

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

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- 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

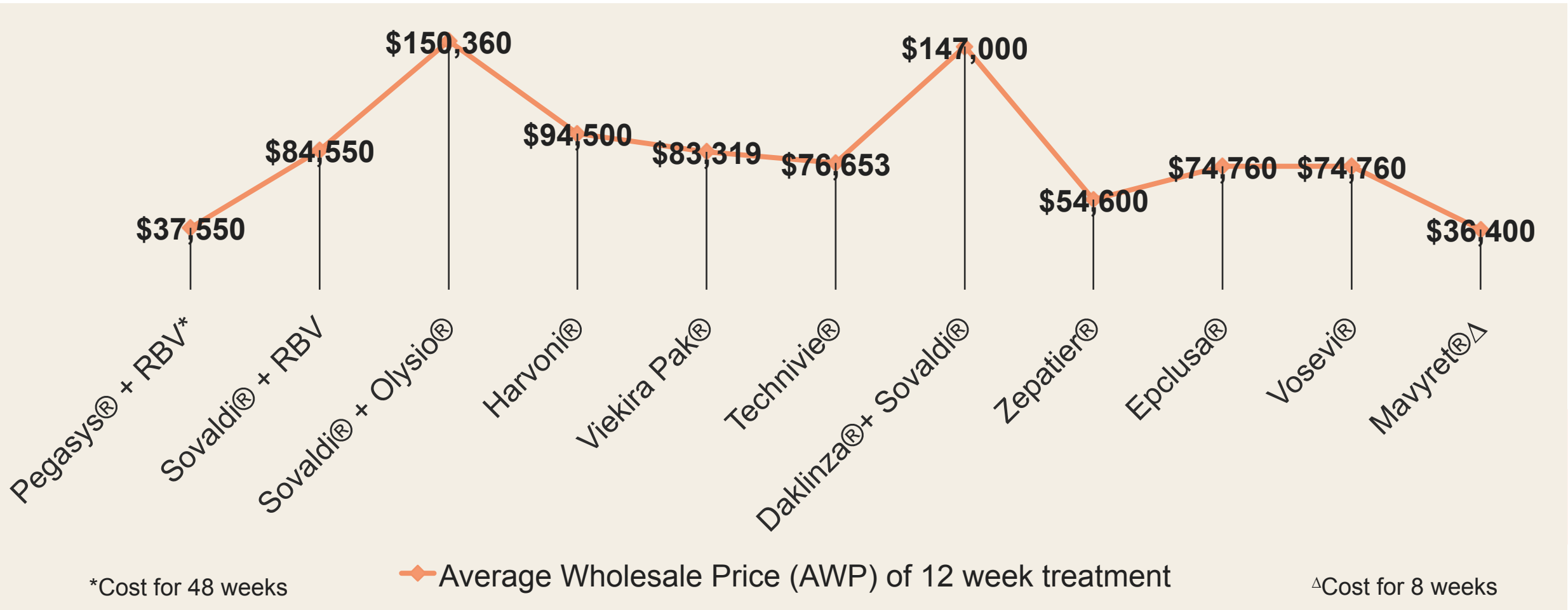
Outline

- 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

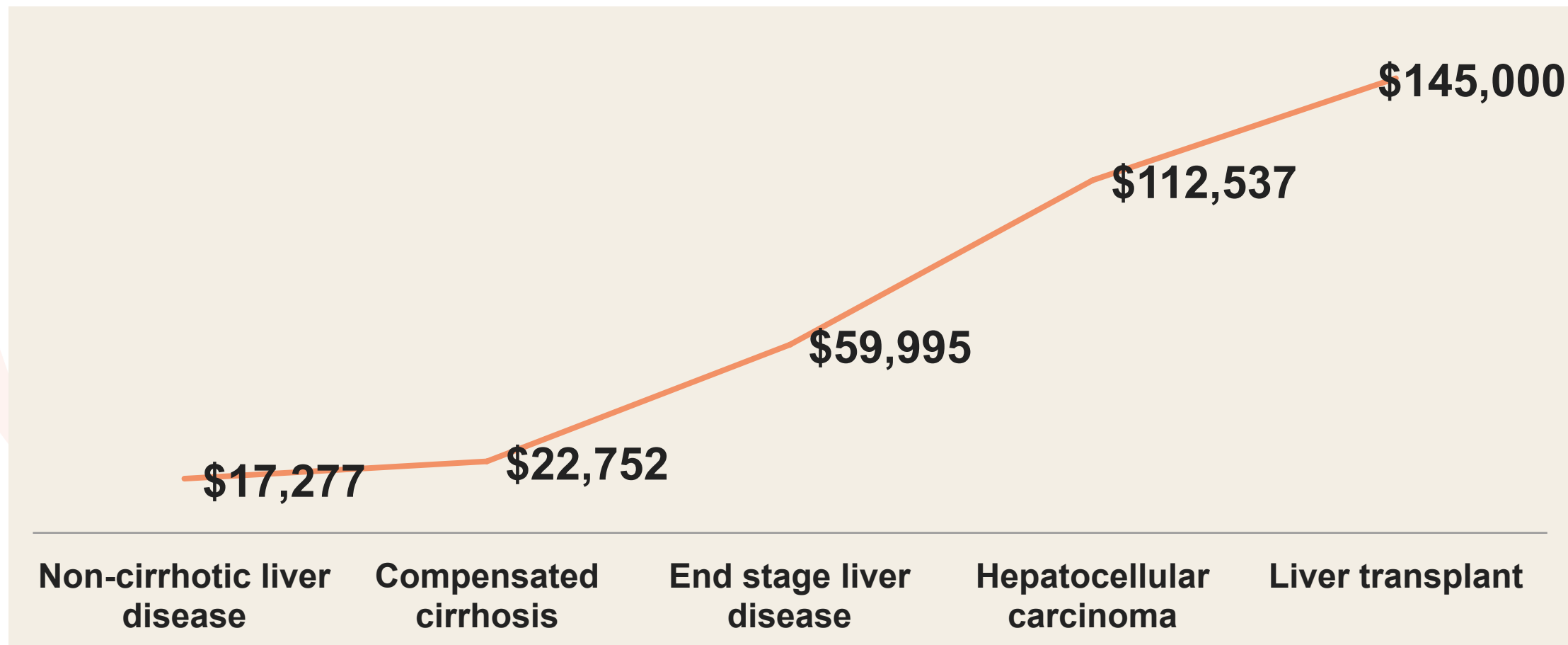
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Average Wholesale Price



Cost related to chronic HCV Infection



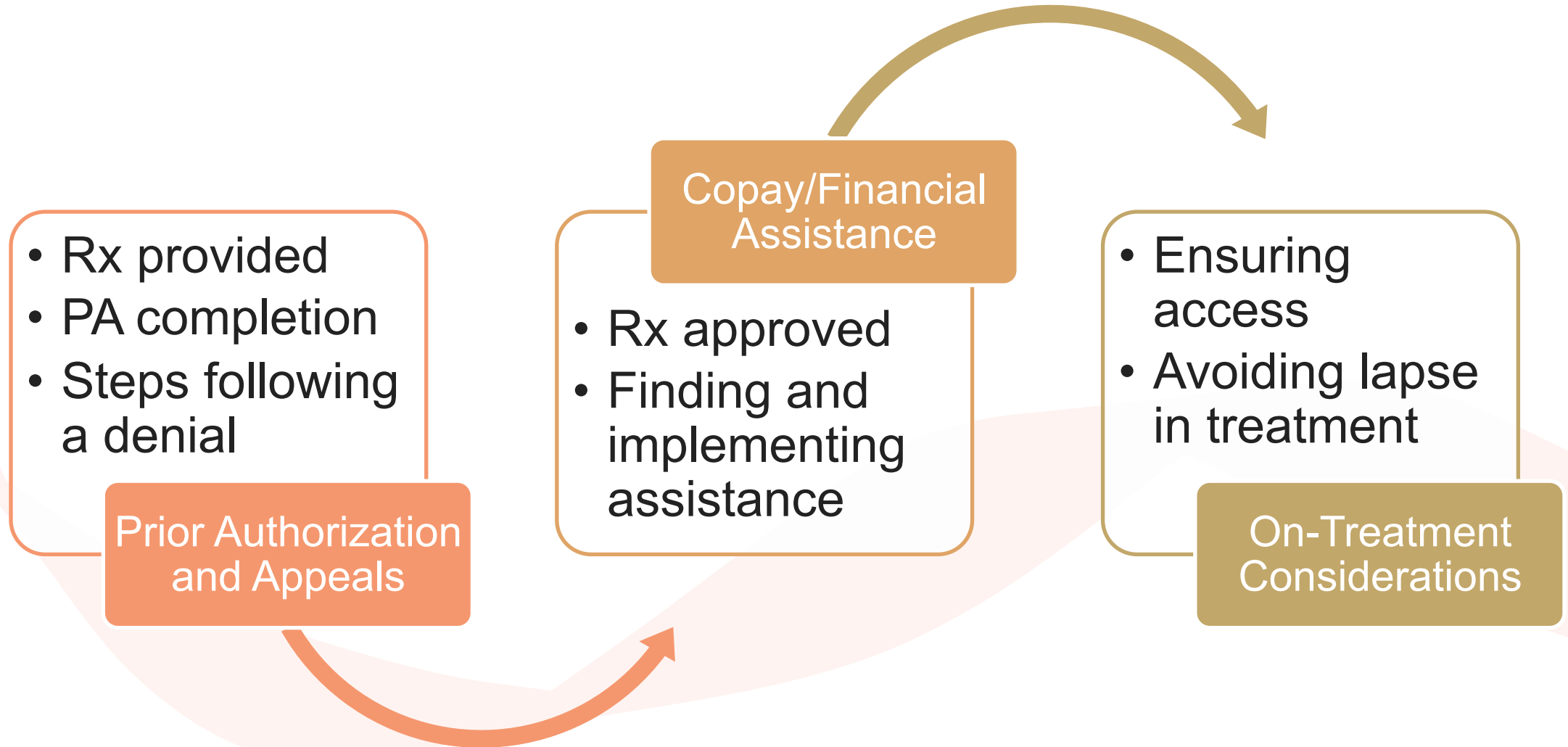
Overview of Cost, Reimbursement, and Cost-effectiveness Considerations for Hepatitis C Treatment Regimens

- 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



Prior Authorization

- Paper Option:
 1. Obtain PA application
 - Call insurance company or obtain forms online
 - TennCare: [TennCare: TennCare.Magellanhealth.com](http://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](#)

SAMPLE Letter of Appeal

Date

Payer Name
Payer Address
City, State, ZIP Code
Payer Fax Number

Attn: Payer Representative
Department Name (optional)

Re: Coverage of VIEKIRA PAK
Patient's First and Last Name
Policy Number/Patient's ID
Group Number
Patient Date of Birth

Dear Pharmacy Director:

I am writing to request a review of a denial for *[patient name]* for VIEKIRA PAK (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets). Your company has denied this claim for the following reason(s).

- List reason(s)

VIEKIRA PAK is indicated for the treatment of *[insert indication description]*. The full prescribing information for VIEKIRA PAK can be accessed at www.rxabbvie.com.

[Patient's name]'s medical history and course of treatment are as follows:

- Describe the patient's history, diagnosis, previous and current treatment regimens and their outcomes.

Based on *[patient's name]*'s condition, medical history, and supporting clinical literature, the use of VIEKIRA PAK is medically appropriate and necessary.

I respectfully request that you review the additional documentation provided and consider overturning your coverage decision for VIEKIRA PAK. I look forward to your reconsideration. If I can provide any additional information, please contact me at *[insert phone number]* to ensure the prompt approval of this course of treatment.

Regards,

[Physician Name]

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:

Proof of Income

- Tax return
- Copy of a disability or Medicare letter
- Social security income statement
- Retirement and/or pension statement
- Pay stub

Proof of residency

- State-issued ID
- Letter of residency
 - Rehab
 - Housing establishment
 - Caregiver

Household size

- All income from anyone in the house

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 obtain at 7 days prior to running out

RESOURCES

Appeal Support



Template Letters of Appeal

Harvoni

Harvoni

Harvoni

March 1, 2016

RE:

Dear Sir or Madam:

Two studies evaluated the re-treatment of persons with chronic hepatitis C who relapsed after the use of sofosbuvir regimens. The first, called the ONCOSTY trial, included 36 patients from the NAVAD PHASE study. These subjects were difficult to treat, genotype 1 who relapsed after 12 weeks of sofosbuvir and ribavirin. All were re-treated with ledipasvir/sofosbuvir (LDV/SOF) single tablet regimen (STR) for 12 weeks and all fourteen achieved a SVR12 (100%). The second study, ELECTRON-2, evaluated patients who failed previous sofosbuvir regimens, including SOF plus ribavirin (RBV) for 24 weeks, LDV/SOF plus RBV for 6 weeks and SOF plus GS5936 plus RBV. These thirteen patients were re-treated with LDV/SOF plus RBV for 12 weeks and all of them achieved a SVR12 (100%) [3, 2]

Both of these studies demonstrate the safety and efficacy of Harvoni® (ledipasvir/sofosbuvir), STR, to re-treat patients who relapsed after treatment with a sofosbuvir based regimen and support its use in this difficult to treat patient population. [1, 2] Therefore, I am requesting reconsideration of your denial for the use of Harvoni for my patient, who suffers from Childs A cirrhosis secondary to chronic hepatitis C (HCV) genotype 1A. He also has a history of depression and esophageal varices which can be exacerbated with an interferon based treatment causing a decline in his overall health.

It is imperative we continue to provide the latest and most efficacious treatments for patients with cirrhosis as they are at high risk for developing hepatocellular carcinoma, liver failure and death. These sequelae can necessitate liver transplant. In 2011, the cost of a liver transplant was \$577,300 [4], far exceeding the cost of treatment with the prescribed regimen.

Compared to data findings from the National Multiple Cause of Death Study during 2005-2010, the mortality rate of persons with HCV is 12 times higher than the national average. Plus, the average age at death was found to be 15 years younger than the "all-cause death age" [5]. Therefore, it is my clinical opinion and assessment will benefit from treatment with Harvoni for 24 weeks to treat the information presented, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

Kris Kowdley, MD, Hepatology

References:
 [1] Brown, L, Hadzi, N, et al. Assessment of Chronic Hepatitis C Virus Genotype 1 Infection After Receipt of Interferon Monotherapy. November 6, 2014. DOI: 10.1093/cq/000-000-000-0000000
 [2] Brown, L, Hadzi, N, et al. Assessment of Chronic Hepatitis C Virus Genotype 1 Infection After Receipt of Interferon Monotherapy. November 6, 2014. DOI: 10.1093/cq/000-000-000-0000000
 [3] Brown, L, Hadzi, N, et al. Assessment of Chronic Hepatitis C Virus Genotype 1 Infection After Receipt of Interferon Monotherapy. November 6, 2014. DOI: 10.1093/cq/000-000-000-0000000
 [4] American Society of Transplantation and Conference of Directors of Hospitals. The National Organ Donor Network. May 18, 2014. DOI: 10.1093/cq/000-000-000-0000000
 [5] American Society of Transplantation and Conference of Directors of Hospitals. The National Organ Donor Network. May 18, 2014. DOI: 10.1093/cq/000-000-000-0000000

Harvoni Appeal 2

RE:

Dear Sir or Madam:

I am requesting reconsideration of your denial for the use of once-daily Harvoni® (ledipasvir-sofosbuvir) for 8 weeks for my patient, who suffers from chronic hepatitis C (HCV) genotype 1A with F2 fibrosis. Even though denied based on a P4 liver disease, he is able to achieve SVR12. This patient with HCV disease. Plus, significant medical costs can be avoided by treating it before the advancement of liver liver disease. [1] The safety and efficacy of Harvoni was established in clinical trials, that including the cost needed to treat adverse events when he has no HCV treatment.

Not only is the regimen HCV approved, it is consistent with the gold recommendations of the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA). These guidelines, updated December 18, 2015, have become the gold standard for the treatment of persons with HCV. The full report of the AASLD/IDSA recommendations is available at www.aasld.org/aasld.

It is eligible for an interferon-based therapy to be a history of depression, diabetes, hypertension, coronary artery disease, chronic fatigue, chronic pain, easy bruising and the combination of which can be exacerbated with an interferon based regimen leading to the deterioration of his health. Plus, Harvoni is the most cost-effective and is the greatest treatment regimen than other HCV approved or investigational treatments for genotype 1. [2, 3, 4]

Table 1. Comparison of Treated Subjects (Response and Weight-based Sustained Cost for Treatment)

| STUDY Regimen Duration | SVR-12 Rate in Weeks | Estimated Sustained Cost for Treatment | Weight-based Sustained Cost for Treatment |
|---------------------------------|----------------------|--|---|
| Sustained No-Response [2, 3, 4] | 5/16 (31%) | \$15,000 | \$15,000 |
| Weight-based Response [2, 3, 4] | 5/16 (31%) | \$15,000 | \$15,000 |

Treatment with Harvoni for 8 weeks is a necessary therapy for HCV. It is if previous disease progression to cirrhosis, hepatocellular carcinoma or even liver failure. These sequelae can necessitate liver transplant. In 2011, the cost of a liver transplant was estimated to be \$577,300 [4], far exceeding the cost of treatment with the prescribed regimen.

Of further interest, compared to data findings from the National Multiple Cause of Death Study during 2005-2010, mortality rate of persons with HCV is 12 times higher than the national average. Plus, the average age at death was 15 years younger than the "all-cause death age" [5]. Therefore, it is my clinical opinion and assessment will benefit from the regimen. I trust the information presented, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

Kris Kowdley, MD, Hepatology

References:
 [1] Brown, L, Hadzi, N, et al. Assessment of Chronic Hepatitis C Virus Genotype 1 Infection After Receipt of Interferon Monotherapy. November 6, 2014. DOI: 10.1093/cq/000-000-000-0000000
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March 1, 2016

RE:

Dear Sir or Madam:

Result of the phase 2 SOLO-3 clinical trial for once-daily Harvoni® (ledipasvir-sofosbuvir) plus Harvoni for 12-24 weeks revealed 87% to 90% SVR12 (sustained viral response 12 weeks post HCV therapy) in patients with Childs A and C cirrhosis. Therefore, I am requesting reconsideration of your denial of daily weight based Harvoni plus Harvoni for the patient, who suffers from compensated cirrhosis secondary to chronic hepatitis C (HCV) genotype 1A. You have approved the Harvoni, however it is only half of the HCV treatment prescribed. It is also worth noting to evaluate for HCV. Not only is the regimen HCV approved, it is consistent with the gold recommendations of the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA). These guidelines, updated December 18, 2015, have become the gold standard for the treatment of persons with HCV. The full report of the AASLD/IDSA recommendations is available at www.aasld.org/aasld.

It is eligible for an interferon-based therapy to be a history of depression, diabetes, hypertension, coronary artery disease, chronic fatigue, chronic pain, easy bruising and the combination of which can be exacerbated with an interferon based regimen leading to the deterioration of his overall health.

Additionally, Harvoni is more cost-effective than other HCV approved or investigational treatments for genotype 1 with cirrhosis. Treatment with Harvoni and daily weight based Harvoni for 24 weeks is a necessary therapy for HCV. The data from clinical trials indicate patients like Mr. X have an exceedingly high chance of attaining SVR within 24 weeks with Harvoni and daily weight based Harvoni. If Mr. X can be treated with HCV, he may have a regression of his cirrhosis. Studies have shown SVR (also early) is associated with decreased incidence of hepatocellular carcinoma, liver related mortality and overall mortality. In this study following 480 patients with HCV and stage B or C disease, SVR (also early) significantly improved cumulative 50-year survival (92.2% with SVR vs 74% without SVR), causing Mr. X self-significantly decrease his chances of liver related death and liver transplant. In 2011, the cost of a liver transplant was estimated to be \$577,300 [4], far exceeding the cost of treatment with the prescribed regimen.

With this in mind, it is my clinical opinion and assessment will benefit from the regimen. I trust the information presented, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

Kris Kowdley, MD

References:
 [1] Brown, L, Hadzi, N, et al. Assessment of Chronic Hepatitis C Virus Genotype 1 Infection After Receipt of Interferon Monotherapy. November 6, 2014. DOI: 10.1093/cq/000-000-000-0000000
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 [5] American Society of Transplantation and Conference of Directors of Hospitals. The National Organ Donor Network. May 18, 2014. DOI: 10.1093/cq/000-000-000-0000000

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.

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 for the following reason(s) .

is a -year-old who has been diagnosed with chronic HCV infection.

was diagnosed with chronic HCV infection on . '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 4: GENERATE LETTER PDF

Grant Funding

| Grant | Patient Cost | Information | Eligibility |
|---|---|--|--|
| Patient Access Network Foundation (PANF) | \$0 | https://pharmacyportal.panfoundation.org/Home.aspx Contact: 1-866-316-7263 | -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 Contact: 1-866-512-3861 | -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/ Contact: 1-972-608-7141 | -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/ Contact: 1-800-675-8416 | -Max of \$30,000/year -Reside in US -Any insurance -Income below 500% FPL |

Copay Cards: Abbvie ProCeed

| Drug | Patient Cost | Copay Card Information | Card Details | Eligibility |
|--------------|--------------|---|--|--|
| Viekira XR® | \$5 | https://www.viekira.com/patient-support/financial-resources | -Max of 25% of the catalog price | -Resident of US |
| Viekira Pak® | \$5 | https://www.viekira.com/content/pdf/viekira-treatment.pdf | -Valid for 12 uses | -No state or federally funded programs |
| Technivie® | \$5 | https://www.viekira.com/content/pdf/viekira-treatment.pdf | -Expires 12 months from 1 st redemption | -Not valid in Massachusetts |
| Mavyret® | \$5 | https://www.mavyret.com/ Contact: 1-877-628-9738 | | |

Copay Cards: Bristol-Myers Squibb Patient Support CONNECT

| Drug | Patient Cost | Copay Card Information | Card Details | Eligibility |
|-----------|--------------|--|--|--|
| Daklinza® | \$0 | https://bmsdm.secure.force.com/patientsupportconnect/patient Contact: 1-844-442-6663 | -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 -No state or federally funded programs -≥18 years old |

Copay Cards: Gilead SupportPath

| Drug | Patient Cost | Copay Card Information | Card Details | Eligibility |
|----------|--------------|---|--|--|
| Harvoni® | \$5 | https://www.harvoni.com/support-and-savings/co-pay-coupon-registration | -Max of 25% of the catalog price of a 12-week regimen -Valid for 6 months from 1 st redemption | -Resident of US, PR, or US territories -No state or federally funded programs -≥18 years old |
| Sovaldi® | \$5 | https://www.sovaldi.com/coupons/ | | |
| Epclusa® | \$5 | http://www.epclusainfo.com/support-and-savings/co-pay-coupon-registration | | |
| Vosevi® | \$5 | https://www.vosevi.com/co-pay-coupon-registration Contact: 1-855-769-7284 | | |

Copay Cards: Janssen CarePath

| Drug | Patient Cost | Copay Card Information | Card Details | Eligibility |
|---------|--------------|--|---|--|
| Olysio® | \$5 | https://olysio.janssencarepathsavings.com/Coupon/Olysio Contact: 1-855-565-9746 | -Max of \$50,000 per calendar year -Program expires 12/31/17 | -Resident of US or Puerto Rico -No state or federally funded programs |

Copay Cards: Merck

| Drug | Patient Cost | Copay Card Information | Card Details | Eligibility |
|-----------|--------------|--|---|--|
| Zepatier® | \$5 | https://www.merckaccessprogram-zepatier.com/hcp/copay-assistance/ Contact: 1-866-251-6013 | -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>
- Case-by-case basis:
 - Financial hardship
 - Lack of insurance coverage
 - Medical necessity
- XR criteria:
 - Provide income and household size
 - <\$100,000 per year

Fax To: 1-855-886-2481
 Phone: 1-855-765-0504
 PO Box 4280, Gaithersburg, MD 20885



1 REQUESTED SERVICE Patient Assistance Program (PAP) Review

2 PATIENT INFORMATION

Patient Name: _____

Address (No PO Box): _____

City / State / ZIP: _____

Primary Phone #: _____ ALT Phone #: _____

DOB: _____ Gender: Male Female

E-mail Address: _____

Language: English Spanish Other: _____

Last 4 SSN: Patient Preferred Pharmacy: _____

Annual Household Income: \$ _____ Number in Household: _____

3 PRESCRIBER INFORMATION

Prescriber Name: _____

State License #: _____ NPI #: _____

Tax ID #: _____ Facility Name: _____

Specialty: Hepatology Gastro ID Other: _____

Address: _____

City / State / ZIP: _____

Contact Person: _____

Contact Phone #: _____ Contact Fax #: _____

Contact E-mail Address: _____

4 INSURANCE INFORMATION Please fax copy of prescription and insurance cards with this form (front and back)

No Insurance Coverage

Insurance Plan: Medicare Medicaid Private/Commercial Other _____

Insurance Company Name: _____

Insurance Company Phone #: _____

Policy #: _____ Group #: _____

Policyholder Name: _____ Policyholder DOB: _____

PBM Name: _____

PBM Phone #: _____ PBM BIN #: _____

PBM Group #: _____

5 DIAGNOSIS AND CLINICAL INFORMATION

HCV Genotype 1a 1b Other _____

Treatment History: Naïve Previously Treated

Post-liver Transplant Renal Insufficiency

Proton Pump Inhibitor (PPI) HCV/HIV Coinfection

Compensated Cirrhosis (Child-Pugh A)

Diagnosis (ICD-10 Code):

B18.2 Chronic Viral Hepatitis C Allergies (List): _____

B19.20 Unspecified Viral Hepatitis C without Hepatic Coma _____

6 PRESCRIPTION INFORMATION (PLEASE CHECK ONE BOX)

| | INDICATION | MEDICATION(S) | DOSE/STRENGTH | DIRECTIONS | QUANTITY | REFILLS |
|--------------------------|--|---------------|--|--|---------------|---------|
| <input type="checkbox"/> | GT1b NON-cirrhotic (OR) Compensated Cirrhotic | VIEKIRA PAK | ombitasvir 12.5 mg, paritaprevir 75 mg, ritonavir 50 mg fixed-dose combination tablets; copackaged with dasabuvir 250 mg tablets | Take two pink-colored tablets po once daily (AM) and one beige-colored tablet po twice daily (AM and PM) with a meal | 28-day supply | |

PAP: Abbvie

- Patient Support
- Complete enrollment form
- <https://www.mavyret.com/content/dam/abbvie-mavyret-brand/enrollment-form.pdf>

To enroll in MAVYRET Patient Support, complete the patient information and sign the HIPAA Authorization.

PATIENT INFORMATION

Patient Name: _____ DOB: _____
Gender: Male Female Other Language: English Spanish Other: _____
Address (No PO Box): _____

City / State / ZIP: _____
Primary Phone #: _____ ALT Phone #: _____
E-mail Address: _____

PATIENT CONSENT

I would like to receive AbbVie communications about its products, services, or offerings that may be of interest to me.
HIPAA Authorization: My signature below certifies that I have read, understood, and agreed to the HIPAA Authorization on page 2.

PATIENT SIGNATURE/LEGAL REPRESENTATIVE (Indicate relationship) Date

PRESCRIBER INFORMATION

Prescriber Name: _____
NPI #: _____
Specialty: Hepatology Gastro ID Other: _____
State License #: _____
Facility Name: _____
Address: _____

City / State / ZIP: _____
Prescriber Contact Person: _____
Prescriber Phone #: _____
Prescriber Fax #: _____
Prescriber E-mail Address: _____
Patient Preferred Pharmacy: _____
Pharmacy Contact & Phone: _____

I certify that the patient and physician information contained in this form is complete and accurate to the best of my knowledge. By signing this form, I certify that I have prescribed MAVYRET to the patient named above and that I have obtained all necessary federal and state authorizations from my patient to allow me to release health information to AbbVie Inc. and the AbbVie Partners (defined on page 2).

Prescriber, please print name _____ Please sign _____ Date _____


Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 3.
Please see full [Prescribing Information](#).

MAVYRET. PATIENT SUPPORT

MAVYRET.
glecaprevir/pibrentasvir

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 $\geq 3\%$ household income spent on prescriptions costs/year
 - Household income below 300% of FPL
 - \$35,640 for one
 - \$48,060 for a couple


Bristol-Myers Squibb

PATIENT ASSISTANCE FOUNDATION
PO Box 220769 Charlotte, NC 28222-0769 Phone 800-736-0003 Fax 800-736-1611

SECTION I: Patient Information (to be completed by patient)

| Patient Name: | | Social Security Number: | | |
|--|---------|---|--------------------|---------------|
| | | *Providing Social Security Number is optional. | | |
| Date of Birth: | | Gender: | | |
| | | <input type="checkbox"/> Female <input type="checkbox"/> Male | | |
| Patient Address: | | | | |
| City: | | State: | Zip: | |
| Home Phone: | | Cell Phone: | Best Time to Call: | |
| Alternate Contact Name: | | Relationship: | Phone: | |
| Allergies: | | | | |
| Current Medications: | | | | |
| Do you have insurance through (check all that apply)? | | | | |
| <input type="checkbox"/> Medicaid | | <input type="checkbox"/> Medicare A or B | | |
| <input type="checkbox"/> VA or Military | | <input type="checkbox"/> Medicare Part D | | |
| <input type="checkbox"/> State Assistance Program for Medication | | <input type="checkbox"/> Private Insurance | | |
| | | <input type="checkbox"/> None | | |
| <input type="checkbox"/> Other: | | | | |
| Insurance Name | Phone # | ID/Policy # | Group # | Policy Holder |
| Primary: | | | | |
| Secondary: | | | | |

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 Name: _____ Date of Birth: _____

SUPPORT PATH PROGRAM INTAKE FORM

PHONE: 1-855-769-7284 FAX: 1-855-298-8700

1 REQUESTED SUPPORT PATH OFFERINGS (REQUIRED) CHECK ALL BOXES THAT APPLY

Benefits Investigation Prior Authorization and Appeals Support Patient Assistance Program (PAP) Eligibility Screening Copay Coupon Program Enrollment

2 GILEAD MEDICATION REQUESTED (REQUIRED)

Product Name: _____ mg: _____

3 PRESCRIBER INFORMATION (REQUIRED)

Prescriber Name: _____ Facility Name: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Office Contact: _____ Phone #: _____ Fax #: _____
NPI #: _____ Tax ID #: _____
State License #: _____

4 DIAGNOSIS / MEDICAL INFORMATION (REQUIRED) MUST BE COMPLETED BY HEALTHCARE PROVIDER

Diagnosis: _____
ICD-10 code: _____ F Score (Fibrosis Score): _____ Other: _____
HCV Genotype 1 2 3 4 5 6 Other: _____ HCV/HIV-1 Co-infection

Patient is (Select one of the following options and indicate below if patient is ready to start therapy.):
 Treatment Naïve Previously Treated Currently on Therapy

Other HCV Medication(s): _____
Is patient ready to start therapy? Yes No Actual or Anticipated Start Date: _____ Therapy Duration: _____

PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY (REQUIRED)

By signing this form, I certify that I am prescribing Gilead medication for the patient identified in Section 5. I certify that this prescription medication is medically necessary for the patient and that it will be used as directed. I certify that I will be supervising the patient's treatments and verify that the information provided is complete and accurate to the best of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed to the patient through the Support Path Patient Assistance Program (PAP) from any government program or third-party insurer.

I certify that I have received the appropriate permission from the patient and met any other applicable requirements imposed under the Health Insurance Portability and Accountability Act of 1996 and/or state law needed to release the above information to Gilead, and contractors designated by Gilead, for the purposes of verifying the patient's insurance coverage, seeking prior authorization if needed, on my patient's behalf, and providing information on appeals for denials of claims.

PRESCRIBER SIGNATURE (REQUIRED)

DATE:

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

The Merck Access Program ENROLLMENT FORM

ZEPATIER™
(elbasvir and grazoprevir)
50 mg/100 mg tablets

P: 866-251-6013 F: 800-803-3104

The Merck Access Program, PO Box 29067, Phoenix, AZ 85038

COMPLETE THE APPROPRIATE SECTIONS OF THE ENROLLMENT FORM AND FAX TO 800-803-3104.

1 REQUESTED SERVICE(S) Check all circles that apply

- Benefits Investigation, Prior Authorization, or Appeal
- Referral to the Merck Patient Assistance Program (offered through the Merck Patient Assistance Program, Inc.)

2 PATIENT INFORMATION (REQUIRED)

Patient Name:

Street Address (no PO Box):

City/State/Zip:

Phone (Home): (Work/Other):


DOB (mm/dd/yyyy): Gender: M F

Resides in US/US Territories: Yes No

For Merck Patient Assistance Program only


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



Fax To: 1-855-886-2481

Phone: 1-855-765-0504
PO Box 4280, Gaithersburg, MD 20885



1 PATIENT INFORMATION AND CONSENT

Patient Name: _____ DOB: _____
 Gender: Male Female Language: English Spanish Last 4 SSN: _____
 Address (No PO Box): _____
 City / State / ZIP: _____
 Primary Phone #: _____ ALT Phone #: _____
 E-mail Address: _____
 Patient Preferred Pharmacy: _____
 Pharmacy Contact & Phone #: _____

Enrollment Consent:
 I agree to enroll in the proCeed services, including nurse support, as described on page 2.

HIPAA Consent:
 My signature below certifies that I have read, understood, and agreed to the Patient Authorization to release my protected health information to AbbVie Inc. and companies working on its behalf, as described on page 3.

x _____
PATIENT SIGNATURE / LEGAL REPRESENTATIVE (indicate relationship)

2 PRESCRIBER INFORMATION

REQUESTED SERVICES (Select all boxes that apply) Prescription/Benefit Verification Prior Authorization/Appeal Assistance

Prescriber Name: _____ State License #: _____
 NPI #: _____ Tax ID #: _____
 Specialty: Hepatology Gastro ID Other: _____ Facility Name: _____
 Address: _____ City / State / ZIP: _____
 Prescriber Contact Person: _____ Prescriber Phone #: _____
 Prescriber Fax #: _____ Prescriber E-mail Address: _____

3 INSURANCE INFORMATION

Please fax copy of prescription and insurance cards with this form (front and back)

No Insurance Coverage Insurance Plan: Medicare Medicaid Private/Commercial Other _____
 Insurance Company Name: _____ Insurance Company Phone #: _____
 Policy #: _____ Group #: _____ Policyholder Name: _____ Policyholder DOB: _____
 PBM Name: _____ PBM Phone #: _____ PBM BIN #: _____ PBM Group #: _____

4 CLINICAL INFORMATION

Treatment History: Naive Previously Treated with pegIFN/ribavirin Other HCV Medications _____
 Fibrosis (F) Score: 0 1 2 3 4
 Diagnosis: _____

Provider Support

- Abbvie Nurse Ambassador
 - Assist with navigating financial information
 - Assigned nurse throughout treatment
 - Call for adherence monitoring
 - Appointment reminder



MAVYRET PATIENT SUPPORT

DESIGNED TO PROVIDE PATIENTS WITH A TAILORED EXPERIENCE.

MAVYRET NURSE AMBASSADORS* PROVIDE A PERSONAL APPROACH AND ARE THERE FOR PATIENTS TO HELP THEM FEEL KNOWLEDGEABLE AND CONFIDENT.

- Knowledgeable about their hepatitis C, their treatment with MAVYRET, and the insurance process, including the financial resources that may be available to them
- Confident to ask questions and make informed health decisions with the support of their healthcare team

*MAVYRET Nurse Ambassadors provide product support but do not provide medical advice and will direct patients to their healthcare professional for any medical advice or questions related to treatment decisions and plans.

**ENROLL YOUR PATIENTS IN THE MAVYRET PATIENT SUPPORT PROGRAM.
CALL 1-877-MAVYRET (1-877-628-9738).**

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



patient support **CONNECT**[™]

Reimbursement Support
Phone: 844-442-6663 Fax: 866-676-4063
P.O. Box 222116
Charlotte, NC 28222-2116

Bristol-Myers Squibb Patient Support Connect[™]

- Patient Support Connect is designed to help patients with reimbursement needs for certain Bristol-Myers Squibb (BMS) medications.
- The program assists patients and their healthcare providers with the following services:
 - Insurance benefit investigations
 - Prior authorization and/or insurance appeals support
 - Referrals to a healthcare provider-preferred specialty pharmacy
 - Referrals to independent charities that provide financial assistance, including non-profit copay foundations that help patients who have coverage for their medications but need help paying for their out-of-pocket costs for treatment
 - Comprehensive coverage research

What Medications Does Patient Support Connect Help With?

- DAKLINZA[™] (daclatasvir)

Program Registration Steps

Once the enrollment form is received, your Patient Support Connect representative will conduct the services requested and notify the healthcare provider of the results and provide additional assistance options that may be available.

Healthcare Providers

Complete the following provider sections:

- **Section 1:** Select services requested at the top of the enrollment form
- **Section 2:** Provide complete treatment information, including diagnosis, duration of therapy, and dosing information
- **Section 4:** Provide state license number and NPI number for the treating healthcare provider
- **Section 5:** Sign and date the Provider Certification
- Have the patient read and sign the Patient Authorization & Agreement (PAA)
- Fax completed enrollment form to Patient Support Connect at 866-676-4063

Patients

Complete the patient section:

- **Section 3:** Provide complete patient information, including financial and insurance information
- Read, sign and date the Patient Authorization & Agreement on pages 3-4

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/velpatasvir 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



The Merck Access Program **ENROLLMENT FORM**

P: 866-251-6013 F: 800-803-3104

The Merck Access Program, PO Box 29067, Phoenix, AZ 85038

COMPLETE THE APPROPRIATE SECTIONS OF THE ENROLLMENT FORM AND FAX TO 800-803-3104.

1 REQUESTED SUPPORT Check all circles that apply

- Benefits Investigation**, and/or information about the **Prior Authorization** or **Appeals Process**.
- Evaluation of eligibility for the **Merck Patient Assistance Program** (offered through the Merck Patient Assistance Program, Inc.)

2 PATIENT INFORMATION (REQUIRED)

Patient Name:

Street Address (no PO Box):

City/State/Zip:

Phone (Home): (Work/Other):

DOB (mm/dd/yyyy): Gender: M F

Resides in US/US Territories: Yes No

For Merck Patient Assistance Program only

Current annual gross household income: \$
(Please include: before-tax wages, pension, interest/dividends, Social Security benefits, and any other sources of income)

Number of household members (including patient):

Other Access Resources

- National Viral Hepatitis Roundtable
 - NVHR.org/hepatitis-c-treatment-access
- Hepatitis C New Drug Research
 - <http://hepatitiscnewdrugresearch.com/hcv-drugs-financial-support.html>
- American Liver Foundation
 - <http://hepc.liverfoundation.org/resources/what-if-i-need-financial-assistance-to-pay-for-treatment/>
- Life Beyond Hepatitis C
 - <http://www.lifebeyondhepatitisc.com/medical-information/financial-assistance/>

QUESTIONS?