Hepatitis C Virus: Case Studies
Disclosures for Cody Chastain, MD

- No financial disclosures
Objectives

At the end of these case discussions, the learner will be able to:

- Diagnose HCV;
- Appropriately evaluate HCV and comorbid conditions;
- Prescribe HCV therapy;
- Monitor HCV treatment;
- Define appropriate post-treatment monitoring.
Case 1: Alfred

- 58 y/o white man presents to clinic for primary care f/u.
- PMH: Hypertension, diabetes
- Medications: lisinopril, glipizide
- Allergies: NKDA
- Family History: Coronary artery disease, “liver disease”
- Social History: smokes 1 ppd; drinks 2-3 beers on weekends; experimental inhaled drug use (i.e. smoked) in distant past but no intranasal or injection drug use; uninsured
Question #1

What is this patient’s indication for HCV screening per the USPSTF?

A. Age
B. Comorbidities
C. Family history
D. Drug use
E. Sex
Who is at Risk for HCV?

- Injection drug use
- Tattoo/piercing recipients
- Blood/clotting protein recipients prior to 1992
- Mother-to-child transmission from HCV+ mother
- Hemodialysis patients
- People with HIV
- Occupational exposures
- Born between 1945-1965 ("baby boomer" generation)
Case 1: Alfred

- HCV antibody is positive; subsequent RNA testing reveals 850,000 copies/ml. Genotype testing reveals 1a.

- Labs reveal:
  - CBC within normal limits (of note, Plt 178)
  - CMP: within normal limits except AST 85 and ALT 155
  - INR: 1.0
  - HAV IgG positive
  - HBV sAg, cAb, and sAg negative
  - HIV negative
Question #2

What are valid options for staging liver disease?

A. Anatomic ultrasound
B. Abdominal CT scan with triple phase contrast
C. AST-to-Platelet-Ratio Index (APRI)
D. FIB-4 Index
E. Fibrosure® Assay
F. Transient elastography (i.e. Fibroscan®)
G. Liver biopsy
Question #2

- What are valid options for staging liver disease?

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  B. Abdominal CT scan with triple phase contrast
  C. AST-to-Platelet-Ratio Index (APRI)
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  G. Liver biopsy
Notes About Anatomic Imaging

- Anatomic imaging (i.e. ultrasound, CT, MRI) are NOT adequate for staging
  - However, if advanced fibrotic changes are present, they likely correlate with tissue pathology

- Appropriate for hepatocellular carcinoma monitoring

- Reasonable to consider in any patient undergoing HCV evaluation with unknown or suspected advanced fibrosis
Alfred’s Staging

- **APRI = 1.194**
  - Impacted by AST and platelets only
  - Cut off of 1 with sensitivity 76% and specificity 72% for cirrhosis

- **FIB-4 = 2.22**
  - Impacted by age, AST, ALT, and platelets
  - If FIB-4 <1.45, negative predictive value of 90% for advanced fibrosis
  - If FIB-4 >3.25, 97% specificity and positive predictive value 65% for advanced fibrosis

- Transient elastography reveals F2 disease (median kPa 8.5)
Question #3

- Based on available information, what treatment would you select on this patient’s behalf?

GT ?, F2,
Treatment Naïve

A. EBR/GZP x 12 weeks
B. GLE/PIB x 8 weeks
C. GLE/PIB x 12 weeks
D. LDV/SOF x 8 weeks
E. LDV/SOF x 12 weeks
F. SOF/VEL x 12 weeks
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 (eg, FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (eg, FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (eg, 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 (ie, 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**

- **Glecaprevir (300 mg) / pibrentasvir (120 mg)** taken with food for a duration of 8 weeks
- **Sofosbuvir (400 mg) / velpatasvir (100 mg)** for a duration of 12 weeks

**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.
Accessing Treatment

- Insurance Status = Uninsured
- What pathway would be utilized?
- What barriers are anticipated?
Uninsured

- Often easiest group to get approved
- Manufacture PAP process relatively simple
- All require the following:

<table>
<thead>
<tr>
<th>Proof of Income</th>
<th>Proof of residency</th>
<th>Household size</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Tax return</td>
<td>• State-issued ID</td>
<td>• All income from anyone in the house</td>
</tr>
<tr>
<td>• Copy of a disability or Medicare letter</td>
<td>• Letter of residency</td>
<td></td>
</tr>
<tr>
<td>• Social security income statement</td>
<td>• Rehab</td>
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<tr>
<td>• Retirement and/or pension statement</td>
<td>• Housing establishment</td>
<td></td>
</tr>
<tr>
<td>• Pay stub</td>
<td>• Caregiver</td>
<td></td>
</tr>
</tbody>
</table>


Proof of Income

- Letter stating income if no other option is available
- Proof of residency is similar

To Whom It May Concern:

I am writing at the request of the Gilead patient assistance program as a statement of my current income. I was previously employed on a farm for seasonal work. However, the farm has not needed my assistance recently. Since that time I have not been able to find another job and therefore do not have any current income.

I live with my wife’s uncle and do not pay rent at this time. I use food stamps for my meals. Unfortunately I am unable to afford health insurance at this time. I use a Merriweather Lewis discount card for my other medications.

I am approved for the Vanderbilt Charity Program for my doctor’s appointments and would greatly appreciate approval of medication for my HCV infection.

Thank you,
PAP: Gilead

- http://www.mysupportpath.com/

- Eligibility:
  - Applied and denied for Medicaid and state insurance marketplace
  - Ineligible for VA benefits
  - Provide household income and size
Patient signature required
PAP: Abbvie

- Patient Support
- Complete enrollment form
PAP Approved

GILEAD

Support Path Program

PTE: (855) 769-7284
FX: (855) 209-9700

August 15, 2016

Dr. Cody Chastain
Vanderbilt Infectious Disease Clinic
1211 21st Ave S, Ste 102A
Nashville, TN 37232

Re: Patient Assistance Program Enrollment

Service Request Number:

Dear Dr. Cody Chastain:

This letter is regarding your patient. Based on the information provided to the Support Path Patient Assistance Program (PAP), your patient has been prequalified for Harvoni™ (Ledipasvir 90mg/Sofosbuvir 400mg). Your patient’s prequalified period is for 30 days from the date of this letter.

The decision to provide your patient with free drug is contingent upon receiving the completed prescription form for Harvoni™. If we do not receive the completed prescription form before the end of the 30-day period, your patient’s eligibility will end. If the patient still needs assistance from the program after the 30-day prequalified period has passed, a new application must be submitted for evaluation.

Please complete the prescription request form on the following page and fax it to US Bioservices at 855-840-2954. Once a valid prescription form is received, a pharmacy representative will contact the shipment contact noted on the prescription form to set up shipment.

Please do not hesitate to contact the Support Path Program at 855-769-7284, Monday through Friday between 9:00AM and 5:00PM Eastern Time, with any questions.

Sincerely,

Support Path Program
PAP Medication Delivery

- Prescription faxed to clinic for provider signature
  - Select delivery to provider or patient
- Pharmacy calls patient for delivery information
- Pharmacy calls monthly for prescription refill
Case 1: Alfred

- Alfred is started on an appropriate DAA regimen.
- He has mild fatigue and intermittent headaches easily managed with over-the-counter therapies.
- CMP with LFTS at week 4 within normal limits.
- He completes therapy and achieves SVR12.
- Does he need further care?
After Sustained Virologic Response ≥12 Weeks After Therapy

Counseling
- HCV antibody will remain positive lifelong
- Reinfection is possible
- Future testing will require HCV RNA PCR or similar test

Need for Follow-Up
- F0-2 = “As if they were never infected”
- F3-4
  - HCC screening with ultrasound every 6 months, CT abdomen with triple phase contrast annually, or MRI abdomen with contrast annually
  - GI/Hepatology referral for endoscopy
QUESTIONS?
Case 2: Carl

- 35 y/o white man referred for HCV evaluation and treatment.
- Recently diagnosed at rehab program.
- PMH: Bipolar disorder, Polysubstance use
- Medications: Oxcarbazepine, Buprenorphine
- Allergies: Sulfur (hives)
- Family History: coronary artery disease, hypertension
- Social History: smokes 1 ppd; drinks 6 beers per day; active injection drug use within past 3 months (heroin)
HCV testing reveals RNA 3,750,000 copies with genotype 1a.

Physical exam notable for multiple tattoos and evidence of prior IDU in bilateral antecubital fossa.

Labs reveal:
- CBC reveals Hgb 11, Hct 33, and Plt 434
- CMP: within normal limits except Cre 0.8, AST 75, and ALT 85
- INR: 1.0
- HBV serology consistent with prior immunization
- HIV serology negative

He undergoes anatomic liver ultrasound, and no HCC is noted.

ARFI as well as FIB-4 are consistent with F0-F1 fibrosis.
Question #4

Based on available information, what treatment would you select on this patient’s behalf?

GT1A, F0-F1, Treatment Naive

A. EBR/GZP x 12 weeks
B. GLE/PIB x 8 weeks
C. GLE/PIB x 12 weeks
D. LDV/SOF x 8 weeks
E. LDF/SOF x 12 weeks
F. SOF/VEL x 12 weeks
Welcome to HCVGuidelines.org

The AASLD and IDSA in partnership with the panel have created an updated web experience to facilitate easier and faster access to this important resource. Please select a patient profile from the menu above, click on a guidance section below, or use the search box to begin.

- Contents and Introduction - Select a Page
- Testing, Evaluation, and Monitoring of Hepatitis C - Browse Topics
- Initial Treatment of HCV Infection - Choose Patient Genotype
- Retreatment of Persons in Whom Prior Therapy Has Failed - Choose Patient Genotype
HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

New and updated:
Updated Testing Recommendations
Review new HCV screening guidance from the AASLD and IDSA.

Search the Guidance
Enter your keywords

Recent Announcements

AIDS Education & Training Center Project
## Treatment-Naive Genotype 1a Without Cirrhosis

Recommended regimens listed by evidence level and alphabetically for:

**Treatment-Naive Genotype 1a Patients Without Cirrhosis**

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>DURATION</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) for patients with baseline NSSA RASs for elbasvir(^a)</td>
<td>12 weeks</td>
<td>I, A</td>
</tr>
<tr>
<td>Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)(^b)</td>
<td>8 weeks</td>
<td>I, A</td>
</tr>
<tr>
<td>Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg)</td>
<td>12 weeks</td>
<td>I, A</td>
</tr>
<tr>
<td>Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) for patients who are HIV-uninfected and whose HCV RNA level is &lt;6 million IU/mL</td>
<td>8 weeks</td>
<td>I, B</td>
</tr>
<tr>
<td>Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)</td>
<td>12 weeks</td>
<td>I, A</td>
</tr>
</tbody>
</table>

\(^a\) Includes genotype 1a resistance-associated substitutions (RASs) at amino acid positions 28, 30, 31, or 93 known to confer antiviral resistance. If 1 or more RASs are present, another recommended regimen should be used.

\(^b\) Dosage is 3 coformulated tablets (glecaprevir 100 mg)/pibrentasvir 40 mg) taken once daily. Please refer to the prescribing information.
Question #5

What medication is likely to result in drug interactions with HCV DAA therapy?

A. Buprenorphine  
B. Oxcarbazepine  
C. Both  
D. Neither
P-gp Interaction Considerations

- All HCV direct acting antiviral agents are substrates of the drug transporter p-gp.

<table>
<thead>
<tr>
<th>P-gp Inducers Contraindicated</th>
<th>P-gp Inhibitors Contraindicated vs. Redose vs. Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiepileptics: Carbamazepine; oxcarbazepine, phenobarbitol, phenytoin</td>
<td>Azole antifungals</td>
</tr>
<tr>
<td>Rifamycins</td>
<td>Verapamil</td>
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<tr>
<td>St. John’s wort</td>
<td>HIV protease inhibitors</td>
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<tr>
<td>Modafanil, armodafanil</td>
<td>Amiodarone</td>
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<td></td>
<td>Cyclosporine</td>
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</tbody>
</table>
HOW DOES ALCOHOL AND SUBSTANCE USE FACTOR INTO HCV TREATMENT?
HCV and Alcohol Use

- Alcohol may contribute to liver disease independently of HCV
- Treatment of HCV may or may not mitigate progressive liver disease due to alcohol use
- Alcohol use is not a contraindication for HCV treatment
- Alcohol use may be considered a reason for denial by payers
- Patients should be counseled to abstain from alcohol use to eliminate impact on liver disease.
- Providers should use discretion when weighing risks/benefits of HCV therapy in these settings.
HCV and Substance Use

- Substance use is unlikely to contribute to liver disease independent of HCV.

- Substance use (including injection drug use) is not a contraindication for HCV treatment.

- Substance use may be considered a reason for denial by payers.

- Patients should be counseled to abstain from drug use for general health.

- Abstinence and/or engagement in rehab may be required by payers.
The Insured

- Rx provided
- PA completion
- Steps following a denial

Prior Authorization and Appeals

Copay/Financial Assistance
- Rx approved
- Finding and implementing assistance

On-Treatment Considerations
- Ensuring access
- Avoiding lapse in treatment
Accessing Treatment

- Insurance Status = Private Insurance

- What pathway would be utilized?
- What barriers are anticipated?
The Insured

- Rx provided
- PA completion
- Steps following a denial

Prior Authorization and Appeals

Copay/Financial Assistance

- Rx approved
- Finding and implementing assistance

On-Treatment Considerations

- Ensuring access
- Avoiding lapse in treatment
Prior Authorization

**Paper Option**
- Obtain PA application
- Call insurance company or obtain forms online
- TennCare: TennCare.Magellanhealth.com
  - Prescriber → Prior Authorization Forms
- Complete PA paperwork
- Gather supporting materials
- Fax

**Electronic Option**
- Covermymeds.com
  - All paperwork completed online

**Phone Option**
- Primarily used for PA extension
Approved...Now what?

- Pharmacy should run a test claim
  - Ensure approval
  - Determine copay

- Determine if patient qualifies copay assistance
  - Medicaid: does not qualify for assistance → copay $0-$3
  - Medicare: obtain foundation assistance → contact patient
    - Pharmacy should do this
  - Commercial: obtain copay card if patient copay is >$10
    - Pharmacy should do this
## Copay Cards: Gilead SupportPath

<table>
<thead>
<tr>
<th>Drug</th>
<th>Patient Cost</th>
<th>Copay Card Information</th>
<th>Card Details</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvoni®</td>
<td>$5</td>
<td><a href="https://www.harvoni.com/support-and-savings/co-pay-coupon-registration">https://www.harvoni.com/support-and-savings/co-pay-coupon-registration</a></td>
<td>-Max of 25% of the catalog price of a 12-week regimen</td>
<td>-Resident of US, PR, or US territories</td>
</tr>
<tr>
<td>Sovaldi®</td>
<td>$5</td>
<td><a href="https://www.sovaldi.com/coupons/">https://www.sovaldi.com/coupons/</a></td>
<td>-Valid for 6 months from 1st redemption</td>
<td>-No state or federally funded programs</td>
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<tr>
<td>Epclusa</td>
<td>$5</td>
<td><a href="http://www.epclusainfo.com/support-and-savings/co-pay-coupon-registration">http://www.epclusainfo.com/support-and-savings/co-pay-coupon-registration</a></td>
<td></td>
<td>-≥18 years old</td>
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<tr>
<td>Vosevi</td>
<td>$5</td>
<td><a href="https://www.vosevi.com/co-pay-coupon-registration">https://www.vosevi.com/co-pay-coupon-registration</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorized Generics SOF/VEL LDV/SOF</td>
<td>$5</td>
<td><a href="https://qv.trialcard.com/Asegua#/app/layout/home">https://qv.trialcard.com/Asegua#/app/layout/home</a></td>
<td>Contact: 1-855-769-7284</td>
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## Copay Cards: Abbvie ProCeed

<table>
<thead>
<tr>
<th>Drug</th>
<th>Patient Cost</th>
<th>Copay Card Information</th>
<th>Card Details</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mavyret®</td>
<td>$5</td>
<td><a href="https://www.mavyret.com/">https://www.mavyret.com/</a></td>
<td>-Max of 25% of the catalog price&lt;br&gt;-Valid for 12 uses&lt;br&gt;-Expires 12 months from 1st redemption</td>
<td>-Resident of US&lt;br&gt;-No state or federally funded programs&lt;br&gt;-Not valid in Massachusetts</td>
</tr>
</tbody>
</table>
Grant Funding

- Complete grant funding application
  - Yearly household income
  - Household size
  - Retired
  - File taxes
  - Submit application online
<table>
<thead>
<tr>
<th>Grant</th>
<th>Patient Cost</th>
<th>Information</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Access Network Foundation (PANF)</td>
<td>$0</td>
<td><a href="https://pharmacyportal.panfoundation.org">https://pharmacyportal.panfoundation.org</a></td>
<td>-$7,000 per year. Patient may apply for second grant during eligibility period</td>
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<td>-US resident</td>
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<td>-Income at or below 500% of FPL</td>
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<td>-Must have health insurance</td>
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<tr>
<td>Contact: 1-866-316-7263</td>
<td></td>
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</tr>
<tr>
<td>Patient Advocate Foundation (PAF)</td>
<td>$0</td>
<td><a href="https://www.copays.org/diseases/hepatitis-c">https://www.copays.org/diseases/hepatitis-c</a></td>
<td>-Max $15,000 per year</td>
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<td>-US resident</td>
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<td>-Income below 400% FPL</td>
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<td>-Must have health insurance</td>
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<tr>
<td>Contact: 1-866-512-3861</td>
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</tr>
<tr>
<td>Chronic Disease Fund (CDF)</td>
<td>Minimum copay based on income</td>
<td><a href="https://www.mygooddays.org/patients/diseases-covered/hepatitis-c">https://www.mygooddays.org/patients/diseases-covered/hepatitis-c</a></td>
<td>-Max $15,000</td>
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<td>-Valid Social Security number</td>
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<td>-Income at or below 500% FPL</td>
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<td></td>
<td>-Medicare or Military insurance coverage</td>
</tr>
<tr>
<td>Contact: 1-972-608-7141</td>
<td></td>
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</tr>
<tr>
<td>Healthwell Foundation</td>
<td>$0</td>
<td><a href="https://www.healthwellfoundation.org/fund/hepatitis-c/">https://www.healthwellfoundation.org/fund/hepatitis-c/</a></td>
<td>-Max $30,000</td>
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<td>-Receive treatment in US</td>
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<td></td>
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<td>-Income at or below 500% FPL</td>
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<tr>
<td></td>
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<td>-Must have health insurance</td>
</tr>
<tr>
<td>Contact: 1-800-675-8416</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Assistance Fund</td>
<td>$0 or $10 based on income</td>
<td><a href="http://www.tafcares.org">http://www.tafcares.org</a></td>
<td>-No clear income requirements (must submit income and household size)</td>
</tr>
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<td></td>
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<td>-US resident</td>
</tr>
<tr>
<td></td>
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<td>-Must have health insurance</td>
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<tr>
<td>Contact: 1-855-845-3663</td>
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</tbody>
</table>
Provider Support: Gilead Support Path

- Benefits investigation
- Prior Authorization and appeals information
- Patient Assistance Program (PAP) eligibility screening
- https://www.mysupportpath.com/providers
- 1-855-7-MYPATH (1-855-769-7284)
Provider Support: Gilead Support Path

Help Along the Way
Support Path is ready to assist patients along the way toward treatment completion

- Educational resources, support for adherence, and progress tracking
- A 24/7 help line with nurses on call to provide answers and assistance
- Ongoing support for access and reimbursement, including help with refill authorizations

Complete the intake form now to enroll and access the full range of resources or call 1-855-7-MYPATH (1-855-769-7284) to learn more about resources that are available to help patients along the way toward treatment completion.
Provider Support: Mavyret Patient Support

- Prior authorization support
- Appeals support
- Co-pay assistance
- Patient assistance program
- https://www.mavyret.com/hcp/patient-support
- 1-877-MAVYRET (1-877-628-9738)
Provider Support

- **Abbvie Nurse Ambassador**
  - Assist with navigating financial information
  - Assigned nurse throughout treatment
  - Call for adherence monitoring
  - Appointment reminder
Merck: The Merck Access Program

- Benefits investigation
- PA/Appeal
  - Obtain the appropriate form and send to office
- Financial assistance after approval
- https://www.merckaccessprogram.com/hcp/
Other Access Resources

- National Viral Hepatitis Roundtable
  - NVHR.org/hepatitis-c-treatment-access

- American Liver Foundation

- Life Beyond Hepatitis C
Case 2: Carl Conclusion

- Carl is approved for HCV therapy and is successfully treated.
QUESTIONS?
Case 3: Evie

- 25 y/o black woman referred for HCV evaluation and treatment.
- Recently diagnosed after high risk pregnancy screening.
- PMH: Polysubstance use in remission
- Medications: None
- Allergies: NKDA
- Family History: adopted
- Social History: smokes 1/2 ppd; does not drink alcohol; prior cocaine use, including injection drug use, none in >1 year s/p rehabilitation
Case 3: Evie

- HCV testing reveals RNA 15,000,000 copies with genotype 3.
- Physical exam unremarkable
- Labs reveal:
  - CBC reveals Hgb 12, Hct 36, and Plt 375
  - CMP: within normal limits except Cre 0.8, AST 95, and ALT 185
  - INR: 1.0
  - HBV serology consistent with prior infection (cAb positive, sAb positive)
  - HIV serology negative
- She undergoes transient elastography which is consistent with F0-F1 fibrosis.
Question #6

- Is she a candidate for HCV DAA therapy due to her HBV status?
  
  A. Yes  
  B. No  
  C. You tell me!
## HBV Diagnosis

<table>
<thead>
<tr>
<th>State</th>
<th>sAg</th>
<th>cAb</th>
<th>sAb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naive</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Immune due to Immunization</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>“Immune” due to Natural Infection</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Chronic Infection</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Multiple Options:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Occult Infection</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>- Lost sAb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Window period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- False positive</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Hepatitis B Virus Reactivation Associated With Direct-Acting Antiviral Therapy for Chronic Hepatitis C Virus: A Review of Cases Reported to the U.S. Food and Drug Administration Adverse Event Reporting System

Susan J. Bersoff-Matcha, MD; Kelly Cao, PharmD; Mihaela Jason, PharmD; Adebola Ajao, PhD; S. Christopher Jones, PharmD, MS, MPH; Tamra Meyer, PhD, MPH; and Allen Brinker, MD, MS

Published June 6, 2017
Case Series

- 29 cases reported from 11/2013 – 10/2016
  - 13 occurred in patients with positive sAg
  - 4 occurred in patients with negative sAg
  - 12 occurred with unknown baseline sAg status

- 2 deaths and 1 liver transplant

- Resulted in boxed warning with all DAA therapies
Hepatitis B virus reactivation during direct-acting antiviral therapy for hepatitis C: a systematic review and meta-analysis

Marcus M Mücke, MD, Lisa I Backus, MD, Victoria T Mücke, MD, Nicola Coppola, MD, Carmen M Preda, MD, Ming-Lun Yeh, MD, Lydia S Y Tang, MBChB, Pamela S Belperio, PharmD, Eleanor M Wilson, MD, Prof Ming-Lung Yu, MD, Prof Stefan Zeuzem, MD, Prof Eva Herrmann, PhD, Johannes Vermehren, MD

Published: 19 January 2018
Meta-Analysis

- 17 observational trials

- 1621 patients treated with DAAs for HCV
  - 242 with chronic HBV (i.e. sAg positive)
  - 1379 with resolved HBV (i.e. cAb positive)

- HBV reactivation rates variable
  - 24% among patients with chronic HBV
  - 1.4% among patients with resolved HBV

- Clinically significant events variable
  - 9% of chronic HBV patients with HBV-reactivation-related hepatitis
    - More common among those with measureable HBV DNA at baseline
    - 1 liver decompensation, 2 with liver failure (one requiring liver transplant)
  - No clinically significant events among those with resolved HBV infection
Approaching HCV In Setting of HBV

- Treat chronic HBV based on guideline recommendations

- Do not withhold HCV therapy if HBV not treated but monitor closely

- Consider treatment of chronic HBV prior to or during HCV therapy, particularly among those with measurable HBV DNA

- Consider closer monitoring of HBV and associated liver disease in those with resolved HBV infection while on DAA therapy
Question #8

Based on available information, what treatment would you select on this patient’s behalf?

GT3, F0-F1, Treatment Naïve

A. EBR/GZP x 12 weeks
B. GLE/PIB x 8 weeks
C. GLE/PIB x 12 weeks
D. LDV/SOF x 8 weeks
E. LDF/SOF x 12 weeks
F. SOF/VEL x 12 weeks
### Treatment-Naive Genotype 3 Patients Without Cirrhosis

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>DURATION</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)</td>
<td>8 weeks</td>
<td>I, A</td>
</tr>
<tr>
<td>Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)</td>
<td>12 weeks</td>
<td>I, A</td>
</tr>
</tbody>
</table>
Accessing Treatment

- Insurance Status = TennCare
- What pathway would be utilized?
- What barriers are anticipated?
Prior Authorization

- What to include:
  1. PA application provided
  2. Genotype and viral load
  3. Staging: FIB-4 score, ultrasound, CT, etc.
  4. Clinical notes
  5. Ancillary items requested by certain PBMs
     - Resistance testing (elbasvir/grazoprevir)
     - Urine drug screen in some cases
     - Rehab documentation
     - Follow-up if no response in 5 days
What if PA is Denied?

1. Call the PBM and ask about rejection.
   - Why was it rejected?
   - Is there a preferred agent?
   - What are the next steps (appeal, peer-to-peer review, external review, etc.)

2. Write appeal letter

3. Fax back appeal, original PA paperwork, and any supporting documentation (AASLD/IDSA Guidelines, clinical trial data, drug interaction analysis, etc.)
Appeal Letter

- Reason for request
- Reason for denial
- Rationale to address each reason for denial, including relevant clinical rationale where applicable
- Relevant overall patient medical history and current condition
- Summary of your professional opinion of likely outcomes with the treatment
- Restatement of request for approval

*Adapted from Abbvie Letter of Medical Necessity Template*
Appeal Supporting Documents

- Any required appeal form from the insurer (if applicable)
- Copy of the denial letter from the insurance company
- Copy of the prescription
- Patient’s signature on consent form for treatment
- Patient’s complete medication profile including patient’s current, previous and discontinued medications
- Patient’s medical profile
- Relevant lab results, diagnostics, pathology reports, including illicit drug screening results
- Relevant treatment guidelines
- Relevant peer-reviewed journal articles
- Relevant clinical trial information
- Relevant cost information (if known)
Appeal Support

Template Letters of Appeal

Harvoni

Harvoni

Harvoni

NVHR.org/hepatitis-c-treatment-access
Appeal Support

- Mavyret® Medical Exception Request
  https://www.mavyret.com/hcp/medical-exception-resource
QUESTIONS?