From Prescription to Patient: Navigating Barriers to HCV Treatment Initiation

Autumn Bagwell, PharmD, BCPS, AAHIVP
Vanderbilt Specialty Pharmacy
Objectives

At the end of this presentation, the learner should be able to:

- Describe the financial impact of HCV treatment on the healthcare system.
- Identify current restrictions to HCV treatment common among third party payers
- Illustrate successful navigation through the prior authorization and appeal process
- Review criteria and options for patient assistance programs (PAP)
- Discuss ancillary financial and treatment assistance available
Disclosure

*No financial disclosures.
*No manufacturer or medication preference or disclosures.
Outline

- The problem:
  - HCV treatment financial burden

- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance

- The possibilities:
  - Manufacturer patient support
  - HCV treatment access resources
Outline

- The problem:
  - HCV treatment financial burden

- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance

- The possibilities:
  - Manufacturer patient support
  - HCV treatment access resources
Cost of HCV Treatment

Average Wholesale Price (AWP) of 12 week treatment

Pegasys® + RBV* $37,550
Sovaldi® + RBV $84,550
Sovaldi® + Olysio® $150,360
Harvoni® $94,500
Viekira Pak® $83,319
Technivie® Daklinza® + Sovaldi® $147,000
Zepatier® $76,653
Epclusa® $54,600

*Cost for 48 weeks

AETC Southeast
Cost of HCV Treatment: Medicaid

- $1.3 billion spent on Sovaldi during CY2014 (prior to rebates)
  - = <2.4% of Medicaid recipients nationwide thought to be infected with HCV
- Sovaldi was among the top 5 pharmaceutical spending items for 33 different states
  - Number 1 for 14 states
Cost of HCV Treatment: Medicare and BOP

- In 2014, $4.8 billion on HCV drugs
- In 2014, $5.9 million on HCV drugs (183 HCV inmates)
The same pill that costs $1,000 in the U.S. sells for $4 in India
Cost related to chronic HCV Infection

Younossi Z, Henry L. The impact of the new antiviral regimens on patient reported outcomes and health economics of patients with chronic hepatitis C. Dig Liver Dis. 2014;46 Suppl 5:S186-96.
Compared treatment of all fibrosis stages vs. stages ≥F3 and by specific fibrosis stage

Cost-effective when treatment is initiated at any stage of fibrosis ($50,000 per Quality-adjusted life-years (QALYs) gained)

Treating earlier results in a substantial decrease in net cost

Outline

- The problem:
  - HCV treatment financial burden

- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance

- The possibilities:
  - Manufacturer patient support
  - HCV treatment access resources
Patient Case 1: Marsha

- Baby boomer female
- Genotype 1a
- Stage F0 per ultrasound with elastography
- HCV treatment naïve
- Private insurance contracted with Express Scripts
Patient Case 2: Bill

- Young male
- Genotype 1a
- Treatment naïve
- Cirrhosis on ultrasound with elastography
- Household income: $21,000 for family of 3
- TennCare insurance
The Insured

Prior Authorization and Appeals
- PA completion
- Steps following a denial

Copay/Financial Assistance
- Finding assistance
- Implementing assistance

On-Treatment Considerations
- Avoiding lapse in treatment
- Insurance changes
Prior Authorization

- Paper Option:
  1. Obtain PA application
     - Call insurance company or obtain forms online
     - TennCare: TennCare.MagellanHealth.com
       - Prescriber → Prior Authorization Forms
  2. Complete PA paperwork
  3. Gather supporting materials
  4. Fax to insurance

- Electronic Option:
  - CovermyMeds.com
    - All paperwork completed online

- Phone Option
  - Primarily used for PA extension
Cover My Meds
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 (Zepatier®)
     - Urine drug screen
     - Rehab documentation

- Follow-up if no response in 5 days
PATIENT CASE 1: MARSHA
Cover My Meds Application

Prescriber Next Steps

Smart Rules

Is the patient 18 years of age or older? Yes: Yes, No: No.

Will the patient be using Harvoni in combination with any other DAAIs (direct acting antivirals) such as Daklinza, Incivek, Victrelis, Olysio, Sovaldi, Technivie, Viekira Pak, Zepatier) (not including ribavirin)? Yes: Yes, No: No.

Is the request for retreatment in patients who have previously received Harvoni? Please Note: This includes retreatment in prior null responders, prior partial responders, prior relapse patients, patients who have not completed a course of therapy due to an adverse reaction or for other reasons. Yes: Yes, No: No.

Is the patient’s life expectancy less than 12 months due to non liver related comorbidities? Yes: Yes, No: No.

Does the patient have recurrent HCV post-liver transplantation (Genotypes 1 and 4)? Yes: Yes, No: No.

Has the patient been started on Harvoni? Yes: Yes, No: No.

Is Harvoni prescribed by, or in consultation with, one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician? Yes: Yes, No: No.

Will Harvoni be prescribed in combination with ribavirin? Yes: Yes, No: No.

Does the patient have chronic hepatitis C? Yes: Yes, No: No.

Has the patient been previously treated for HCV? Yes: Yes, No: No.

Is the requested medication prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician? Yes: Yes, No: No.

What is the patient’s chronic HCV genotype? Chronic Hepatitis C (CHC) genotype 1: Chronic Hepatitis C (CHC) genotype 2: Chronic Hepatitis C (CHC) genotype 3: Chronic Hepatitis C (CHC) genotype 4: Chronic Hepatitis C (CHC) genotype 5:

Chronic Hepatitis C (CHC) genotype 6:

Other diagnoses:

Does the patient have Child-Pugh Class B (to indicate moderate hepatic impairment) or Child-Pugh Class C (to indicate severe hepatic impairment) liver disease? Yes: Yes, No: No.

Is the patient treatment naive? Please Note: Treatment-naive includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy they have not been treated for HCV. Treatment-naive also includes patients who have not started HCV therapy and have never previously been treated for HCV. Yes: Yes, No: No.

Does the patient have cirrhosis? Yes: Yes, No: No.

Does the patient have HIV? Yes: Yes, No: No.

Is the patient awaiting liver transplantation? Yes: Yes, No: No.

Is the patient’s baseline HCV RNA less than 6 million IU/mL? Yes: Yes, No: No.

Has the patient been previously treated for HCV? Yes: Yes, No: No.

Does the patient have fibrosis? Yes: Yes, No: No.

Does the patient have compensated (Child-Pugh A) cirrhosis or decompensated (Child-Pugh B or C) cirrhosis? Compensated (Child-Pugh A): Decompensated (Child-Pugh B or C): Will Harvoni be prescribed in combination with ribavirin? Yes: Yes, No: No.

What is the patient’s chronic HCV genotype? Chronic Hepatitis C (CHC) genotype 1: Chronic Hepatitis C (CHC) genotype 2: Chronic Hepatitis C (CHC) genotype 3: Chronic Hepatitis C (CHC) genotype 4: Chronic Hepatitis C (CHC) genotype 5: Chronic Hepatitis C (CHC) genotype 6: Other diagnoses:

Is the patient treatment naive? Please Note: Treatment-naive includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy they have not been treated for HCV. Treatment-naive also includes patients who have not started HCV therapy and have never previously been treated for HCV. Yes: Yes, No: No.
Cover My Meds Application

Has the patient been previously treated for HCV?:
- Yes:
- No:

Does the patient have compensated (Child-Pugh A) cirrhosis?:
- Yes:
- No:

Does the patient have cirrhosis?:
- Yes:
- No:

Does the patient have HIV?:
- Yes:
- No:

Is the patient awaiting liver transplantation?:
- Yes:
- No:

Is the patient’s baseline HCV RNA less than 6 million IU/mL?:
- Yes:
- No:

How many weeks of Harvoni have been dispensed to the patient?:
- 4 weeks:
- 8 weeks or more:

Document upload
Upload any supporting documentation below. Must be .jpg, .pdf, or .tif file format:
PATIENT CASE 2: BILL
**Prior Authorization Form**

**Epclusa®**

**Access this PA form at:** [https://tenncare.massifhealth.com/Secure/PriorAuthorizationForm/TenCare_Epclusa_PA_Request_Form.pdf](https://tenncare.massifhealth.com/Secure/PriorAuthorizationForm/TenCare_Epclusa_PA_Request_Form.pdf)

---

**1. What is the diagnosis and duration of therapy for which this drug is being requested?**

- [ ] Chronic Hepatitis C, genotype 1
- [ ] Chronic Hepatitis C, genotype 2
- [ ] Chronic Hepatitis C, genotype 3
- [ ] Chronic Hepatitis C, genotype 4
- [ ] Chronic Hepatitis C, genotype 5
- [ ] Chronic Hepatitis C, genotype 6
- [ ] Other: ______________________

Requested duration of therapy: ______________________

---

**2. Does the patient have decompensated cirrhosis, defined as a Child-Pugh score of greater than 6 (Class B or C)?**

- [ ] Yes
- [ ] No

---

**3. Does the patient have a diagnosis of compensated cirrhosis?**

- [ ] Yes
- [ ] No

---

**4. Is the patient post liver transplant?**

- [ ] Yes
- [ ] No

---

**5. Please check if the patient has any of the following: if yes, documentation must be attached.**

- [ ] Liver biopsy showing Metavir score of F2-F4
- [ ] Fibroscan (Fibrotest) score of > 0.49
- [ ] Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa
- [ ] Fibrotest-4 index (FIB-4) > 1.45
- [ ] Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5

---

**Note:** None of the above or not otherwise specified, provide staging: F3-F4 fibrosis on US with cirrhotic changes.

---

**6. Please check the box corresponding to the specialty of the prescribing physician:**

- [ ] Gastroenterologist
- [ ] Hepatologist
- [ ] Infectious Disease Specialist
- [ ] Other: ______________________

**Instructs to the Provider:** Please refer to the note if the patient is not a single patient contract holder for this benefit.

---

**Summary of Criteria for Approval**

- Requestor must be a physician with experience in the treatment of Hepatitis C infection (e.g., infectious disease, gastroenterologist, or hepatologist).
- Must be prescribed and requested by a provider with a Tennessee Medicaid Provider ID.
- Documentation must be attached showing disease severity.
- Daily dose of one tablet per day.
- Chronic Hepatitis C, Genotype 1, 2, 3, 4, 5 or 6.
- Usual per FDA package insert.

**Summary of Criteria for Denial**

- Patient has severe renal failure or ESRD.
- Patient has actively participated in illicit substance or alcohol abuse within the past 6 months.
- Daily dose of greater than one tablet per day.
- Off-label usage.

---

**Clinical Laboratory Documentation**

- Complete chart and attach documentation of lab values.

**Laboratory Documentation**

<table>
<thead>
<tr>
<th>Test</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HCV RNA level</td>
<td>115.971 Hu/mL</td>
</tr>
<tr>
<td>Week 4 HCV RNA level</td>
<td></td>
</tr>
<tr>
<td>Week 12 HCV RNA level</td>
<td></td>
</tr>
</tbody>
</table>
15. Yes, what is the reason:

The patient is no prior medication that would impact with Velpatasvir plus Sofosbuvir/ and risk for Gould increase. 6. Did the prior medicine (AP class 60) Exposure has significant efficacy with decreased injury risk over within 1200 mg (560 mg
bleb of 99% plus) with change in FIB4V1 as 4000 x 10 (phi) with additional for example.

16. For prior medicine 6 8 does the patient have a relapse? [ ] Yes  [ ] No

If yes, what is the reason:

________________________________________

Please note any other information pertinent to this PA request: Patient with sars and cirrhosis.

Egular is a superior option as the baseline preferred agent as it is less toxic (not having severe MIP in cirrhosis) and has been approved in clinical trials (99% cure) and a shorter treatment duration (8.8 vs. 48)

Additionally, patient would be off all prior medications that have been

Please note: if approved, compliance with therapy is required. Authorization will be terminated for patients who are non-compliant with therapy.

Patient Signature Required

(For patients the physician authorizes PA when completion a month are warranted by written consent)

Fax this form to 669-916-5552

Mail request to TermCare Pharmacy Program

AIDS Education & Training Center Program

1118 Virginia Street, Suite 400

VIRGINIA BEACH, VA 23462

Phone: 833-659-3541

Healthcare providers will be notified within 24 hours upon receipt.

__________________________ 1-11-17

Date
Patient Case 1: Marsha
APPROVED!

Document and monitor dates of approval.
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>][1]</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>][2]</td>
<td>-Valid for 6 months from 1st redemption</td>
<td>-No state or federally funded programs</td>
</tr>
</tbody>
</table>

Contact: 1-855-769-7284
## 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>Viekira XR®</td>
<td>$5</td>
<td><a href="https://www.viekira.com/patient-support/financial-resources">https://www.viekira.com/patient-support/financial-resources</a></td>
<td>-Max of 25% of the catalog price</td>
<td>-Resident of US</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-Valid for 12 uses</td>
<td>-No state or federally funded programs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-Expires 12 months from 1st redemption</td>
<td>-Not valid in Massachusetts</td>
</tr>
<tr>
<td>Viekira Pak®</td>
<td>$5</td>
<td><a href="https://www.viekira.com/content/pdf/viekira-treatment.pdf">https://www.viekira.com/content/pdf/viekira-treatment.pdf</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technivie®</td>
<td>$5</td>
<td><a href="https://www.viekira.com/content/pdf/viekira-treatment.pdf">https://www.viekira.com/content/pdf/viekira-treatment.pdf</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Contact:**
1-844-277-6233
### Daklinza®

**Patient Cost:** $0  
**Copay Card Information:** [https://bmsdm.secure.force.com/patientsupportconnect/patient](https://bmsdm.secure.force.com/patientsupportconnect/patient)  
**Contact:** 1-844-442-6663  
**Card Details:**  
- Max of $5,000 per 28-day supply of 30mg or 60mg tablets OR up to max of $10,000 per 28-day supply of 90mg  
- Must activate before 12/31/16  
- Program expires 12/31/17 (except in Mass. 6/30/17)  
**Eligibility:**  
- Resident of US or Puerto Rico  
- No state or federally funded programs  
- ≥18 years old
## Copay Cards: Merck

<table>
<thead>
<tr>
<th>Drug</th>
<th>Patient Cost</th>
<th>Copay Card Information</th>
<th>Card Details</th>
<th>Eligibility</th>
</tr>
</thead>
</table>
| Zepatier®| $5           | [https://www.merckaccessprogram-zepatier.com/hcp/copay-assistance/](https://www.merckaccessprogram-zepatier.com/hcp/copay-assistance/) | -Max of 25% of the catalog price per prescription  
-Program expires 6/30/17 | -Resident of US or Puerto Rico  
-No state or federally funded programs  
-≥18 years old |
## Copay Cards: Janssen CarePath

<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>Olysio®</td>
<td>$5</td>
<td><a href="https://olysio.janssencarepathsavings.com/Coupon/Olysio">https://olysio.janssencarepathsavings.com/Coupon/Olysio</a></td>
<td>-Max of $50,000 per calendar year</td>
<td>-Resident of US or Puerto Rico</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-855-565-9746</td>
<td>-Program expires 12/31/17</td>
<td>-No state or federally funded programs</td>
</tr>
</tbody>
</table>
Grant Funding

- Complete grant funding application
  - Yearly household income
  - Household size
  - Retired
  - File taxes
  - Submit application online
# Grant Funding

<table>
<thead>
<tr>
<th>Grant</th>
<th>Patient Cost</th>
<th>Information</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Access Network Foundation (PANF)</strong></td>
<td>$0</td>
<td><a href="https://pharmacyportal.panfoundation.org/Home.aspx">https://pharmacyportal.panfoundation.org/Home.aspx</a></td>
<td>- Max of $30,000/year</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-866-316-7263</td>
<td>- Reside in US</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Income below 400% or 500% FPL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Any insurance</td>
</tr>
<tr>
<td><strong>Patient Advocate Foundation (PAF)</strong></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 of $25,000/year</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-866-3861</td>
<td>- Reside in US</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Income below 400% FPL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Any insurance</td>
</tr>
<tr>
<td><strong>Chronic Disease Fund (CDF)</strong></td>
<td>Based on poverty percentage- up to $50</td>
<td><a href="http://www.mygooddays.org/for-patients/patient-assistance/">http://www.mygooddays.org/for-patients/patient-assistance/</a></td>
<td>- Max of $30,000/year</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-972-608-7141</td>
<td>- Reside in US</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Any insurance, must pay at least 50% of copay</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Income below 500% FPL</td>
</tr>
<tr>
<td><strong>Healthwell Foundation</strong></td>
<td>$5/fill</td>
<td><a href="https://www.healthwellfoundation.org/fund/hepatitis-c/">https://www.healthwellfoundation.org/fund/hepatitis-c/</a></td>
<td>- Max of $30,000/year</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-800-675-8416</td>
<td>- Reside in US</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Any insurance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Income below 500% FPL</td>
</tr>
</tbody>
</table>
BACK TO CASES
Patient Case 2: Bill

**Notice of Prior Authorization Determination**

Megellan Health Services has reviewed a request for coverage of a prescription medication under the TennCare Pharmacy Program. The outcome of our review, requesting provider, recipient medication and pharmacy are listed below. Blank fields indicate information we were unable to determine from our records or the request.

<table>
<thead>
<tr>
<th>PATIENT INFORMATION:</th>
<th>MEDICATION INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID Number: 342972548932</td>
<td>Name: EPCLUSA</td>
</tr>
<tr>
<td>First Name:</td>
<td>Strength: 400-100MG</td>
</tr>
<tr>
<td>Last Name:</td>
<td>Dosage Form: TABLET</td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEDICAL PROVIDER:</th>
<th>PHARMACY PROVIDER:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: CODY CHASTAIN</td>
<td>Name:</td>
</tr>
<tr>
<td>Address 1: 1211 21ST AVE S</td>
<td>Address 1:</td>
</tr>
<tr>
<td>Address 2: STE 102A</td>
<td>Address 2:</td>
</tr>
<tr>
<td>City State Zip: NASHVILLE, TN 372122700</td>
<td>City State Zip:</td>
</tr>
</tbody>
</table>

**OUTCOME OF CLINICAL REVIEW OF REQUEST 2014629**

Prior Authorization Status: Denied
Date of Review: 10/03/2015
Prior Authorization Begin Date: 10/07/2015
Prior Authorization End Date: 10/07/2015

**IMPORTANT:**

Pharmacy updates and Preferred Drug List changes can be found at http://tenncare.megallanhealth.com. Please mark this site as a "favorite" and use it to help answer pharmacy benefit questions for TennCare Members.
Denied- Now What?

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 Elements

- 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
Gilead sample Letter of Medical Necessity
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)

*From Abbvie Letter of Medical Necessity Template*
Bill Appeal

- Relevant medical history
- Reason for denial
- Summary as to why she should be approved
- Guideline recommendations and support
Bill Appeal

- Clinical trial and other relevant data for recommended treatment
- Summary statement: why treat now, why this regimen, potential benefit(s) for patient
- List inclusions
- References

---

has completed the requirements of TennCare to meet approval by providing proof of addiction counseling. Delaying his access to treatment at this time could result in significant adverse outcomes including hepatic decompensation.

was prescribed velpatasvir/sofosbuvir over the other AASLD/IDSA Guidelines recommended regimens for the following reasons. Elbasvir/glecaprevir would require additional testing for NS5A resistance which is not clinically necessary at this time. Velpatasvir/sofosbuvir had an SVR12 rate of 99% (n=120/122) in cirrhotics in the ASTRAL-1 trial. Rates of SVR12 were lower with the use of dasabuvir/paritaprevir/ritonavir/ombitasvir plus ribavirin for 24 weeks in the TURQUOISE-II trial at 95%.

In summary, it is recommended that Mr. HCV be treated now without further delay in his care to avoid additional potential costs associated with worsening liver function and development of HCC. Treatment with velpatasvir/sofosbuvir has been prescribed and is recommended by the AASLD/IDSA Guidelines over the TennCare-preferred agent for multiple reasons including a higher rate of SVR12 in clinical trials without the unnecessary burden of adding ribavirin and extending treatment to 6 months. This regimen has a substantially lower pill burden and risk for serious adverse effects related to both ribavirin and dasabuvir/paritaprevir/ritonavir/ombitasvir in this patient with cirrhosis. Mr. meets criteria for approval based on TennCare requirements given that he has advanced liver disease and has completed addiction counseling, evidenced by his certificate from the Recover Community, Inc. I appreciate your review of this request. Please contact me as needed.

Sincerely,

[Signature]

Cody Chastain, MD
Infectious Diseases Specialty
CASE 2: BILL APPROVED!
On-Treatment Considerations

- PA continuation requirements
  - 4 week viral load
- PA extension
  - Starting later than expected
  - On treatment viral load detectable
- Insurance changes
- Refills
  - Encourage the patient to call 7-10 days before running out
- Emergency shipments
  - Insurance
  - Manufacturer
Outline

- The problem:
  - HCV treatment financial burden
- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance
- The possibilities:
  - Manufacturer patient support
  - HCV treatment access resources
The Un-Insured and Under-Insured

Patient Assistance Programs (PAP)
- Criteria for approval
- Process of Application

Medication Delivery
- Setting up the first fill
- Patient Support on therapy
Underinsured

- PA denied → Appeal denied → sent to Legal Solutions Hearing → denied

- Apply for Patient Assistance Programs (PAP)
  - Coverage in the insured varies by manufacturer
  - Denied → Exception Committee
    - Discuss this option with a supervisor at the PAP
Uninsured

- 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>
<td></td>
</tr>
<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

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

- Eligibility:
  - Applied and denied for Medicaid and state insurance marketplace
  - Ineligible for VA benefits
  - Provide household income and size
### Patient Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td></td>
</tr>
<tr>
<td>Patient’s Preferred Language</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Zip Code</td>
<td></td>
</tr>
<tr>
<td>Phone #</td>
<td></td>
</tr>
<tr>
<td>SS &amp; DOB</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Resides in U.S. territory</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Alternate Contact Name</td>
<td></td>
</tr>
<tr>
<td>Phone #</td>
<td></td>
</tr>
<tr>
<td>Relationship</td>
<td></td>
</tr>
</tbody>
</table>

I authorize support staff to leave a message, including the prescription name, if I am unavailable when they call.

- Yes
- No

### Insurance Information

**Primary Insurance**

- [ ] Is this a Medicare Part D plan?

**Policy Holder**

- Policy Holder Name
- Policy Holder Relationship to Patient
- Policy Issuer
- Policy #
- Group #
- Rx Bin #
- Rx FCH #

Check here if patient has secondary insurance coverage and has a copy of insurance cards, if available.

**Additional Insurance Information**

- Has the patient applied for Medicaid?
  - [ ] Yes
  - [ ] No
  - If Yes, date of application

- Is the patient eligible for Medicaid?
  - [ ] Yes
  - [ ] No
  - If No, data reason

- Is the patient eligible for VA benefits?
  - [ ] Yes
  - [ ] No
  - If Yes, has the patient tried to obtain the medication through the VA?
    - [ ] Yes
    - [ ] No

- Has the patient applied for insurance plan offered through state insurance marketplace (also known as an exchange)?
  - [ ] Yes
  - [ ] No
  - If Yes, date of application

- Is the patient eligible for an insurance plan offered through the state insurance marketplace (also known as an exchange)?
  - [ ] Yes
  - [ ] No
  - If No, data reason

### Patient Financial Information

- [ ] Current Annual Household Income

- [ ] Number of People in Household

Please submit current documentation local sources of income (e.g., tax return, W2, 1099s, etc.), bank account and other income data, (e.g., social security, utilities bill, house, rent statement, etc.).

**Applicant Declarations and Authorizations (Required Only If Applying for the PAP)**

I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program services will terminate if any fraud or if the information is no longer current. I certify that the application does not exceed that which would qualify for patient assistance. I will receive a prescription from my pharmacist through the PAP, I certify that I will not seek reimbursement or credit for the prescription from any insurer, health plan, or governmental program. If I am a member of a Medicare Part D plan, I will not seek to have this prescription or any associated costs charged or paid by my plan.

I understand that the PAP reserves the right to refuse the application form, may revoke or discontinue the program, or terminate assistance at any time and without notice. I understand the PAP and its administrator is required to forward any prescription to a dispensing pharmacy on my behalf.

### Patient Signature

- [ ] Patient signature if applying for PAP

**Date:**

Patient signature required.
PAP: Abbvie Viekira Pak®

- https://www.viekirahcp.com/proceed
- Case-by-case basis:
  - Financial hardship
  - Lack of insurance coverage
  - Medical necessity
PAP: Abbvie Viekira XR®

- [https://www.viekira.com/hcp/access-and-support-resources](https://www.viekira.com/hcp/access-and-support-resources)
- **Eligibility:**
  - Provide income and household size
  - <$100,000 per year
PAP: Merck

- http://www.merckhelps.com/ZEPATIER
- Eligibility:
  - US resident
  - No insurance or an exception based on case
  - Household income
    - $59,400 for one
    - $80,100 for a couple
    - $121,500 for family of 4
PAP: BMS

- http://www.bmspaf.org/Pages/Home.aspx
- Eligibility:
  - US resident
  - No insurance or 2 appeals denied by insurance or Medicare Part D and ≥3% household income spent on prescriptions costs/year
  - Household income below 300% of FPL
    - $35,640 for one
    - $48,060 for a couple
BACK TO PATIENT CASE 2: BILL
WHAT IF HE HAD BEEN DENIED?
Bill

- Gilead Exception Committee
  - Reviews appeals on case-by-case basis
  - Include:
    - Original PA/appeal/denial information
    - Additional letter of medical necessity
    - List of medications and how they are obtained

The appeal letter is attached. In summary, this patient was denied treatment by TennCare as she does not have F3 or greater fibrosis. As multiple studies have shown, treating patients with early fibrosis both can prevent complications and is cost-effective in addition to the public health benefits.

is of child-bearing age. Unfortunately, the CDC recently released an MMWR regarding the drastic increase in HCV among women of childbearing age and vertical transmission (attached). Treating her HCV at this time would eliminate vertical and household transmission risk.

Additionally, is coinfected with HIV, increasing her risk of hepatic complications, decompensation, and HCC (detailed in appeal).

was denied by TennCare three times, a process which took five months to complete. The reason for her denial citing that her disease was not yet advanced enough to require treatment. This type of restriction is not based on clinical evidence or guidelines and has been reprimanded by CMS (see attached notice). However, TennCare refuses to change their laws at this time.

Unfortunately, obtaining medication through Gilead is this patient’s last hope at treatment. We believe that treatment at this time is most appropriate given the above concerns. We greatly appreciate your review of this request and would gladly discuss her case further if needed. Thank you!

Best,

Autumn Bagwell, PharmD, BCPS
Bill

APPROVED!

Support Path Program

August 15, 2016

Dr. Cody Chastain
Vanderbilt Infectious Disease Clinic
1211 21st Ave S, Bldg 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 855-850-2954. 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 8:00PM 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
Outline

- The problem:
  - HCV treatment financial burden
- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance
- The possibilities:
  - HCV treatment access resources
  - Manufacturer patient support
Provider Support: Gilead SupportPath

**Gilead SupportPath iAssist**

<table>
<thead>
<tr>
<th>ePrescription Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Submit an ePrescription</td>
</tr>
<tr>
<td>• Confirm patient’s insurance</td>
</tr>
<tr>
<td>• Complete and submit a PA</td>
</tr>
<tr>
<td>• Send all information directly to a pharmacy</td>
</tr>
<tr>
<td>• Register for the patient education program</td>
</tr>
<tr>
<td>• Enroll a patient for copay coupon</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ePA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Send an online PA without an ePrescription</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Support Path Assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Benefits investigation and summary of benefits</td>
</tr>
<tr>
<td>• Comprehensive PA support</td>
</tr>
<tr>
<td>• Support for claims appeals and denials</td>
</tr>
<tr>
<td>• Access to Support Path representatives who work on patient’s behalf</td>
</tr>
</tbody>
</table>
Provider Support: Abbvie ProCeed

- Benefits Verification
- PA/Appeal
  - Obtain the appropriate form
  - Track the PA
- Triage prescription to the pharmacy
Provider Support: Merck Access Program

- Benefits investigation
- PA/Appeal
  - Obtain the appropriate form and send to office
- Financial assistance after approval
Provider Support: BMS
Patient Support CONNECT

- Benefits investigation
  - 24 hour turnaround
- PA/Appeal
  - Obtain the appropriate form and send to office
  - Tracks PA and appeal
- Clinical trials data support
- Financial assistance after approval
Other Access Resources

- National Viral Hepatitis Roundtable
  - NVHR.org/hepatitis-c-treatment-access
- Hepatitis C New Drug Research
- American Liver Foundation
  - http://hepc.liverfoundation.org/resources/what-if-i-need-financial-assistance-to-pay-for-treatment/
- Life Beyond Hepatitis C
Outline

- The problem:
  - HCV treatment financial burden

- The players:
  - Patients with prescription insurance
  - Patients without prescription insurance

- The possibilities:
  - HCV treatment access resources
  - Manufacturer patient support
Patient Support through Manufacturers

- Abbvie Nurse Connector
  - Assist with navigating financial information
  - Assigned nurse throughout treatment
  - Call for adherence monitoring
  - Appointment reminder
Patient Support through Manufacturers

- Gilead
  - Educational resources, support for adherence, and progress tracking
  - 24/7 help line with nurses on call
  - Ongoing support for access and reimbursement
  - Intake form:
    http://www.mysupportpath.com/~media/Files/mysupportpath_com/Support_Path_Intake_Form.pdf
Summary

- Though costly, the price of HCV treatment should not limit prescribing of these medications.
- Complete documentation and supplementary support can improve PA approval rates.
- Do not give up after initial PA denial!
- Uninsured patients with low income are the MOST likely to get approved for treatment.
- Manufacturer support is available to assist prescribers and their staff.
Thank you!

Questions?

Autumn.D.Bagwell@Vanderbilt.edu
615-936-6353