cirrhosis](#)

\* Indicates a Required Field

**Figure A.6. Template: Formulary Exception- Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 5 of 5)**

Template: Formulary Exception - HCV Outpt PADR

☒ CKD (CrCl < 30 or HD)  
☒ None

HCV Regimen Requested:  
[Hep C Treatment Regimen - Patients WITH Cirrhosis](#)  
[Hep C Treatment Regimen - Patients WITHOUT Cirrhosis](#)

•

☐ Harvoni, 1 tablet daily  
☐ Zepatier, 1 tablet daily  
☐ Viekira, use as directed, following package instructions  
☐ Sofosbuvir, 1 tablet daily  
☐ Simeprevir, 1 tablet daily  
☐ Epclusa, 1 tablet daily  
☒ Daclatasvir, 1 tablet daily

Expected duration of treatment: \*tes weeks.

☒ Is Ribavirin needed?  
☐ No  
☒ Yes  
RBV Dose: \*tst

☒ Special Request(s):

Labs:

CHEM 7 PANEL 03/06/2017 10:12  
UREA NITROGEN 132

No CBC in the past 1Y

LIVER FUNCTION PANEL 03/06/2017 13:38  
PROTEIN, TOTAL 120

No HEPATITIS B SURFACE ANTIGEN in the last 1Y  
No HEPATITIS B CORE ANTIBODY TOTAL in the last 1Y

All None \* Indicates a Required Field Preview OK Cancel

Figure A.7. Fibrosis- 4 (FIB-4) Calculator (Image 1 of 2)

**Hepatitis C Online** Sign In

HCV Medications Course Modules Tools & Calculators Resource Library Master Bibliography

**Clinical Calculators**

- Clinical Calculators
- APRI Calculator
- BMI Calculator
- CrCl Calculator
- CTP Calculator
- FIB-4 Calculator**
- Glasgow Coma Scale
- GFR Calculator
- MELD Calculator
- SAAG Calculator

**Fibrosis-4 (FIB-4) Calculator** Share

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count (10}^9\text{/L)} \times \sqrt{\text{ALT (U/L)}}} = \text{Yellow Oval}$$

**Interpretation:**

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

Figure A.8. Fibrosis- 4 (FIB-4) Calculator (Image 2 of 2)

**FIB-4 Calculator**

- Glasgow Coma Scale
- GFR Calculator
- MELD Calculator
- SAAG Calculator

**Substance Use Screening Tools**

- AUDIT-C Questionnaire
- CAGE Questionnaire

**Interpretation:**

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

**Sources**

Sterling RK, Ussien E, Clumeck N, et. al. Development of a simple noninvasive index to predict significant fibrosis patients with HIV/HCV co-infection. Hepatology 2006;43:1317-1325.

This calculator operates entirely from your device. No input variables or data is transmitted between your computer and our servers.

Funded by a grant from the Centers for Disease Control and Prevention

UNIVERSITY of WASHINGTON

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

IAS-USA International AIDS Society-USA

Figures A.9 through A.11 for the Hepatitis C - Ledipasvir/Sofosbuvir - Order Set are from the Portland VAMC.

**Figure A.9. Template: Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 1 of 3)**

Template: Formulary Exception - HCV Outpt PADR

☒ <- CLICK HERE TO START \*\*\*\*\* HCV Treatment \*\*\*\*\*

I verify that I am a provider in conjunction with the liver clinic authorized to prescribe this medication: \* ☐ Yes

HCV Genotype: \*

HCV Viral Load: \*

FIB 4: \* [Fibrosis-4 \(FIB-4\) Calculator](#)

☒ Treatment History:

☐ Naive

☒ Experienced

Previous treatment(s): \*

Response: \*

☐ Relapsed

☐ Breakthrough

☐ Non-responder

☒ Unable to tolerate

☒ Resistance Testing: \* ☐ No ☐ Yes

☒ Is the patient cirrhotic?

Fibroscan (if applicable):

Liver Biopsy (if applicable):

Imaging (if applicable):

☐ No

☐ Yes

Child Pugh Scoring Tool (information only):

	1 point	2 points	3 Points
Ascites:	Never had ascites	Completely managed on diuretics	Not responsive to diuretics
Hepatic	Never had	Controlled w/	Recurrent

All None \* Indicates a Required Field Preview OK Cancel

**Figure A.10. Template: Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 2 of 3)**

Template: Formulary Exception - HCV Outpt PADR

☐ Yes

Child Pugh Scoring Tool (information only):

	1 point	2 points	3 Points
Ascites:	Never had ascites	Completely managed on diuretics	Not responsive to diuretics
Hepatic Encephalopathy:	Never had encephalopathy	Controlled w/ meds	Recurrent encephalopathy
Total Bilirubin:	Less than 2.0	2.0 to 3.0	Over 3.0
INR:	Less than 1.7	1.7 to 2.2	Over 2.2
Albumin:	Over 3.5	2.8 to 3.5	Less than 2.8

Child Pugh

Ascites Score: \* ☐ 1 ☐ 2 ☐ 3

Hepatic Encephalopathy Score: \* ☐ 1 ☐ 2 ☐ 3

Total Bilirubin Score: \* ☐ 1 ☐ 2 ☐ 3

INR Score: \* ☐ 1 ☐ 2 ☐ 3

Albumin Score: \* ☐ 1 ☐ 2 ☐ 3

TOTAL Child Pugh Score (from above): \* ☐ A ☐ B ☐ C

Child-Pugh Scoring: 5-6 = A; 7-9 = B; 10-15 = C

☐ Further work-up

☒ Does the patient have any of the following special conditions?

- ☒ HIV
- ☒ Liver Transplant
- ☒ CKD (CrCl < 30 or HD)
- ☐ None

HCV Regimen Requested:

[Hep C Treatment Regimen - Patients WITH Cirrhosis](#)

[Hep C Treatment Regimen - Patients WITHOUT Cirrhosis](#)

All None \* Indicates a Required Field Preview OK Cancel

**Figure A.11. Template: Hepatitis C Virus (HCV) Output Phenolic Acid-responsive Transcriptional Regulator (PADR) (Image 3 of 3)**

Template: Formulary Exception - HCV Outpt PADR

☒ CKD (CrCl < 30 or HD)  
☐ None

HCV Regimen Requested:  
[Hep C Treatment Regimen - Patients WITH Cirrhosis](#)  
[Hep C Treatment Regimen - Patients WITHOUT Cirrhosis](#)

\*  
☐ Harvoni, 1 tablet daily  
☐ Zepatier, 1 tablet daily  
☒ Viekira, use as directed, following package instructions  
☐ Sofosbuvir, 1 tablet daily  
☐ Simeprevir, 1 tablet daily  
☐ Epclusa, 1 tablet daily  
☐ Daclatasvir, 1 tablet daily

Expected duration of treatment: \* weeks.

☒ Is Ribavirin needed?  
☐ No  
☒ Yes  
 RBV Dose: \*

☒ Special Request(s):

Labs:

CHEM 7 PANEL 03/06/2017 10:12  
 UREA NITROGEN 132

No CBC in the past 1Y

LIVER FUNCTION PANEL 03/06/2017 13:38  
 PROTEIN, TOTAL 120

No HEPATITIS B SURFACE ANTIGEN in the last 1Y  
 No HEPATITIS B CORE ANTIBODY TOTAL in the last 1Y

All None \* Indicates a Required Field Preview OK Cancel

Tables A.1 through A.10 are from the Portland VAMC.

Patients Without Cirrhosis:

**Table A.1. Genotype 1**

Treatment History	Baseline Viral Load	Preferred Regimen (Cost)	Alternative Regimen(s) (Cost)	Comments
Treatment naive	<6 million IU/mL (Including HCV/HIV coinfection)	Harvoni x 8 weeks (\$10,446) (Not African American)	Genotype 1a: Zepatier x12 weeks in patients without baseline NS5A RAV (\$15,522) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,892) Genotype 1b: Harvoni x 12 weeks (\$15,669)	Consider Zepatier for patients who are not candidates for Harvoni: -CrCl <30ml/min -Drug interactions (amiodarone) - Patients who are on high dose PPI and cannot hold PPI while on treatment
	>6 million IU/mL	Genotype 1a: Harvoni x 12 weeks (\$15,669) Genotype 1b: Zepatier x 12 weeks (\$15,522)		

Treatment Experienced INF/RBV	N/A	Genotype 1a: Harvoni x 12 weeks (\$15,669) *May consider ribavirin (-) RBV: 33/35 (94%) (+) RBV: 38/38 (100%) Genotype 1b: Zepatier x 12 weeks (\$15,522)	Genotype 1a: Zepatier x12 weeks in patients without baseline NS5A RAV (\$15,522) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,892) Genotype 1b: Harvoni x 12 weeks (\$15,522)	
Treatment Experienced PI/INF/RBV	N/A	Genotype 1a: Harvoni x 12 weeks (\$15,669) *May consider ribavirin (-) RBV: 50/52 (96%) (+) RBV: 51/51 (100%) Genotype 1b: Harvoni x 12 weeks (\$15,669) *May consider ribavirin	Genotype 1a: Zepatier + Ribavirin x12 weeks in patients without baseline NS5A RAV (\$15,522) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,892) Genotype 1b: Zepatier + Ribavirin x 12 weeks (\$15,522)	
DAA Treatment Experienced *Non NS5A*	N/A	Harvoni + RBV x 12 weeks (\$15,669) Epclusa +/- RBV x 12 weeks (\$45,048.51)	Harvoni x 24 weeks (\$31,338)	Likely will not need resistance testing
DAA Treatment Experienced *NS5A*	N/A	Zepatier + Sofosbuvir + RBV x 12 to 16 weeks (Consider 16 weeks for Y93 mutation) Epclusa + RBV x 24 weeks (if strong NS5A mutation is present) (\$90,000)	Harvoni + RBV x 12 weeks (If no NS5A mutation) Harvoni x 24 weeks (if no NS5A mutation) (\$31,338) Epclusa +/- RBV x 12 weeks (If no or weak NS5A mutation)	Obtain resistance testing (NS5A +/- PI) Consider waiting for future options if no urgency to treat Treatment option depends on duration of previous treatment, presence of NS5A RAS, and what kind of NS5A RAS
CrCl <30mL/min or ESRD	N/A	Genotype 1a: Zepatier x 12 weeks in patients without baseline NS5A RAV, 16 weeks with RAV (\$15,522) Genotype 1b: Zepatier x 12 weeks (\$15,522)	Genotype 1a: Viekira Pack + Low Dose RBV x 12 weeks (\$15,522.36) Genotype 1b: Viekira Pack x 12 weeks (\$15,522.36)	RBV 200mg daily if used in CKD/ESRD patients

Table A.2. Genotype 2

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Epclusa x 12 weeks (\$45,048.51)	Harvoni + Ribavirin x 12 weeks (\$15,669)	

Treatment Experienced INF/RBV	Epclusa +/- RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir +/- RBV x24 weeks per AASLD/IDSA (\$164,220)	Epclusa x 12 achieved 97% SVR in GT2 DAA experienced non-NS5A
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**Table A.3. Genotype 3**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Epclusa x 12 weeks (\$45,048.51)	Sofosbuvir + Daclatasvir x 12 weeks (\$82,110) ALLY 3 SVR12- 97% (73/75)	
Treatment Experienced INF/RBV	Epclusa + RBV x 12 weeks (\$45,048.51)	Sofosbuvir + Daclatasvir + RBV x 12 weeks (\$82,110) ALLY 3 SVR12- 94% (32/34)	Can omit RBV with Epclusa if no NS5A RAS
Treatment Experienced Sofosbuvir/RBV	Epclusa + RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir + RBV x 24 weeks per AASLD/IDSA (\$164,220)	Epclusa x 12 achieved 85% SVR in GT 3 DAA experienced non-NS5A
Treatment Experienced Harvoni/RBV	Epclusa + RBV x 12 weeks (if no Y93 mutation) (\$45,048.51)	Epclusa + RBV x 24 weeks (if Y93 mutation is present) (\$90,000)	Unlikely to have Y93 mutation
Treatment Experienced Daclatasvir or Velpatasvir	Epclusa + RBV x 24 weeks (\$90,000) - 13/16 (81%) SVR overall - 9/11 (82%) with Y93 mutation		Patients will almost certainly have the Y93 mutation SHOULD wait for new drugs if possible

**Table A.4. Genotype 4**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Zepatier x 12 weeks (\$15,522)	Harvoni x 12 weeks (\$15,669)	
Treatment experienced INF/RBV	Harvoni x 12 weeks (\$15,669)	Zepatier + Ribavirin x 16 weeks (\$20,892) Paritaprevir/Ritonavir/Om bitasvir + RBV (no Dasabuvir) x 12 weeks (\$15,522)	
DAA treatment experienced	Zepatier + Sofosbuvir + RBV x 12 to 16 weeks		Obtain resistance testing Consider waiting for future options if no urgency to treat

**Table A.5. Genotype 5 and 6**

Treatment History	Preferred Regimen(s)	Alternative Regimen(s)	Comments
Treatment Naïve and Experienced	Harvoni x 12 (\$15,669)	Epclusa x 12 weeks (\$45,048.51)	Limited data

Patients With Cirrhosis:

**Table A.6. Genotype 1**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
-------------------	-----------------------------	------------------------	----------



Naïve	Genotype 1a: Harvoni + RBV x 12 weeks (\$15,585.36) Genotype 1b: Zepatier x 12 weeks (\$15,436.68)	Genotype 1a: Zepatier x12 weeks in patients without baseline NS5A RAV (\$15,436.68) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,582.24) Genotype 1b: Harvoni x 12 weeks (\$15,585.36) Genotype 1: Epclusa x 12 weeks (\$45,048.51)	Consider Zepatier for patients who are not candidates for Harvoni: - CrCl <30ml/min - Drug interactions (amiodarone) - Patients who are on high dose PPI and cannot hold PPI while on treatment
Treatment Experienced INF/RBV	Genotype 1a: Harvoni + RBV x 12 weeks (\$15,585.36) Genotype 1b: Zepatier x 12 weeks (\$15,436.68)	Genotype 1a: Zepatier x12 weeks in patients without baseline NS5A RAV (\$15,436.68) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,582.24) Genotype 1b: Harvoni + RBV x 12 weeks (\$15,585.36) Genotype 1: Epclusa x 12 weeks (\$45,048.51)	
Treatment Experienced INF/RBV/PI	Genotype 1a: Harvoni + RBV x 12 weeks (\$15,585.36) Genotype 1b: Zepatier + Ribavirin x 12 weeks (\$15,436.68)	Genotype 1a: Zepatier + Ribavirin x12 weeks in patients without baseline NS5A RAV (\$15,436.68) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,582.24) Genotype 1b: Harvoni + RBV x 12 weeks (\$15,585.36)	
DAA Treatment Experienced *Non NS5A*	Harvoni + RBV x 24 weeks (\$31,170.72) Epclusa + RBV x 12 weeks (\$45,048.51)		Likely will not need resistance testing
DAA Treatment Experienced *NS5A*	Zepatier + Sofosbuvir + RBV x 12 to 16 weeks (Consider 16 weeks for Y93 mutation) Epclusa + RBV x 24 weeks (if strong NS5A mutation is present)	Harvoni + RBV x 24 weeks (if no NS5A mutation) (\$31,170.72) Epclusa + RBV x 12 weeks (if no NS5A mutation) (\$45,048.51)	Obtain resistance testing (both PI and NS5A) Consider waiting for future options if no urgency to treat Treatment option depends on duration of previous treatment, presence of NS5A RAS, and what kind/number of NS5A RAS
CrCl < 30 mL/min or ESRD	Genotype 1a: Zepatier x12 weeks in patients without baseline NS5A RAV (\$15,522) Zepatier + Ribavirin x 16 weeks in patients with baseline NS5A RAV (\$20,892) Genotype 1b: Zepatier x 12 weeks (\$15,522)	Genotype 1a: Viekira Pack + Low Dose RBV x 12 weeks (\$15,522.36) Genotype 1b: Viekira Pack x 12 weeks (\$15,522.36)	RBV 200mg daily if used in CKD/ESRD patients
Decompensated Cirrhosis	Harvoni + RBV x 12	Harvoni x 24 weeks	

	weeks (\$15,585.36) Epclusa + RBV x 12 weeks (\$45,048.51)	(\$31,338) Epclusa x 12 weeks (\$45,048.51) - 44/50 (88%) in GT1a - 16/18 (89%) in GT1b	
--	--	--	--

**Table A.7. Genotype 2**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Epclusa x 12 weeks (\$45,048.51)	Harvoni + RBV x 16 weeks (\$20,780.48)	
Treatment experienced INF/RBV	Epclusa x 12 weeks (\$45,048.51)	Harvoni + RBV x 16 weeks (\$20,780.48)	
Treatment Experienced Sofosbuvir/RBV	Epclusa + RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir +/- RBV x24 weeks per AASLD/IDSA (\$164,220)	Epclusa x 12 achieved 97% SVR in GT2 DAA experienced non-NS5A
Decompensated Cirrhosis	Epclusa +/- RBV x 12 weeks - 4/4 without RBV - 4/4 with RBV		

**Table A.8. Genotype 3**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Epclusa + RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir + Ribavirin x 12 weeks (\$82,110)	Can omit RBC with Epclusa if no NS5A RAS
Treatment experienced INF/RBV	Epclusa + RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir + Ribavirin x 12 (\$82,110)	Can omit RBV with Epclusa if no NS5A RAS
Treatment Experienced Sofosbuvir/RBV	Epclusa + RBV x 12 weeks (\$45,048.51)	Daclatasvir + Sofosbuvir + Ribavirin x 24 weeks (\$164,220); Per AASLD)	Epclusa x 12 achieved 85% SVR in GT 3 DAA experienced non-NS5A
Treatment Experienced Harvoni/RBV	Epclusa + RBV x 12 weeks (if no Y93 mutation) (\$45,048.51)	Epclusa + RBV x 24 weeks (if Y93 mutation is present or decomp cirrhosis) (\$90,000)	
Treatment Experienced Daclatasvir or Velpatasvir	Epclusa + RBV x 24 weeks (\$90,000) - 13/16 (81%) SVR overall - 9/11 (82%) with Y93 mutation		Patients will almost certainly have the Y93 mutation SHOULD wait for new drugs if possible
Decompensated Cirrhosis	Epclusa + RBV x 12 weeks		

**Table A.9. Genotype 4**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Naïve	Zepatier x 12 weeks (\$15,436.68)	Harvoni x 12 weeks (\$15,585.36)	Omit dasabuvir from Viekira pack when using it to treat GT 4
Treatment experienced INF/RBV	Harvoni x 12 weeks (\$15,585.36)	Zepatier + Ribavirin x 16 weeks (\$20,582.24) Paritaprevir/Ritonavir/Ombitasvir + RBV x 12 weeks	Omit dasabuvir from Viekira pack when using it to treat GT 4

		(\$15,522.36)	
DAA treatment experienced	Zepatier + Sofosbuvir + RBV x 12 to 16 weeks		Obtain resistance testing Consider waiting for future options if no urgency to treat
Naïve CrCl 30 mL/min or ESRD	Zepatier x 12 weeks (\$15,522)	Viekira Pack + RBV x 12 weeks (\$15,522.36)	RBV 200mg daily if used in CKD/ESRD patients
Decompensated Cirrhosis	Harvoni + RBV x 12 weeks (\$15,585.36)	Epclusa +/- RBV x 12 weeks (\$45,048.51) - 4/4 without RBV - 2/2 with RBV	

**Table A.10. Genotype 5 and 6**

Treatment History	Preferred Regimen (Cost)	Alternative Regimen(s)	Comments
Treatment Naïve and Experienced	Harvoni x 12 weeks (\$15,585.36)	Epclusa x 12 weeks (\$45,048.51)	Limited data
Decompensated Cirrhosis	Harvoni + RBV x 12 weeks (\$15,585.36)	Epclusa + RBV x 12 weeks (\$45,048.51)	

Figures A.12 through A.19 for the Hepatitis C - Ledipasvir/Sofosbuvir - Order Set are from the Greater Los Angeles VAMC.

**Figure A.12. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 1 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

HEPATITIS C CLINIC NOTE

HISTORY OF PRESENT ILLNESS:

\*

REVIEW OF SYSTEMS:

\*

☐ PAST MEDICAL HISTORY:

ACTIVE PROBLEMS

Diabetic peripheral neuropathy asso

Proteinuria

Orbital cellulitis (SNOMED CT 19400

HSV DENDRITIC

Prostate cancer

Dementia Due to Head Trauma

Organic Brain Syndrome

HTN \* (ICD-9-CM 401.9)

Acute Confusional State

Jaundice

Tachycardia

Colostomy and Enterostomy complicat

Epigastric Pain

Gynecomastia, Male

Pneumonia

Visit Info

Finish

Cancel

HISTORY OF PRESENT ILLNESS:

<No encounter information entered>

\* Indicates a Required Field

**Figure A.13. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 2 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

Pneumonia  
Hemoglobin SC Disease  
Hypertensive kidney disease, unspec  
Psychotic disorder (SNOMED CT 69322  
Pica  
Trichotillomania  
Glaucoma  
Chronic Obstructive Pulmonary Disea  
Diabetes Mellitus Type II or unspec  
Nonspecific Abnormal Papanicolaou S  
Narcissistic personality disorder (

☐ MEDICATIONS:  
  
Active Outpatient Medications (excluding Supplies):  
  

Active Outpatient Medications	Status
1) ACETAMINOPHEN 325MG TAB TAKE ONE TABLET BY MOUTH EVERY 6 HOURS AS NEEDED FOR PAIN	ACTIVE
2) CIMETIDINE 400MG TAB TAKE ONE TABLET BY MOUTH TWICE A DAY FOR STOMACH	ACTIVE
3) DIGOXIN (LANOXIN) 0.125MG TAB TAKE ONE TABLET BY MOUTH EVERY DAY FOR HEART	ACTIVE
4) FUROSEMIDE 20MG TAB TAKE ONE TABLET BY MOUTH EVERY DAY WATER PILL	ACTIVE

Additional medications/OTC:  
  
☐ ALLERGIES:  
SULFA-GYN, LORAZEPAM, SULFABENZAMIDE/SULFACETAMIDE/SULFATHIAZOLE, IODINE, LATEX  
TERAZOSIN, DIPHENHYDRAMINE 12.5MG/5ML ELX, TAPE, CHOCOLATE, ORANGE JUICE

Visit Info

Finish

Cancel

HISTORY OF PRESENT ILLNESS:  
  
<No encounter information entered>

\* Indicates a Required Field

**Figure A.14. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 3 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

☐ ALLERGIES:  
SULFA-GYN, LORAZEPAM, SULFABENZAMIDE/SULFACETAMIDE/SULFATHIAZOLE, IODINE, LATEX  
TERAZOSIN, DIPHENHYDRAMINE 12.5MG/5ML ELX, TAPE, CHOCOLATE, ORANGE JUICE  
POWDER FREE GLOVES, SEAFOOD, PENICILLIN, PLASTIC TAPE, VASELINE, GOLDENROD  
SKELAXIN 800MG TAB, BUTTER, ACTIVASE, AMOXICILLIN, DOCUSATE/MINERAL OIL, MANGOS  
GREEN BELL PEPPERS, HAIR SPRAY, MILK, LUBRICANT,VAGINAL, SHELLFISH, CURRY  
MAYONNAISE, HONEY BEE STINGS, GREEN TEA, MUSTARD, STRAWBERRIES, SIMVASTATIN  
FOOD DYES, MORPHINE, HEPARIN, APPLE CIDER VINEGAR, ASPIRIN RELATED MEDICATIONS  
IBUPROFEN/PSEUDOEPHEDRINE, BEE STINGS

SOCIAL HISTORY:  
- Alcohol use (history of use, quit dates, current use): \*  
☐ - Tobacco use (history of use, quit dates, current use): \*  
☐ - Recreational drug use (history of use, quit dates, current use): \*  
☐ - Living situation\Functional status:  
\*

OBJECTIVE:  
☐ T: 97.5 F [36.4 C] (11/21/2016 08:58)  
P: 101 (11/21/2016 08:58)  
R: 21 (11/21/2016 08:58)  
BP: 140/90 (12/08/2016 12:20)  
☐ Ht: 60 in [152.4 cm] (11/21/2016 08:58)  
Wt: 150 lb [68.2 kg] (11/21/2016 08:58)  
BMI:29.4

Visit Info

Finish

Cancel

HISTORY OF PRESENT ILLNESS:  

<No encounter information entered>

\* Indicates a Required Field

**Figure A.15. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 4 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

☐ PHYSICAL EXAM

- GENERAL: \*
- HEENT: \*
- CARDIOVASCULAR: \*
- LUNGS: \*
- ABDOMEN: \*
- EXTREMITIES: \*

LABS

CBC:

- Hgb: No Data
- WBC: No Data
- Platelet: No Data

LIVER STUDIES AND CHEMISTRIES:

- CREAT: No Data
- ALK PHOSPHATASE: No Data
- ALT SGPT: No Data
- AST SGOT: No Data
- DIRECT BILIRUBIN: No Data

[Visit Info](#) [Finish](#) [Cancel](#)

HISTORY OF PRESENT ILLNESS:

<No encounter information entered>

\* Indicates a Required Field

**Figure A.16. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 5 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

DIRECT BILIRUBIN: No Data  
TOTAL BILIRUBIN: No Data  
INR: No Data  
ALBUMIN: No Data  
AFP: No Data

HEPATITIS SEROLOGIES/STUDIES:  
HCV antibody: No Data  
HCV RNA PCR: No Data  
HCV genotype: No Data

TOTAL ANTI-HAV: No Data  
HepBsAg: No Data  
HepBsAb: No Data  
HepBcAb: No Data

HIV antibody: No data available  
HIV VL: No Data

Fib-4 Score:   
[FIB-4 Score Calculator \(Use labs noted: ALT, AST, Platelets and Age\)](#)

APRI Score:   
[APRI Score Calculator \(Use labs noted: AST and Platelets\)](#)

☐ Cirrhotic:

CTP Score:  [CTP Score Calculator](#) MELD Score:   
[MELD Score Calculator](#)

IMAGING (please include dates):

☐ Abdominal US:  
SRI2 - Abdominal Ultrasound  
No data available for US ABDOMEN COMPLETE

☐ Fibroscan:

[Visit Info](#) [Finish](#) [Cancel](#)

HISTORY OF PRESENT ILLNESS:

<No encounter information entered>

\* Indicates a Required Field



**Figure A.17. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 6 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

☐ Fibroscan:

LIVER BIOPSY RESULTS:

\*

EGD RESULTS:

\*

ASSESSMENT AND PLAN:

This is a 77-year-old FEMALE with Hepatitis C

GENOTYPE: No Data

FIBROSIS STAGE (METAVIR SCORE):

☐ F0-F3

Visit Info Finish Cancel

HISTORY OF PRESENT ILLNESS:

<No encounter information entered>

\* Indicates a Required Field

**Figure A.18. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 7 of 8)**

Reminder Dialog Template: Hep C clinic SOAP (I & II combined)

FIBROSIS STAGE (METAVIR SCORE):

☐ F0-F3

☐ F4 (cirrhosis) \* ☐ compensated ☐ decompensated

☐ Unknown

PRIOR TREATMENTS:

☐ Treatment-naive.

☐ Treatment-experienced:

MEDICAL DECISION MAKING:

☐ The patient is ready for treatment and the work-up is complete.

☐ The patient is not ready for treatment at the VA.

Vaccinations needed:

☐ Not applicable

☐ Hepatitis A vaccine

☐ Hepatitis B vaccine

For pneumococcal vaccine, use clinical reminders Pneumococcal PPSV 23 (Pneumovax) or Pneumococcal PCV 13 (Prevnar13), if due.

Cirrhosis:

☐ Yes

☐ No

Other recommendations:

\*

Visit Info Finish Cancel

HISTORY OF PRESENT ILLNESS:

<No encounter information entered>

\* Indicates a Required Field

**Figure A.19. Reminder Dialog Template: Hepatitis C Clinic Subjective Objective Assessment Plan (SOAP) (I & II combined) (Image 8 of 8)**

Interval until follow-up:  ... ☐ N/A

Recommended laboratory follow-up while on therapy:

- Week 2: Hepatic panel, CBC (if receiving ribavirin).
- Week 4: HCV RNA, hepatic panel, chem panel, CBC (if receiving ribavirin).
- Week 6: HCV RNA (only if HCV RNA is quantifiable on prior visit); optional: hepatic panel, chem panel, CBC (if receiving ribavirin).
- Week 8: HCV RNA (only if HCV RNA is quantifiable on prior visit), CBC (if receiving ribavirin); optional: hepatic panel, chem panel.
- End of Treatment: optional: HCV RNA, CBC, hepatic panel, chem panel.
- Post-treatment in 3 months: HCV RNA, hepatic panel, chem panel, CBC (if received ribavirin, otherwise, optional).

Discussed with Attending: Dr. \*  .

REFERENCES (display only, not in progress note)

VA Web Links:

- VA Hepatitis website: <http://www.hepatitis.va.gov/>
- VA HCV Treatment considerations: <http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf>

**HISTORY OF PRESENT ILLNESS:**

<No encounter information entered>

\* Indicates a Required Field

APRI Score: <http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>

CTP Score: <http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp>

MELD Score: <http://www.hepatitisc.uw.edu/page/clinical-calculators/meld>

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

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# Appendix B. Clinical Guidelines

The below links are from the Greater Los Angeles VAMC.

Aspartate aminotransferase (AST) to Platelet Ratio Index (APRI) Score:  
<http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>

CTP Score: <http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp>

Model for End-Stage Liver Disease (MELD) Score: <http://www.hepatitisc.uw.edu/page/clinical-calculators/meld>

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

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# Appendix C. Basic Laboratory Panel Definition

- Blood Urea Nitrogen
- Calcium
- Chloride
- CO<sub>2</sub> (Carbon Dioxide, Bicarbonate)
- Creatinine
- Glucose
- Potassium
- Sodium

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# Acronyms

APRI	AST to Platelet Ratio Index
AST	Aspartate Aminotransferase
BMI	Body Mass Index
CDS	Clinical Decision Support
CO2	Carbon Dioxide, Bicarbonate
CT	Computed Tomography
CTP	Child Turcotte Pugh Class
FIB-4	Fibrosis-4
HAVAb	Hepatitis A Antibody
HBcAb	Hepatitis B Core Antibody
HBsAB	Hepatitis B Surface Antibody
HBsAg	Hepatitis B Surface Antigen
HCG	Human Chorionic Gonadotropin
HCV	Hepatitis C Virus
HL7	Health Level 7
INR	International Normalized Ratio
KBS	Knowledge Based Systems
KNART	Knowledge Artifact
MELD	Model for End-Stage Liver Disease
MRI	Magnetic Resonance Imaging
OIIG	Office of Informatics and Information Governance
PADR	Phenolic Acid - Responsive
RNA	Ribonucleic Acid
SME	Subject Matter Expert
SOAP	Subjective Objective Assessment Plan
TO	Task Order
VA	Department of Veteran Affairs
VAMC	VA Medical Center