From Prescription to Patient:
Navigating Barriers to HCV Treatment Initiation

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Disclosures

- Research supported by Gilead Sciences Inc.:
  - Site investigator for HIV/HCV SWITCH Registry Study
  - Key personnel for FOCUS HCV Screening Program through Vanderbilt University Medical Center Emergency Department
Special Thanks

- Autumn Zuckerman
Objectives

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

- Understand how DAA cost impacts access
- Discuss successful navigation from prescription through the prior authorization and appeal process
- Review criteria for patient assistance programs (PAP)
- Be aware of ancillary financial and treatment assistance programs
Outline

- Cost
- The Approach to the Insured
  - Prior Authorizations
  - Appeals
  - Accessing Once Approved: Copay Cards and Grants
- The Approach to the Underinsured and Uninsured
  - Patient Assistance Programs (PAPs)
- Provider Resources
Outline

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Average Wholesale Price

*Cost for 48 weeks

Average Wholesale Price (AWP) of 12 week treatment

^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: $0 to $31,452 per QALY gained

“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.”
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The Insured

- Rx provided
- PA completion
- Steps following a denial

Prior Authorization and Appeals

Copay/Financial Assistance

- Rx approved
- Finding and implementing assistance

On-Treatment Considerations

- Ensuring access
- Avoiding lapse in treatment
Prior Authorization

- **Paper Option:**
  1. Obtain PA application
     - Call insurance company or obtain forms online
       - TennCare: TennCare.MagellanHealth.com
  2. Complete PA paperwork
  3. Gather supporting materials
  4. Fax to insurance/pharmacy benefit manager

- **Electronic Option:**
  - Covermymeds.com

- **Phone Option**
  - Primarily used for extension of therapy
Prior Authorization

- What to include to maximize likelihood of approval:
  1. PA application
  2. HCV genotype and viral load
  3. Staging (APRI, FIB-4, Fibrosure®, Fibroscan®, etc.)
  4. Clinical notes
  5. Ancillary items requested by some groups:
     - Resistance testing (i.e. for elbasvir/grazoprevir)
     - Drug screen
     - Alcohol or drug rehabilitation documentation

Consider follow-up if no response in 5 days...
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PA Denied - Now What?

1. Review PA rejection
   - Why was it rejected?
     - Call pharmacy benefit manager if needed
   - Is there a preferred agent?
   - What are the next steps?
     - Appeal
     - Peer-to-peer review
     - External review

2. Write appeal letter (most cases)

3. Return appeal, original PA application, and any supporting documentation
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 Support Documents

- Required appeal form (if applicable)
- Copy of the denial letter
- 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 drug screening results
- Relevant treatment guidelines
- Relevant peer-reviewed journal articles
- Relevant clinical trial information
- Relevant cost information (if known)
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Approved - Now What?

- Determine copay (with pharmacy assistance)
  - Test claim may be run by pharmacy
- Determine if patient qualifies for copay assistance
  - Medicaid: does not qualify for assistance → copay $0-$3
  - Medicare: obtain foundation grant assistance
    - Pharmacy may assist
  - Commercial: obtain copay card if patient copay is >$10
    - Pharmacy may assist
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The Underinsured and Uninsured

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

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

- Process may be convoluted prior to moving to other resources
  - PA denied → Appeal denied → Sent to legal arbitration → FINAL DENIAL
- Apply for patient assistance programs (PAP) once other options exhausted
  - Coverage varies by manufacturer
  - If initially denied by PAP, appeal to exception committee
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...

- Letter stating income and/or proof of residency if no other option is available
- Similar approach for other factors

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 Medication Delivery

- Prescription form sent from PAP to provider for signature
- Delivery set up for provider vs. patient
- Pharmacy calls monthly for prescription refill
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Provider Support

- Multiple types of support
- Vary by pharmaceutical selected
- Services include benefits investigation, prior authorization tracking, electronic resources, and even nursing support
- For novice or low volume treaters, consider engaging with one or two manufacturers to streamline process
On-Treatment Considerations

- PA may have continuation requirements for refills
  - I.e. Week 4 viral load
- PA extension may be required in some cases
  - When starting later than expected
  - When provider desires to extend treatment course (i.e. on treatment viral load detectable)
- Insurance changes may impact ability to refill
- Refills should be obtained at 7 days prior to running out
Template Letters of Appeal

Harvoni

Harvoni

Harvoni

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

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

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 7-year-old who has been diagnosed with chronic HCV infection.
- was diagnosed with chronic HCV infection. It’s 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 2: GENERATE MEDICAL EXCEPTION INFORMATION BASED ON YOUR CHOICES

Step 4: GENERATE LETTER PDF
## 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](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](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/](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 |
-Reside in US  
-Any insurance  
-Income below 500% FPL |
# 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>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>
</tbody>
</table>

**Contact:** 1-877-628-9738
# 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>
<tbody>
<tr>
<td>Daklinza®</td>
<td>$0</td>
<td><a href="https://bmsdm.secure.force.com/patientsupportconnect/patient">https://bmsdm.secure.force.com/patientsupportconnect/patient</a></td>
<td>-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</td>
<td>-Resident of US or Puerto Rico</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Contact:</strong> 1-844-442-6663</td>
<td></td>
<td>-No state or federally funded programs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-≥18 years old</td>
</tr>
</tbody>
</table>
# Copay Cards: Gilead SupportPath

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<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(^{st}) 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: Janssen CarePath

<table>
<thead>
<tr>
<th>Drug</th>
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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.janssencarepathssavings.com/Coupon/Olysio">https://olysio.janssencarepathssavings.com/Coupon/Olysio</a></td>
<td>-Max of $50,000 per calendar year&lt;br&gt;-Program expires 12/31/17</td>
<td>-Resident of US or Puerto Rico&lt;br&gt;-No state or federally funded programs</td>
</tr>
</tbody>
</table>

**Contact:** 1-855-565-9746
# Copay Cards: Merck

<table>
<thead>
<tr>
<th>Drug</th>
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</tr>
</thead>
</table>
| Zepatier® | $5           | 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 |
PAP: Abbvie

- [https://www.viekirahcp.com/proceed](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: 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
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
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
Provider Support: Abbigie ProCeed

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

- Abbvie Nurse Ambassador
  - Assist with navigating financial information
  - Assigned nurse throughout treatment
  - Call for adherence monitoring
  - Appointment reminder
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
Provider Support: Gilead Support Path

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

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

Complete the intake form now to enroll and access the full range of resources or call 1-855-7-MYPATH (1-855-769-7284) to learn more about resources that are available to help patients along the way toward treatment completion.
Provider Support: 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), EPCLUSA® (sofosbuvir 400 mg/valopicitavir 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 faxes
  - May help reduce the delays often associated with the typical "back-and-forth" between provider, payer, and pharmacy
Provider Support: Merck Access Program

- Benefits investigation
- PA/Appeal
  - Obtain the appropriate form and send to office
- 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
QUESTIONS?