From Prescription to Patient: Navigating Barriers to HCV Treatment Initiation

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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
  - Access on the horizon
Outline

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Cost of HCV Treatment

*Average Wholesale Price (AWP) of 12 week treatment

- Pegasys® + RBV: $37,550
- Sovaldi® + RBV: $84,550
- Sovaldi® + Olysio®: $94,500
- Harvoni®: $150,360
- Viekira Pak®: $83,319
- Technivie®: $76,653
- Daklinza® + Sovaldi®: $147,000
- Zepatier®: $54,600
- Epclusa®: $74,760
- Vosevi®: $74,760
- Mavyret®: $36,400

*Cost for 48 weeks

^Cost for 8 weeks
Cost related to chronic HCV Infection

- Non-cirrhotic liver disease: $17,277
- Compensated cirrhosis: $22,752
- End stage liver disease: $59,995
- Hepatocellular carcinoma: $112,537
- Liver transplant: $145,000

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.
Genotype 1: ICERs from $0 to $31,452 per QALY gained

Limitations

- Newer agents
- Analyzed using WAC pricing

“..actual current cost of HCV DAAs, competition and negotiated pricing…continue to limit the public health impact of these new therapies”

“To be clear, this section is informational. As explained below, **actual costs are rarely known.** Accordingly, the HCV Guidance **does not utilize cost-effectiveness analysis to guide recommendations at this time.**
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
  - Access on the horizon
Patient Case 1: Jaime Lannister

- Baby boomer male
- Genotype 1a
- Stage F0 per ultrasound with elastography
- HCV treatment naïve
- HIV coinfection
- Private insurance contracted with Express Scripts
Patient Case 2: Jon Snow

- Baby boomer male
- Genotype 1a
- Treatment naïve
- F4 per fibrosure; F2-F3 per US with elastography
- Binge drinker with multiple rehab visits
- Household income: $21,000 for family of 3
- Tenncare insurance
The Insured

- PA completion
- Steps following a denial

Prior Authorization and Appeals

- Finding assistance
- Implementing assistance

Copay/Financial Assistance

- Avoiding lapse in treatment
- Insurance changes

On-Treatment Considerations
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

Dashboard

Logged in as Autumn Bagwell

Current
0 requests

Sent to Plan
0 requests

Search

Start a Prior Authorization Request

- Don't worry – your request won't be sent to the plan until you are ready to print and fax it.
- Feel free to create a fake request – you can delete it at any time.
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
     - Rehab documentation
- Follow-up if no response in 5 days
PATIENT CASE 1: JAIME LANNISTER
Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll free number listed below. Upon receipt of the completed form, benefit coverage will be determined based on the plans rules.

**SECTION A Please answer the following questions.**

**Please note:** For completion of all reviews documentation MUST be provided to confirm the patient’s genotype.

1. **Yes** **No** Is the indication genotype 1 or genotype 4 hepatitis C virus? **(Yes,** please specify below)**
   - **Genotype 1**
   - **Genotype 4**

2. **Yes** **No** Will the patient be using Harvoni in combination with any other DAA’s (direct acting antivirals such as Vosevi, Invok, Olyx, Sovaldi, Viekira Pak) (not including ribavirin)?

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

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

5. **Yes** **No** Does the patient have chronic hepatitis C and HCC (hepatocellular carcinoma) and is awaiting liver transplant?

If “Yes” to question 5 please answer questions 6-8 if the request is for a new start
OR 9-16 if the request is for a continuation of therapy

**If “No” to question 5 proceed to question 11.

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

7. **Yes** **No** Is the patient treatment naïve? **Please Note:** Treatment-naïve 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-naïve also includes patients who have not started HCV therapy and have never previously been treated for HCV.

8. **Yes** **No** Does the patient have cirrhosis?

9. **Yes** **No** How many weeks of Harvoni has the patient received? **Please list:_____ Weeks**

10. **Yes** **No** Has the patient been previously treated for HCV?

11. **Yes** **No** Does the patient have recurrent HCV post-liver transplantation?

Continued on Page 2

continued from page 1

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

13. **Yes** **No** Is the patient treatment naïve for recurrent HCV? **Please Note:** Treatment-naïve 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-naïve also includes patients who have not started HCV therapy and have never previously been treated for HCV.

14. **Yes** **No** Does the patient have cirrhosis?

15. **Yes** **No** How many weeks of Harvoni has the patient received? **Please list:_____ Weeks**

16. **Yes** **No** Has the patient been previously treated for their recurrent HCV?

17. **Yes** **No** Does the patient have chronic hepatitis C?

If “Yes” to question 17 please answer questions 18-24 if the request is for a new start
OR 25-31 if the request is for a continuation of therapy

18. **Yes** **No** Is Harvoni prescribed by, or in consultation with, one of the following prescribers: gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician?

19. **Yes** **No** Does the patient have advanced fibrosis?

20. **Yes** **No** Is the patient treatment naïve? **Please Note:** Treatment-naïve 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-naïve also includes patients who have not started HCV therapy and have never previously been treated for HCV.

21. **Yes** **No** Does the patient have cirrhosis?

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

23. **Yes** **No** Has the patient been previously treated with a Sofosbuvir-containing regimen (note: this does not include Harvoni)?

24. **Yes** **No** Has the patient been previously treated for HCV with PR [ Pegylated interferon (Pegasys, Peg-Interon) and ribavirin] with or without a protease inhibitor for HCV (such as Occulix, Vocalli, or Olys)

25. **Yes** **No** How many weeks of Harvoni has the patient received? **Please list:_____ Weeks**

Continued on Page 3
PRIOR AUTHORIZATION REQUEST

Harvoni

PATIENT
Name & DOB: 
Address: 

O: Name - Conn Chastain
Address 111 2nd Ave South, Seattle, WA 98101
Phone/Fax: 

Continued from Page 2

Please document the diagnoses, symptoms, and/or any other information important to this review:

Patient with GT1a HCV, complicated by HIV coinfection, placing him at high risk for fibrosis progression. Harvoni is compatible with HIV ART.

SECTION B
Physician Signature

[Signature]

PHYSICIAN SIGNATURE
DATE

9-9-16

FAX COMPLETED FORM TO: 1 877-329-3760

This fax is barcoded for this specific patient; do NOT re-use for other patients

If you have any questions regarding your patient's plan drug limits you may call us at: 800-753-2351

Page 3 of 3
PATIENT CASE 2: JON SNOW
Prior Authorization Form

Member Information

LAST NAME: ___________________________ FIRST NAME: ___________________________

ID NUMBER: ___________________________ DATE OF BIRTH: _____-____-____

Prescriber Information

LAST NAME: Greene

FIRST NAME: Matthew

NPI NUMBER: ___________________________

CEA NUMBER: ___________________________

PHONE NUMBER: _______________________

FAX NUMBER: ___________________________

Is the prescriber a Tenncare provider with a Medicaid ID? [ ] Yes [ ] No
Is the prescriber a single-patient contract holder for this patient? [ ] Yes [ ] No

INSTRUCTIONS TO THE PROVIDER — Please note the following criteria for approval and for denial of sobriety:

Summary of Criteria for Approval
- Requestor must be a physician specialist 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
- Usage 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

For additional details, please refer to the clinical criteria available at https://tenncare.medicaihealth.com

Clinical Criteria Documentation
- ***Do not include documentation that is not requested on this form***
- ***Complete Chart and attach documentation of lab values***

<table>
<thead>
<tr>
<th>Laboratory Documentation</th>
<th>Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HCV RNA level</td>
<td>2875352 IU/ml</td>
<td>11/01/2017</td>
</tr>
<tr>
<td>Week 4 HCV RNA level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 12 HCV RNA level</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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: 12 weeks

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
   - Fibrotest (FibroSure) score of ≥ 0.45
   - Ultrasound-based transient elastography (Fibroscan) score ≥ 7.1 kPa
   - Fibro-4 index (FIB-4) > 1.45
   - Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5
   - None of the above or not otherwise specified, provide noting: ____________________

6. Please check the box corresponding to the specialty of the prescribing physician:
   - Gastroenterologist
   - Hepatologist
   - Infectious Disease Specialist
   - Other: ____________________

7. Does the patient have a past history of illicit substance or alcohol abuse? (If no, skip to #11)
   - If yes, attach confirmation that the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of Chronic Hepatitis C treatment
   - Yes
   - No

8. Has the patient been free of substance abuse for the previous 6 months?
   - Yes
   - No

9. Has the patient been free of alcohol abuse for the previous 6 months?
   - Yes
   - No

10. For females: Is the member currently pregnant?
    - Yes
    - No

11. Is the patient’s Creatinine clearance greater than 30 ml/minute?
    - Yes
    - No

12. Does the patient have End-stage renal disease?
    - Yes
    - No

13. Will the patient be taking in combination with ribavirin?
    - Yes
    - No

14. For genotype 1 and 4, does the patient have a reason they cannot take the preferred agent?
    - Yes
    - No
Prior Authorization Form

15. If yes, what is the reason:

Viura is no longer recommended in GT1a with cirrhosis.

16. For genotypes 5 and 6, does the patient have a reason they cannot take ledipasvir/sofosbuvir?
   - Yes □ No □
   - If yes, what is the reason:

Please note any other information pertinent to this PA request:

Patient with GT1a HCV and cirrhosis who is naive to treatment. He recently completed alcohol rehab (records attached) and currently lives in a recovery home. He does not use illicit drugs.

Please Note: If approved, compliance with therapy is required. Authorizations will be terminated for patients who are noncompliant with therapy.

[Date]

(B) Medical Signature (required)

Fax this form to: 866-434-5523

Mail requests to: TennCare Pharmacy Program
 c/o Magellan Health Services
 5th Floor South, 1400 Magellan Plaza
  Maryland Heights, MO 63043
  Phone: 866-434-5524

Magellan Health Services will provide a response within 24 hours upon receipt.
Patient Case 1: JL
APPROVED!

Dr. CODY CHASTAIN
1211 21ST AVES
STE 102 A
NASHVILLE, TN 37232

Case ID:

Patient: JL
Patent DOB:
Plan Name: EXPRESS SCRIPTS MEDICARE
Plan ID (EBP Code): 114

Date of Request: 09/14/2016 03:13PM
Date of Decision: 09/15/2016

September 15, 2016

Dear Dr. CHASTAIN:

We have reviewed a request to obtain Harvoni Tablet under your patient’s Medicare prescription drug plan. As we informed your patient, this request has been approved from 09/15/2016 until 12/08/2016.

If you have any questions, please call us at 1.800.535.6103, 24 hours a day, 7 days a week (including holidays). (TTY users should call 1.800.715.3231.)

Sincerely,
Coverage Review Department
Express Scripts
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></td>
<td></td>
<td></td>
<td>-Valid for 6 months from 1&lt;sup&gt;st&lt;/sup&gt; redemption</td>
<td>-No state or federally funded programs</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></td>
<td>-≥18 years old</td>
</tr>
<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></td>
</tr>
<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>
</tbody>
</table>

Contact: 1-855-769-7284
## Copay Cards: Abbvie ProCeed

<table>
<thead>
<tr>
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<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>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>-Valid for 12 uses</td>
<td>-No state or federally funded programs</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>-Expires 12 months from 1st redemption</td>
<td>-Not valid in Massachusetts</td>
</tr>
<tr>
<td>Mavyret®</td>
<td>$5</td>
<td><a href="https://www.mavyret.com/">https://www.mavyret.com/</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-877-628-9738</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Copay Cards: Bristol-Myers Squibb Patient Support CONNECT

<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>
| Daklinza® | $0           | [https://bmsdm.secure.force.com/patientsupportconnect/patient](https://bmsdm.secure.force.com/patientsupportconnect/patient) | -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 | -Resident of US or Puerto Rico  
|          |              | **Contact:** 1-844-442-6663 |              | -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 | -Resident of US or Puerto Rico  
- No state or federally funded programs  
- ≥18 years old |
# Copay Cards: Janssen CarePath

<table>
<thead>
<tr>
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<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>
</table>
| Patient Access Network Foundation (PANF)   | $0           | https://pharmacyportal.panfoundation.org/Home.aspx | - Max of $30,000/year  
- Reside in US  
- Income below 400% or 500% FPL  
- Any insurance |
| Patient Advocate Foundation (PAF)          | $0           | https://www.copays.org/diseases/hepatitis-c | - Max of $25,000/year  
- Reside in US  
- Income below 400% FPL  
- Any insurance |
| Chronic Disease Fund (CDF)                 | Based on poverty percentage- up to $50 | http://www.mygooddays.org/for-patients/patient-assistance/ | - Max of $30,000/year  
- Reside in US  
- Any insurance, must pay at least 50% of copay  
- Income below 500% FPL |
| Healthwell Foundation                      | $5/fill      | https://www.healthwellfoundation.org/fund/hepatitis-c/ | - Max of $30,000/year  
- Reside in US  
- Any insurance  
- Income below 500% FPL |
Patient Case 2: Jon

Notice of Prior Authorization Determination

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

**PATIENT INFORMATION:**

<table>
<thead>
<tr>
<th>ID Number:</th>
<th>Name:</th>
<th>MEDICATION INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td>Name: MAVYRET</td>
<td>Strength: 100MG-40MG</td>
</tr>
<tr>
<td>Last Name:</td>
<td>Dosage Form: TABLET</td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MEDICAL PROVIDER:**

| Name: MATTHEW GREENE | |
| Address 1: | Address 1: |
| Address 2: | Address 2: |
| City State Zip: | City State Zip: |

**PHARMACY PROVIDER:**

| Name: | |
| Address 1: | |
| Address 2: | |
| City State Zip: | |

**OUTCOME OF CLINICAL REVIEW OF REQUEST**

Prior Authorization Status: Denied
Prior Authorization Begin Date: 11/10/2017
Prior Authorization End Date: 11/10/2017

Date of Review: 11/11/2017

The patient does not meet the criteria for approval of this medication. The request has been denied to allow pursuit of the appeal process. The patient will receive an official denial letter, complete with instructions regarding the appeal process, if applicable. You may initiate the appeal by calling 1-800-878-3192.

Pharmacy updates and Preferred Drug List changes can be found at http://tenncare.magellanhealth.com. Please mark this site as a 'favorite' and use it to help answer pharmacy benefit questions for TennCare Members.

**IMPORTANT:**

Magellan Health Services contracts with TennCare to provide prior authorization services. All prior authorization determinations are based on the information submitted with the request as reviewed in light of Clinical Criteria approved by TennCare. Prior authorization is not a guarantee of payment. Final payment status is determined by Magellan Health Services and is affected by the patient's current eligibility status with TennCare. If you have any questions or would like to discuss this request with a clinical pharmacist, please call (866)434-5523. Send return fax documents to (866)434-5524. This fax is intended solely for the use of the listed medical and/or pharmacy provider and may contain confidential and/or privileged information. The unauthorized use, reproduction or distribution of this information may subject user to civil and/or criminal penalties. If you are not the intended recipient, please contact the sender at (866)434-5524, and destroy any and all copies of the original fax. Thank you.
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*
Appeal Support

- Mavyret® Medical Exception Request

MEDICAL EXCEPTION TEMPLATE

We have created an online Medical Exception Resource for your use.

As you navigate through the Medical Exception Resource, please make selections based on your clinical judgment for your specific patient. Based on your selections, the tool will generate pre-populated information consistent with the approved U.S. full Prescribing Information. The Medical Exception Resource also provides 2 unique functions. You may:

1) Copy to Clipboard: This functionality allows you to copy, then fully edit and transfer the pre-populated information to your own EMR or medical exception form.

and/or

2) Create full-form letter. This functionality contains additional fields for you to complete, based on your clinical judgment, and creates a full-form letter.

Step 1: My patient...

- has mild, moderate, or severe renal insufficiency
- has experienced direct-acting antiviral (DAA) failure
- is currently being treated with concomitant proton-pump inhibitors
- has intolerance for ribavirin (RBV)
- has HIV coinfection
- would benefit from a shortened treatment duration

Step 2: GENERATE MEDICAL EXCEPTION INFORMATION BASED ON YOUR CHOICES

Date: 2017-09-07
Payer Name:
Payer Address:
AL
Payer Fax Number:
Attn:
Re: Coverage of MAVYRET (glecaprevir/pibrentasvir)
Patient Name:
Patient Date of Birth:
Patient Member ID:
To whom it may concern,

I am writing to request approval of MAVYRET (glecaprevir/pibrentasvir) to treat my patient. This product was denied on the following reason(s):

- is a year-old who has been diagnosed with chronic HCV infection
- was diagnosed with chronic HCV infection on...medical history includes...

Approval is being requested for MAVYRET (glecaprevir/pibrentasvir) based on my clinical opinion of the following clinical evidence and rationale:

Clinical Considerations: Concomitant PPI Use

Step 4: GENERATE LETTER PDF
PATIENT CASE 2: JON APPEAL
Jon Appeal

Division of Infectious Diseases, Vanderbilt University Medical Center
1211 21st Ave. South
Medial Arts Building, Suite 102A
Nashville, TN 37232
Phone: 615-936-1174 Fax: 615-343-1103

November 15th, 2017

RE: Appeal for glecaprevir/pibrentasvir (Maviret®)

To Whom It May Concern:

I am contacting you on behalf of my patient Mr. ___ (DOB ___, Member ID # ___, Case ID # ___). He has been prescribed a 12 week course of dual acting antiviral therapy containing glecaprevir/pibrentasvir (Maviret®) for his hepatitis C (HCV) infection. He has a history of HCV infection (ICD 10: B18.2), genotype 1a with compensated cirrhosis as evidenced by a CT in October 19th, 2006, and more recent fibrosis score of 0.84 by Fibrosure testing on 11/1/17. Additionally, an abdominal ultrasound with elastography revealed F2-F3 fibrosis on 11/6/17. He is naïve to previous HCV treatment and has evidence of active viremia as shown by his viral load of 2,875,352 IU/mL on 11/1/17. He was recently denied HCV treatment, with no specified rationale other than “does not meet the criteria for approval.” Given Mr. ___’s advanced disease, he is at high risk for hepatocellular carcinoma and hepatic decompensation which could require transplant and therefore should be treated at this time. He has completed alcohol rehab 1 month ago and currently lives in a recovery home. He has abstained from alcohol use since completion of rehab. Denial of treatment in this patient with advanced disease due to a history of alcohol abuse places him at high risk for hepatic decompensation. This type of restriction is in direct opposition to CMS guidance (attached) and the Social Security Act and is not applied to other disease states.
The AASLD/IDSA Hepatitis C Treatment Guidelines recommend patients with chronic HCV infection abstain from alcohol and drug use, but do not exclude these patients from being considered for treatment, specifically stating “Data are lacking to support exclusion of HCV-infected persons from considerations for hepatitis C therapy based on the amount of alcohol intake or the use of illicit drugs. Based on data from IFN-based treatment, SVR rates among people who inject drugs are comparable to those among people who do not inject drugs.” On the contrary, they recommend treatment for patients with ongoing drug and alcohol use, highlighting the benefit of treating this patient population:

“There are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy. These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy. Scale up of HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the United States and globally.”

These guidelines can be viewed in their entirety at https://www.hcvguidelines.org and recommend treatment for all patients with chronic HCV infection, except those with short life expectancies. The goal of treatment is to “reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma.” Prior to the update in October 2015, the guidelines panel classified patients with compensated cirrhosis (F4) as highest priority to treat owing to “highest risk of severe complications.” Mr. ____ does not have a short life expectancy and could greatly benefit from treatment to reduce all-cause mortality including the development of HCC and need for liver transplant.

Furthermore, in November 2015, CMS issued guidance to states regarding coverage for medications used to treat HCV infection addressing these types of restrictions. CMS advised in accordance with the Social Security Act under section 1927(d)(1) and (2), states that have entered into rebate agreements may only exclude a drug if:

“Based on the drug’s labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation.”
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

Matthew Greene, MD
Infectious Diseases Specialty

Enclosed: Denial letter, original PA submission, viral load, ultrasound, clinic visit notes

References:
CASE 2: JON APPROVED!
SPECIAL DENIALS
Early fibrosis

- Try to find an additional reason to treat:
  - Cryoglobulinemia
  - Proteinuria, nephrotic syndrome, membranoproliferative glomerulonephritis
  - HIV or HBV coinfection
  - Coexistent liver disease (i.e. NASH)
  - Debilitating fatigue
  - Type 2 Diabetes mellitus
  - Porphyria cutanea tarda
  - Child-bearing age
The AASLD and IDSA Society released Hepatitis C Treatment Guidelines that were updated in September 2017, and recommend treatment for all individuals infected with HCV with very few caveats. The recommendation to treat patients who have not yet advanced to stage F3-F4 fibrosis is supported by evidence suggesting that initiating HCV therapy in patients with lower stage fibrosis may extend the benefits of SVR including a better long-term survival rate, morbidity and mortality reductions, decreased hepatocellular carcinoma (HCC) and cirrhosis, and decreased HCV prevalence. If we wait until this progression occurs, it would likely result in substantial increased medical expenses, including additional procedures, laboratory testing, imaging, and medications. These guidelines can be viewed in their entirety at http://hcvguidelines.org.

Ms. xxx is of child-bearing age. Withholding HCV treatment at this time places her at risk for vertical transmission. 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.

Centers for Disease Control and Prevention

World Hepatitis Day —
July 28, 2016

World Hepatitis Day, recognized on July 28, was established by the World Health Organization (WHO) to raise awareness and promote understanding of viral hepatitis, the第七

Increased Hepatitis C Virus (HCV)
Given Ms. ’s advanced disease and HIV coinfection, she is at high risk for hepatocellular carcinoma and hepatic decompensation which could require transplant and therefore should be treated at this time. She has proven adherence to HIV medication with consistently undetectable HIV viral loads. The AASLD/IDSA Hepatitis C Treatment Guidelines recommend patients with chronic HCV infection abstain from alcohol and drug use, but do not exclude these patients from being considered for treatment, specifically stating “Data are lacking to support exclusion of HCV-infected persons from considerations for hepatitis C therapy based on the amount of alcohol intake or the use of illicit drugs. Based on data from IFN-based treatment, SVR rates among people who inject drugs are comparable to those among people who do not inject drugs.” On the contrary, they recommend treatment for patients with ongoing drug and alcohol use, highlighting the benefit of treating this patient population:

“There are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy. These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy. Scale up of HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the United States and globally.”
Centers for Medicare/Medicaid Services (CMS) Guidance

Furthermore, in November 2015, CMS issued guidance to states regarding coverage for medications used to treat HCV infection addressing these types of restrictions. CMS advised in accordance with the Social Security Act under section 1927(d)(1) and (2), states that have entered into rebate agreements may only exclude a drug if:

“Based on the drug’s labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation.”

The currently cited reason for denying Ms., a patient with cirrhosis and HIV coinfection who has been free of drug and alcohol abuse for over one year, does not meet the criteria for exclusion based on the SSA.
Adherence Readiness

- Denial: “Physician/provider asserts that the patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen. The information sent in does not show your patient meets these criteria.”
Psychosocial Readiness Evaluation to Prepare for hepatitis C treatment (PREP-C)

<table>
<thead>
<tr>
<th>PREP-C Assessment Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Motivation</strong>: Reasons client wants to begin HCV treatment, concerns about treatment, and importance of treatment.</td>
</tr>
<tr>
<td>2. <strong>Information</strong>: Knowledge about HCV treatment and one's own HCV disease status.</td>
</tr>
<tr>
<td>3. <strong>Medication Adherence</strong>: Current prescribed medications and adherence to them in prior month.</td>
</tr>
<tr>
<td>5. <strong>Social Support and Stability</strong>: Stability of financial, housing, and social support resources.</td>
</tr>
<tr>
<td>6. <strong>Alcohol and Substance Use</strong>: Alcohol and substance use behaviors and current treatment.</td>
</tr>
<tr>
<td>8. <strong>Energy Level</strong>: Sleep and fatigue.</td>
</tr>
<tr>
<td>9. <strong>Cognitive Functioning</strong>: Perceived difficulty with communication in health care setting, problem-solving ability, and memory.</td>
</tr>
</tbody>
</table>

https://prepc.org/
ON-TREATMENT CONSIDERATIONS
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
Ongoing Alcohol/Illlicit Substance Use Considerations

- Counseling:
  - Payer restrictions if reinfected
  - ADHERENCE!!
    - Tools: apps, phone alarm, pill box, alarmed pill box, accountability (friends/family), checklist
    - Plan, plan, plan- be specific
- Close monitoring while on treatment
**Weekly Med Checklist**

It is important to bring this completed list with you to each healthcare visit. Always speak with your healthcare provider about any changes to your medications.

<table>
<thead>
<tr>
<th>Time</th>
<th>Medication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>9am</td>
<td>Harvoni® (Ledipasvir/Sofosbuvir) 90 mg/400 mg</td>
<td>1 Tablet(s)</td>
</tr>
<tr>
<td></td>
<td>Prezcobix® (Darunavir/Cobicistat) 800 mg/150 mg</td>
<td>1 Tablet(s)</td>
</tr>
<tr>
<td></td>
<td>Descovy® (Emtricitabine/Tenofovir Alafenamide) 200 mg/25 mg</td>
<td>1 Tablets(s)</td>
</tr>
<tr>
<td></td>
<td>Bactrim® (Sulfamethoxazole; Trimethoprim) DS - 800 mg/160 mg</td>
<td>1 Tablet(s)</td>
</tr>
</tbody>
</table>

Date: / / / / / / /
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
  - Access on the horizon
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

- 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>
<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
- 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 Information

<table>
<thead>
<tr>
<th>ITEM</th>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Patient's Preferred Language:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Address:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>City:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>State:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Zip Code:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Phone #:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>SS #:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>DOB:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Gender:</td>
<td>[Male/Female]</td>
</tr>
<tr>
<td>Resides in U.S. territory:</td>
<td>[Yes/No]</td>
</tr>
<tr>
<td>Alternate Contact Name:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Phone #:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Relationship:</td>
<td>[Fill in]</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

<table>
<thead>
<tr>
<th>ITEM</th>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this a Medicare Part D plan?</td>
<td>[Yes/No]</td>
</tr>
<tr>
<td>Plan Name:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Policy Holder Name:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Policy No.:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Policy Holder Relationship to Patient:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Additional Insurance Information:</td>
<td>[Fill in]</td>
</tr>
</tbody>
</table>

### Patient Financial Information

<table>
<thead>
<tr>
<th>ITEM</th>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Annual Household Income:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Number of People in Household:</td>
<td>[Fill in]</td>
</tr>
<tr>
<td>Please submit documentation of all sources of income (e.g., tax return, W-2, 1099s, etc.) and social security statement, etc.</td>
<td></td>
</tr>
</tbody>
</table>

### Applicant Declarations and Authorizations

I certify that all of the information provided on this application is true and complete and accurate. I understand that program assistance will terminate if the program becomes aware of any false or if the information is no longer true for me. I understand that completing this application does not entitle me to receive any assistance. If I receive assistance through this PAP, I certify that I will not seek reimbursement or credit for the prescription from any insurance, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek reimbursement or credit for the prescription from any insurance, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek reimbursement or credit for the prescription from any insurance, health plan, or government program. I understand that the PAP reserves the right to terminate the application, or modify or discontinue the program, or terminate assistance at any time and without notice. I accept the PAP and its determination to dispense any prescription to a dispensing pharmacy or pharmacy chain as required.  

### Patient Signature

Patient Signature: [Signature]  
Date: [Fill in]  

Fax completed form to support Path Program at 1-855-298-8700  

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Patient signature required.
PAP: Abbvie

- https://www.viekirahcp.com/proceed
- Case-by-case basis:
  - Financial hardship
  - Lack of insurance coverage
  - Medical necessity
- XR criteria:
  - Provide income and household size
  - <$100,000 per year
PAP: Abbvie

- Patient Support
- Complete enrollment form
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](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: JON
WHAT IF HE HAD BEEN DENIED?
Daenerys

- 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

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 child-bearing 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,

[Signature]

Autumn Bagwell, PharmD, BCPS
August 15, 2016

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

Re: Patient Assistance Program Enrollment
Service Request Number:

Dear Dr. Cody Chastain:

This letter is regarding your patient, [Patient Name]. 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 9:30AM 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:
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- The players:
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  - Patients without prescription insurance
- The possibilities:
  - HCV treatment access resources
  - Manufacturer patient support
  - Access on the horizon
Provider Support: Gilead iAssist

**iAssist**: ePrescribing (eRx) and online prior authorization (ePA) support in one easy-to-access web-based platform

- iAssist is designed to simplify and expedite patient access to HARVONI® (ledipasvir 90 mg/sofosbuvir 400 mg), EPOLUX® (sofosbuvir 400 mg/valravir 100 mg), or SOVALDI® (sofosbuvir 400 mg) prescriptions.
  - Allows you to ePrescribe, confirm patient benefits, complete and submit PAs, enroll for Support Path resources, and more, all in one platform.
  - Allows you to request benefits investigation and additional PA support, if needed.
  - Includes co-pay coupon enrollment for eligible patients.

- Confirms patient insurance plan coverage and provides a plan-specific online PA form.
  - Smart Form technology only asks patient-relevant and payer-required questions and automatically populates forms with your responses.
  - Helps minimize processing errors.
  - Ensures all required fields are completed prior to submission of eRx, ePA, and other documentation.

- Complete and expedited submissions to the pharmacy.
  - Delivers each eRx to the pharmacy online—no need for paper or fax.
  - May help reduce the delays often associated with the typical "back-and-forth" between provider, payer, and pharmacy.
Provider Support: Abbvie ProCeed

- Viekira Pak®/XR®
  - ProCeed
    - Benefits Verification
    - PA/Appeal
      - Obtain the appropriate form
      - Track the PA
    - Triage prescription to the pharmacy
- Mavyret®
  - Patient Support
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
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Provider Support

- Abbvie Nurse Ambassador
  - Assist with navigating financial information
  - Assigned nurse throughout treatment
  - Call for adherence monitoring
  - Appointment reminder
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.
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- The problem:
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  - Patients without prescription insurance
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  - Access on the horizon
Access on the Horizon

- Current state of treatment access
  - Overall improved with few Pharmacy Benefit Managers denying treatment
  - Barriers remain
- Hopeful in the near future
  - Decreased cost
  - Increased competition
  - Increased access
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.Zuckerman@Vanderbilt.edu
615-936-6353