Hepatitis C Virus: Treatment Selection
Disclosures for Cody Chastain, MD

- No financial disclosures
Objective

At the end of this lecture, the learner will be able to:

- Describe the history of HCV treatment options
- Discuss past and current direct acting antiviral (DAA) therapies for HCV
- Navigate treatment selection for patients with HCV
Caveats

- Focus on treatment selection for genotypes 1, 2, and 3.
  - Majority of US population infected with GT 1, 2, or 3
  - GT 4 is relatively rare in the US and treatment closely reflects GT 1
  - GT 5 and 6 are rare in the US and treatment has relatively little clinical data

- Focus on treatment naïve
  - Majority of patients who present for HCV care reflect this group

- Emphasis on simplified recommendations
  - Most accessible for most non-specialty settings
Case: Brad

- Brad is a 39 y/o man with a medical history of HIV well controlled on abacavir/lamivudine/dolutegravir.
- He started a new job and move to your area.
- He was screened for hepatitis C on intake at your clinic and was found to be antibody positive.
- He has never been evaluated nor treated for HCV.
Case: Brad’s Evaluation

- HCV testing reveals RNA 3,500,000 copies with genotype 1a.

Labs reveal:
- CBC within normal limits (of note, Plt 206)
- CMP within normal limits except AST 54 and ALT 88
- INR 1.0
- HBV sAg negative, cAb positive, sAb positive
- HIV Ab positive, RNA <40

- He undergoes liver ultrasound and elastography.
  - No HCC is noted and elastography is consistent with F2 fibrosis.
Questions

- How has HCV treatment changed in recent years, and how does that impact Brad’s treatment?

- What factors define an appropriate DAA regimen and duration?

- How would his treatment change if his medical history or laboratory studies were different?
Overview

- History of HCV Treatment
- Selecting HCV Treatment
- Genotype 1
- Genotypes 2 and 3
- DAA Failures
- Simplified Guidance
Overview

- History of HCV Treatment
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- Simplified Guidance
History of HCV Treatment: The Bad, The Ugly, and The Good

- Early therapies had poor efficacy and poor tolerability:
  - Interferon (1986)
  - Ribavirin (1998)
  - Pegylated interferon (2001)

- Direct-acting antivirals (DAAs) improved efficacy with additional adverse effects and cost:
  - Telaprevir (2011)
  - Boceprevir (2011)

- New DAAs dramatically improve efficacy with few adverse effects at substantial cost:
  - Simeprevir and Sofosbuvir (2013)
  - Many others since 2014…

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Treatment Response in Direct Acting Antiviral (DAA) Era

- IFN (1986)
- PEG-IFN (2001)
- IFN + RBV (1998)
- P/R (2001)
- TPV/BOC + P/R (2011)
- DAA + P/R (2013)
- DAA +/- RBV (2014)

SVR (%)
# HCV Therapies: The Past, Present, and Future

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FDA Approved HCV Therapies

**Nonspecific Antivirals**
- Interferon (IFN)
- Ribavirin (RBV)
- Pegylated Interferon (PEG-IFN)

**NS3/4 Protease Inhibitors**
- Telaprevir (TPV)
- Boceprevir (BOC)
- Simeprevir (SMV)
- Paritaprevir (PTV)
- Grazoprevir (GZP)
- Voxilaprevir (VOX)
- Glecaprevir (GLE)

**NS5A Inhibitors**
- Ledipasvir (LDV)
- Ombitasvir (OBV)
- Daclatasvir (DCV)
- Elbasvir (EBR)
- Velpatasvir (VEL)
- Pibrentasvir (PIB)

**NS5B Polymerase Inhibitors**
- Sofosbuvir (SOF)
- Dasabuvir (DBV)
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Overview

- History of HCV Treatment
- Selecting HCV Treatment
- Genotype 1
- Genotypes 2 and 3
- DAA Failures
- Simplified Guidance
Primary Factors when Selecting HCV Treatment

- Genotype

- Degree of fibrosis
  - I.e. Non-cirrhotic vs. cirrhotic

- Treatment history
  - I.e. Treatment naïve vs. treatment experienced
  - Recommendations may differ depending on what therapies were used previously (i.e. PEG-IFN vs. DAA-based therapy)
Secondary Factors when Selecting HCV Treatment

- Side effect profile
- Drug-drug interactions
- Pharmacodynamics
- Access
Do Genotypes Matter Any More?

- Historically have been important for predicting prognosis of infection and response to treatment
- More recently have allowed appropriate DAA selection
- Not required for treatment with simplified guidance

Roles?
- Selection of cost-effective therapies
- Prognosis prediction (i.e. worse for GT 3)
- Tool for determining relapse vs. reinfection (in some cases)
- Needed for when selecting certain HCV therapy in setting of cirrhosis
QUESTIONS?
HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

Last Updated: November 2019   |   www.hcvguidelines.org
Overview

- History of HCV Treatment
- Selecting HCV Treatment
- **Genotype 1**
  - Genotypes 2 and 3
  - DAA Failures
- Simplified Guidance
# Recommended Regimens for HCV GT 1 in Treatment Naïve Patients

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Non-Cirrhotic</th>
<th>Comp. Cirrhotic</th>
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<tbody>
<tr>
<td>Ledipasvir/Sofosbuvir</td>
<td>8 Weeks*</td>
<td>12 Weeks</td>
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<tr>
<td>Sofosbuvir/Velpatasvir</td>
<td>12 Weeks</td>
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<tr>
<td>Elbasvir/Grazoprevir</td>
<td>12 Weeks**</td>
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<tr>
<td>Glecaprevir/Pibrentasvir</td>
<td>8 Weeks</td>
<td>8 Weeks***</td>
</tr>
</tbody>
</table>

*12 weeks for HIV coinfected patients OR baseline viral load <6 million
**If GT 1a NS5A polymorphisms detected, consider alternative
***12 weeks for HIV coinfected patients

QUESTIONS?
Overview

- History of HCV Treatment
- Selecting HCV Treatment
- Genotype 1
- Genotypes 2 and 3
- DAA Failures
- Simplified Guidance
## Recommended Regimens for HCV GT 2 & 3 in Treatment Naïve Patients

<table>
<thead>
<tr>
<th>Therapy</th>
<th>GT 2</th>
<th>GT 3</th>
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<tr>
<td>Sofosbuvir/Velpatasvir</td>
<td>12 weeks</td>
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<td>Glecaprevir/Pibrentasvir</td>
<td>8 weeks**</td>
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</tbody>
</table>

* For patients with compensated cirrhosis and Y93H, consider alternative
** 12 weeks for HIV coinfected patients with compensated cirrhosis
QUESTIONS?
Overview

- History of HCV Treatment
- Selecting HCV Treatment
- Genotype 1
- Genotypes 2 and 3
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Treating DAA Failures

- Often most complex patient population
- Resistance may or may not be helpful depending on prior as well as anticipated regimen
- Two approved regimens for retreatment
  - Sofosbuvir/velpatasvir/voxilaprevir
  - Glecaprevir/pibrentasvir
- Consult guidelines, literature, and HCV treatment experts
Overview

- History of HCV Treatment
- Selecting HCV Treatment
- Genotype 1
- Genotypes 2 and 3
- DAA Failures
- Simplified Guidance
Simplified HCV Treatment Algorithm for Treatment-Naive Adults Without Cirrhosis

**WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT**
- Adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment

**WHO IS NOT ELIGIBLE FOR SIMPLIFIED TREATMENT**
- Patients who have any of the following characteristics:
  - Prior hepatitis C treatment
  - Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
  - End-stage renal disease (i.e., eGFR <30 mL/min/m²) (see Patients with Renal Impairment section)
  - HIV or HBsAg positive
  - Current pregnancy
  - Known or suspected hepatocellular carcinoma
  - Prior liver transplantation
## PRETREATMENT ASSESSMENT

- **Calculate FIB-4 score.**
- **Cirrhosis assessment:** Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or any of the following findings from a previously performed test:
  - Transient elastography indicating cirrhosis (e.g., FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (e.g., FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm³, etc)
  - Prior liver biopsy showing cirrhosis
- **Medication reconciliation:** Record current medications, including over-the-counter drugs, and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.

## Pretreatment laboratory testing

**Within 6 months of initiating treatment:**
- Complete blood count (CBC)
- Hepatic function panel (i.e., albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
- Calculated glomerular filtration rate (eGFR)

**Any time prior to starting antiviral therapy:**
- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen

**Before initiating antiviral therapy:**
- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.
### RECOMMENDED REGIMENS*

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Duration</th>
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<tr>
<td>Gilecaprevir (300 mg) / pibrentasvir (120 mg)</td>
<td>8 weeks</td>
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<tr>
<td>Sofosbuvir (400 mg) / velpatasvir (100 mg)</td>
<td>12 weeks</td>
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</table>

* taken with food

### ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.
**POST-TREATMENT ASSESSMENT OF CURE (SVR)**

- Assessment of quantitative HCV RNA and a hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

**FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)**

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (eg, intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Advise patients to avoid excess alcohol use.

**FOLLOW-UP FOR PATIENTS WHO DO NOT ACHIEVE A VIROLOGIC CURE**

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- For patients unable to be retreated, assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Advise patients to avoid excess alcohol use.

*More detailed descriptions of the patient evaluation process and antivirals used for HCV treatment, including the treatment of patients with cirrhosis, can be found at www.hcvguidelines.org. Updated: December 10, 2019 © 2019 American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.*
COMPENSATED CIRRHOSIS
Simplified HCV Treatment Algorithm for Treatment-Naive Adults With Compensated Cirrhosis

WHO IS NOT ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients who have any of the following characteristics:
- Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score ≥7 (ascites, hepatic encephalopathy, total bilirubin >2.0 mg/dL, albumin ≤3.5 g/dL, or INR ≥1.7)
- Prior hepatitis C treatment
- End-stage renal disease (i.e., eGFR <30 mL/min/m²)
  (see Patients with Renal Impairment section)
- HIV or HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation
(See HCV guidance for treatment recommendations for these patients.)

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

- Adults with chronic hepatitis C (any genotype) who have compensated cirrhosis (Child-Pugh A) and have not previously received hepatitis C treatment
- Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or any of the following findings from a previously performed test:
  - Transient elastography indicating cirrhosis (e.g., FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (e.g., FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm², etc)
  - Prior liver biopsy showing cirrhosis
### PRETREATMENT ASSESSMENT

- **Calculate FIB-4 score.**
- **Calculate CTP score:** Patients with a CTP score ≥7 (ie, CTP B or C) have decompensated cirrhosis and this simplified treatment approach is **not** recommended.
- **Ultrasound of the liver** (conducted within the prior 6 months): Evaluate to exclude HCC and subclinical ascites.
- **Medication reconciliation:** Record current medications, including over-the-counter drugs and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.
- **Pretreatment laboratory testing** (see next column)

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<th>Within 3 months of initiating treatment</th>
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<tr>
<td>Complete blood count (CBC)</td>
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<td>International normalized ratio (INR)</td>
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<td>Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])</td>
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**Any time prior to starting antiviral therapy**
- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen
- HCV genotype (if treating with sofosbuvir/velpatasvir)

**Before initiating antiviral therapy**
- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.
### RECOMMENDED REGIMENS*

<table>
<thead>
<tr>
<th>Genotype 1-6:</th>
<th>Glecaprevir (300 mg)/pibrentasvir (120 mg)</th>
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<th>Genotype 1, 2, 4, 5, or 6:</th>
<th>Sofosbuvir (400 mg)/velpatasvir (100 mg)</th>
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**NOTE:** Patients with genotype 3 require baseline NS5A resistance-associated substitution (RAS) testing. Those without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir. If Y93H is present, see HCV guidance for treatment recommendations.

### ON-TREATMENT MONITORING

- Providers may order blood tests to monitor for liver injury during treatment because hepatic decompensation (eg, jaundice, etc) occurs rarely among patients with cirrhosis receiving HCV antiviral treatment.
- Patients should see a specialist if they develop worsening liver blood tests (eg, bilirubin, AST, ALT, etc); jaundice, ascites, or encephalopathy; or new liver-related symptoms.
- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.
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- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

**FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)**

- Ultrasound surveillance for HCC (with or without alpha-fetoprotein testing) every 6 months is recommended for patients with cirrhosis in accordance with AASLD guidance.
- Upper endoscopic surveillance for esophageal varices is recommended in accordance with AASLD guidance on portal hypertensive bleeding in cirrhosis.
- Patients with ongoing risk for HCV infection (e.g., IV drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Patients should abstain from alcohol to avoid progression of liver disease.

**FOLLOW-UP FOR PATIENTS WHO DO NOT ACHIEVE A VIROLOGIC CURE**

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- Ultrasound surveillance for hepatocellular carcinoma (with or without alpha-fetoprotein testing) every 6 months is recommended for patients with cirrhosis, in accordance with AASLD guidance.
- Assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Patients should abstain from alcohol to avoid progression of liver disease.

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Summary

- HCV treatment has transformed over the past several years.
- High efficacy therapies with limited side effects are available for all genotypes.
- Select HCV treatment is based on primary (genotype, stage, treatment experience) and secondary factors.
- Simplified guidance may be sufficient for many patients.
QUESTIONS?