AETC AIDS Education & Training Center Program Southeast

From Prescription to Patient:

Navigating Barriers to HCV Treatment Initiation

Autumn Bagwell, PharmD, BCPS, AAHIVP
Vanderbilt Specialty Pharmacy

Objectives

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

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

Disclosure

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

Outline

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

Outline

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  - **HCV treatment financial burden**
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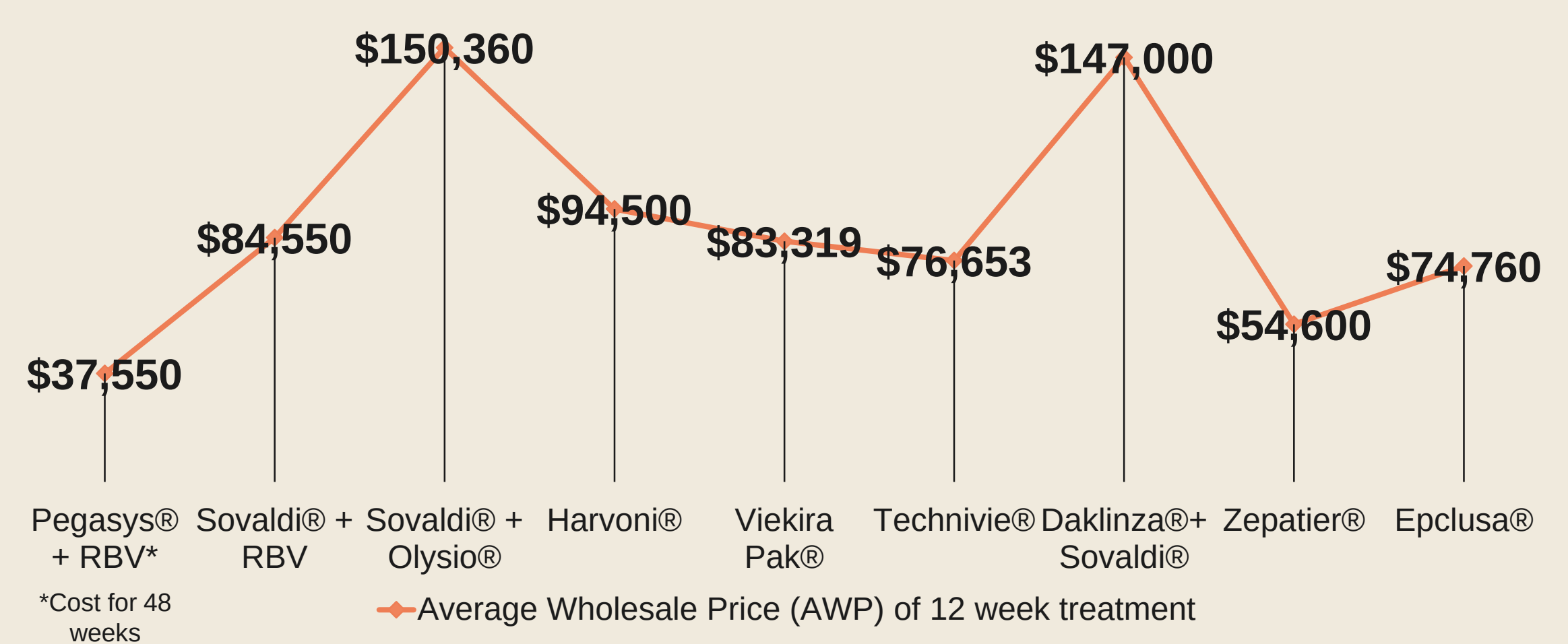
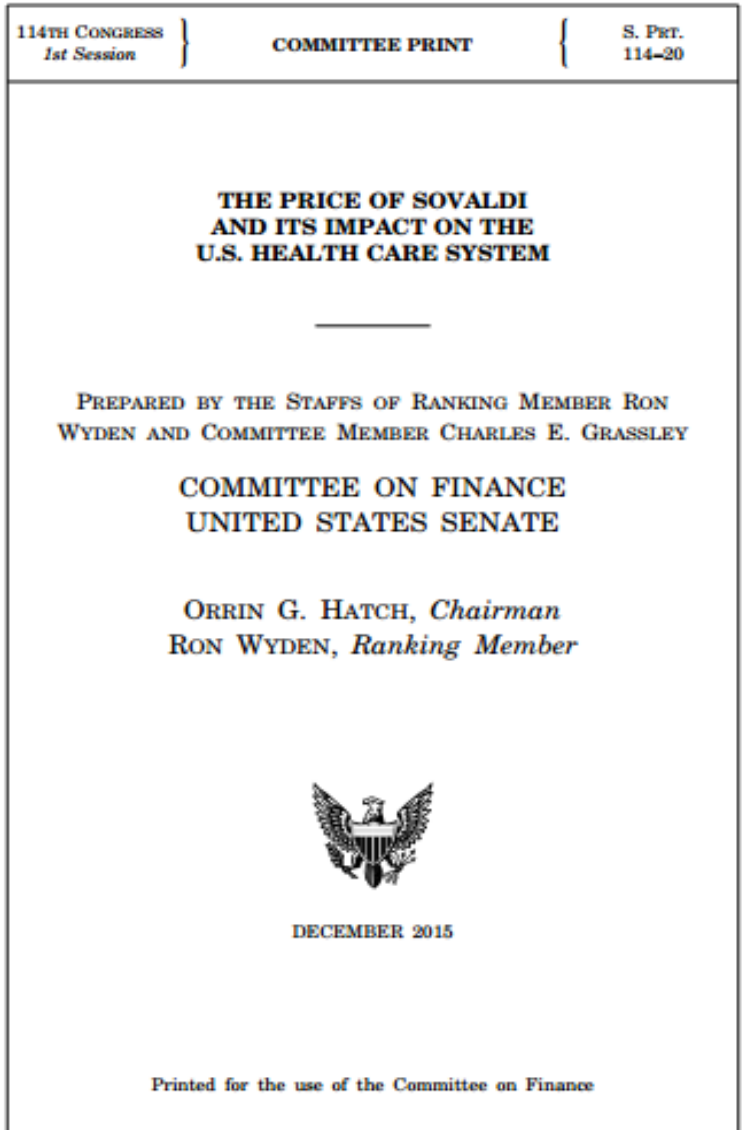
Cost of HCV Treatment



Cost of HCV Treatment: Medicaid

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



114TH CONGRESS *1st Session* | COMMITTEE PRINT | S. PRT. 114–20

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

PREPARED BY THE STAFFS OF RANKING MEMBER RON WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

COMMITTEE ON FINANCE
UNITED STATES SENATE

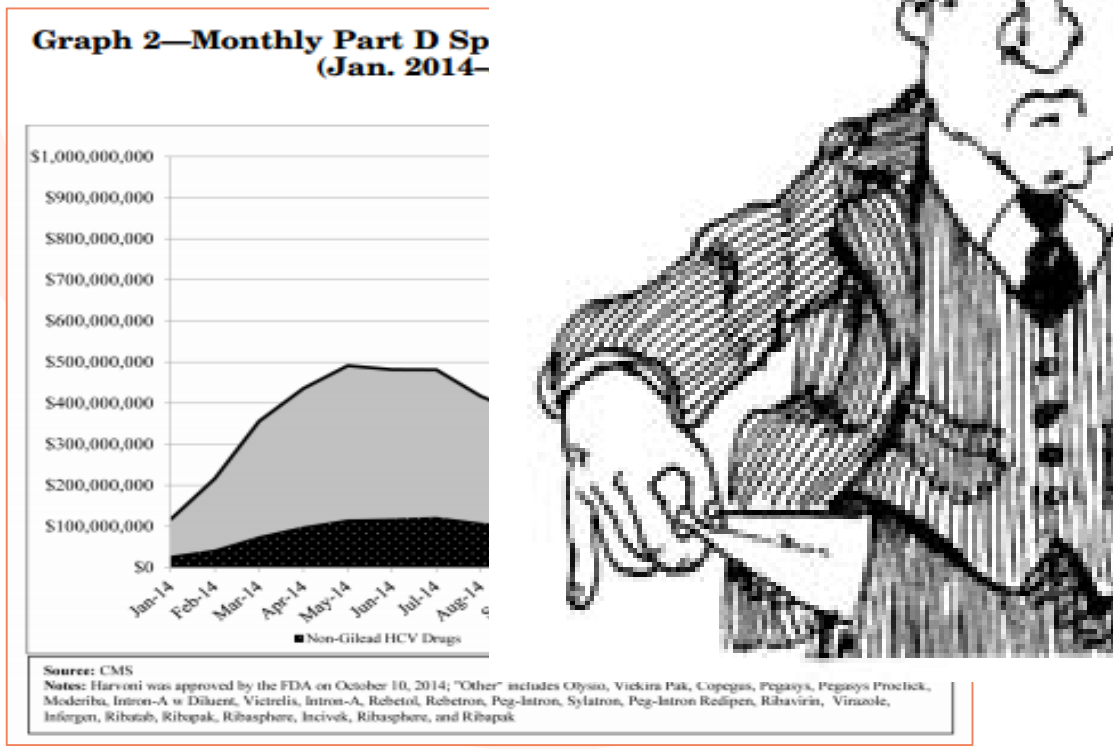
ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

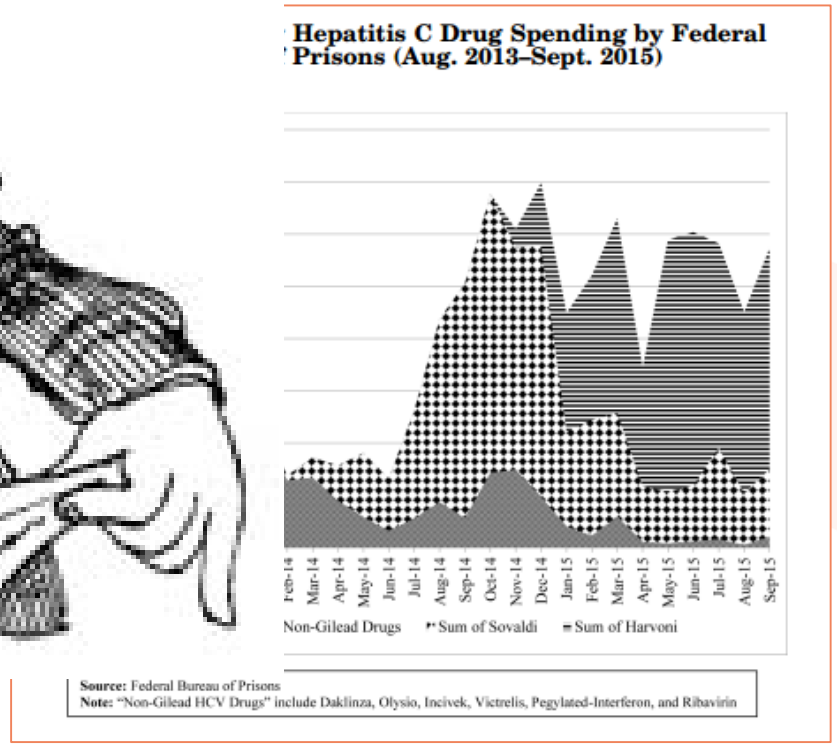
DECEMBER 2015

Printed for the use of the Committee on Finance

Cost of HCV Treatment: Medicare and BOP

- In 2014, $4.8 [illegible] $5.9 million on HCV HCV drugs 83 HCV inmates)





The Bos

Hepatitis C

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Help with the high cost of hepatitis C drugs

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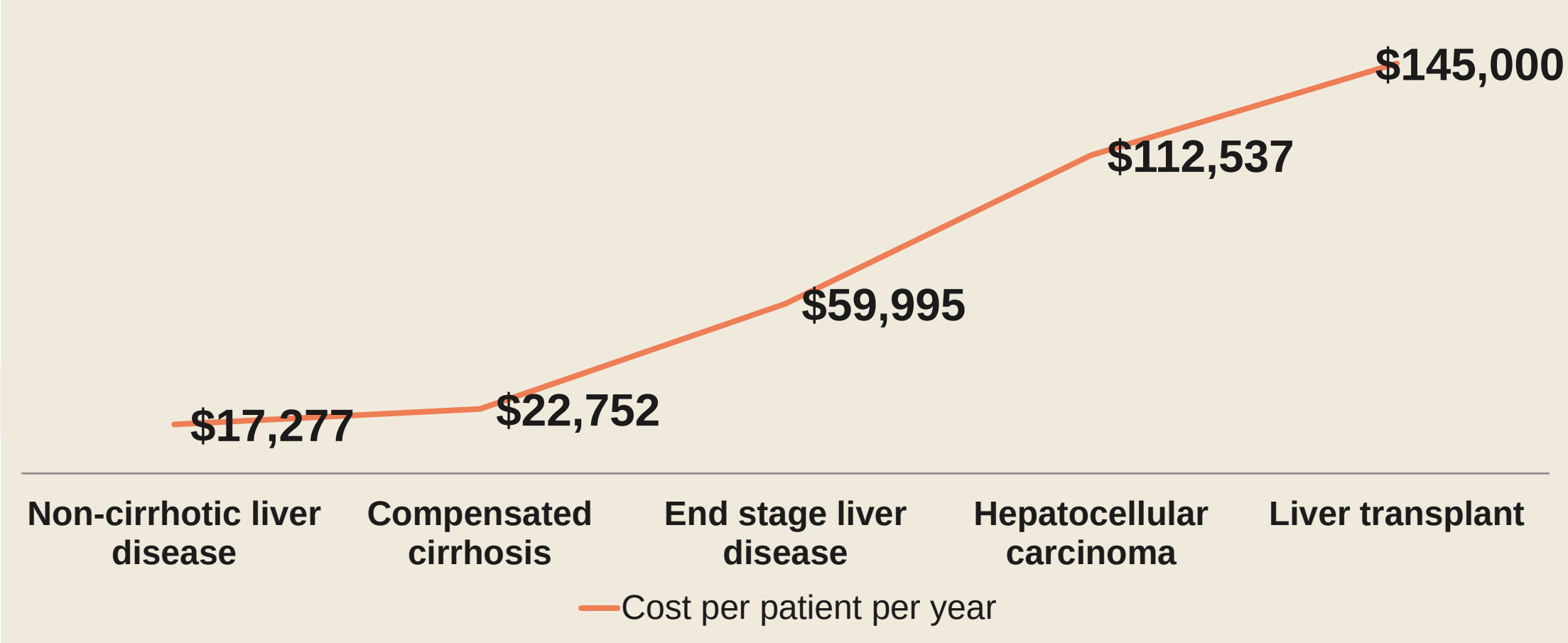
The same pill that costs $1,000 in the U.S. sells for $4 in India

Cost related to chronic HCV Infection



Younossi Z, Henry L. The impact of the new antiviral regimens on patient reported outcomes and health economics of patients with chronic hepatitis C. Dig Liver Dis. 2014;46 Suppl 5:S186-96.

Original Investigation

Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naive Population

Harinder S. Chahal, PharmD, MSc; Elliot A. Marseille, PhD; Jeffrey A. Tice, MD; Steve D. Pearson, MD, MSc; Daniel A. Ollendorf, PhD; Rena K. Fox, MD; James G. Kahn, MD, MPH

- Compared treatment of all fibrosis stages vs. stages ≥F3 and by specific fibrosis stage
- Cost-effective when treatment is initiated at any stage of fibrosis ($50,000 per Quality-adjusted life-years (QALYs) gained)
- Treating earlier results in a substantial decrease in net cost

Chahal, Harinder S., et al. "Cost-effectiveness of early treatment of hepatitis C virus genotype 1 by stage of liver fibrosis in a US treatment-naive population." *JAMA internal medicine* 176.1 (2016): 65-73.

Outline

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

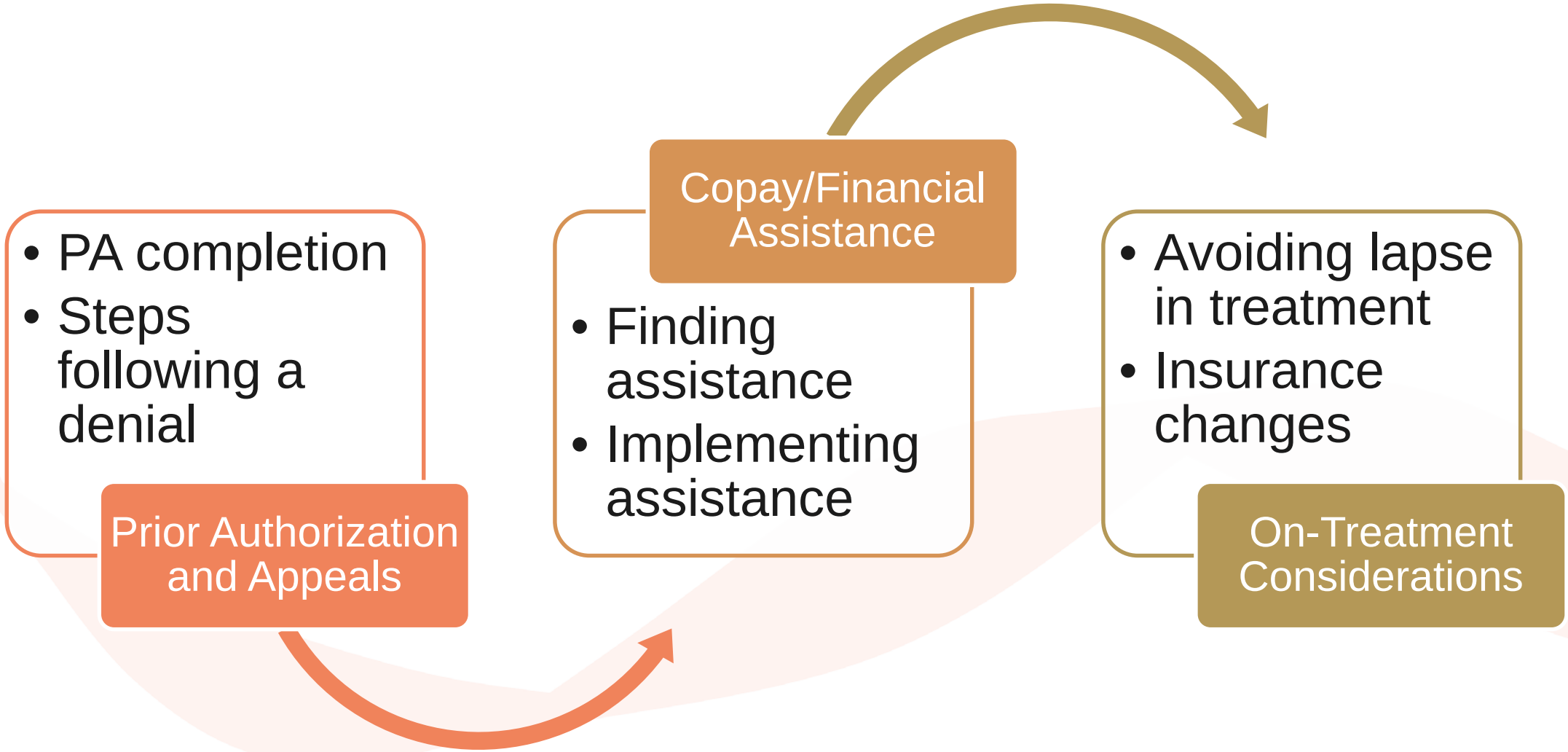
Patient Case 1: Marsha

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

Patient Case 2: Bill

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

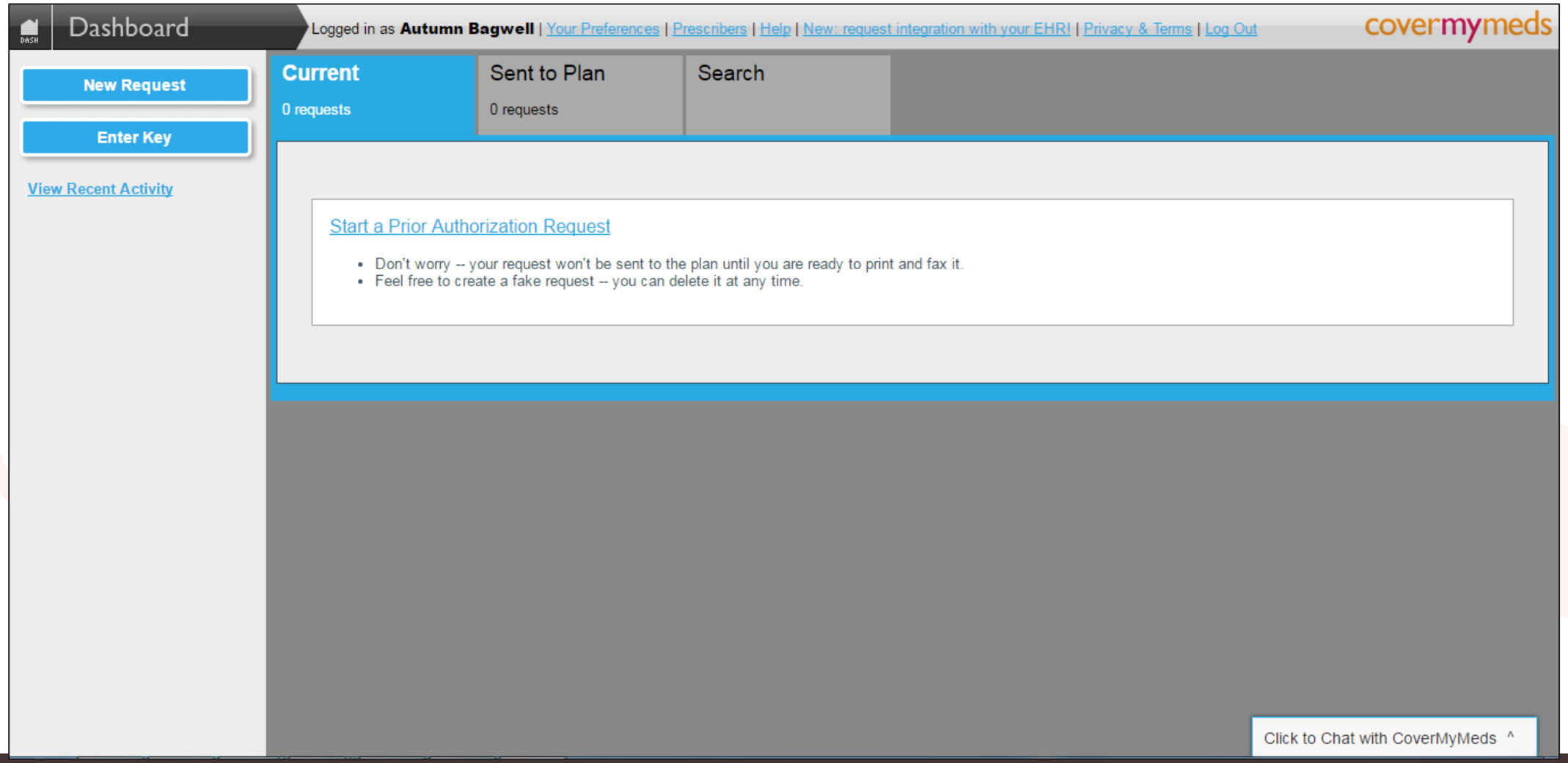
The Insured


• PA completion
• Steps following a denial
Prior Authorization and Appeals
Copay/Financial Assistance
• Finding assistance
• Implementing 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



Prior Authorization

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

PATIENT CASE 1: MARSHA

Cover My Meds Application

Prescriber Next Steps

Smart Rules

Is the patient 18 years of age or older?: Yes
Yes:
No:
Will the patient be using Harvoni in combination with any other DAAs (direct acting antivirals such as Daklinza, Incivek, Victrelis, Olysio, Sovaldi, Technivie, Viekira Pak, Zepatier) (not including ribavirin)?: No
Yes:
No:
Is the request for retreatment in patients who have previously received Harvoni? Please Note: This includes retreatment in prior null responders, prior partial responders, prior relapse patients, patients who have not completed a course of therapy due toan adverse reaction or for other reasons.: No
Yes:
No:
Is the patient's life expectancy less than 12 months due to non-liver related comorbidities?:
Yes:
No:
Does the patient have recurrent HCV post-liver transplantation (Genotypes 1 and 4)?:
Yes:
No:
Has the patient been started on Harvoni?:
Yes:
No:
Is Harvoni prescribed by, or in consultation with, one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician?:
Yes:
No:
Will Harvoni be prescribed in combination with ribavirin?:
Yes:
No:
Does the patient have chronic hepatitis C?:
Yes:
No:
Has the patient been started on Harvoni?:
Yes:
No:
Is the requested medication prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician?:
Yes:
No:
What is the patient's chronic HCV genotype?:
Chronic Hepatitis C (CHC) genotype 1:
Chronic Hepatitis C (CHC) genotype 2:
Chronic Hepatitis C (CHC) genotype 3:
Chronic Hepatitis C (CHC) genotype 4:
Chronic Hepatitis C (CHC) genotype 5:
Chronic Hepatitis C (CHC) genotype 6:
Other diagnoses:
Does the patient have Child-Pugh Class B (to indicate moderate hepatic impairment) or Child-Pugh Class C (to indicate severe hepatic impairment) liver disease?:
Yes:
No:
Is the patient treatment naive? Please Note: Treatment-naive includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy they have not been treated for HCV. Treatment-naive also includes patients who have not started HCV therapy and have never previously been treated for HCV.:
Yes:
No:
Does the patient have cirrhosis?:
Yes:
No:
Does the patient have HIV?:
Yes:
No:
Is the patient awaiting liver transplantation?:
Yes:
No:
Is the patient's baseline HCV RNA less than 6 million IU/mL?:
Yes:
No:
Has the patient been previously treated for HCV?:
Yes:
No:
Does the patient have cirrhosis?:
Yes:
No:
Does the patient have compensated (Child-Pugh A) cirrhosis OR decompensated (Child-Pugh B or C) cirrhosis?:
Compensated (Child-Pugh A):
Decompensated (Child-Pugh B or C):
Will Harvoni be prescribed in combination with ribavirin?:
Yes:
No:
What is the patient's chronic HCV genotype?:
Chronic Hepatitis C (CHC) genotype 1:
Chronic Hepatitis C (CHC) genotype 2:
Chronic Hepatitis C (CHC) genotype 3:
Chronic Hepatitis C (CHC) genotype 4:
Chronic Hepatitis C (CHC) genotype 5:
Chronic Hepatitis C (CHC) genotype 6:
Other diagnoses:
Is the patient treatment naive? Please Note: Treatment-naive includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy they have not been treated for HCV. Treatment-naive also includes patients who have not started HCV therapy and have never previously been treated for HCV.:
Yes:
No:

Cover My Meds Application

Has the patient been previously treated for HCV?:

Yes:

No:

Does the patient have compensated (Child-Pugh A) cirrhosis?:

Yes:

No:

Does the patient have cirrhosis?:

Yes:

No:

Does the patient have HIV?:

Yes:

No:

Is the patient awaiting liver transplantation?:

Yes:

No:

Is the patient's baseline HCV RNA less than 6 million IU/mL?:

Yes:

No:

How many weeks of Harvoni have been dispensed to the patient?:

4 weeks:

8 weeks or more:

How many weeks of Harvoni have been dispensed to the patient?:

How many weeks of Harvoni have been dispensed to the patient?:

Document upload

Upload any supporting documentation below. Must be .jpg, .pdf, or .tif file format.:

PATIENT CASE 2: BILL

Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Epclusa®

Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_Epclusa_PA_Request_Form.pdf

If the following information is not complete, correct, or legible, the PA process can be delayed. Use one form per member please.

Member Information

LAST NAME: | FIRST NAME:

ID NUMBER: | DATE OF BIRTH: ___ - ___ - ___

Prescriber Information

LAST NAME: CHASTAIN | FIRST NAME: CODY

NPI NUMBER: | DEA NUMBER:

PHONE NUMBER: 615-936-1174 | FAX NUMBER: 615-875-0666

Is the prescriber a TennCare provider with a Medicaid ID? [X] Yes [ ] No

Is the prescriber a single-patient contract holder for this patient? [ ] Yes [X] No

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

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 I.D.
- 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.magellanhealth.com

Clinical Criteria Documentation ****Do not include documentation that is not requested on this form****

Complete Chart and attach documentation of lab values

Laboratory Documentation		
Baseline HCV RNA level	115,971 IU/mL	10/05/2016
Week 4 HCV RNA level		
Week 12 HCV RNA level		

Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Epclusa

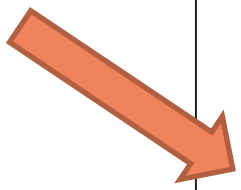
Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_Harvoni_PA_Request_Form.pdf

1. What is the diagnosis and duration of therapy for which this drug is being requested?
   - [X] 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 [X] No
3. Does the patient have a diagnosis of compensated cirrhosis? [X] Yes [ ] No
4. Is the patient post liver transplant? [ ] Yes [X] 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 ≥ 0.49
   - [X] Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa
   - [ ] Fibrosis-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 staging: _____

   F3-F4 fibrosis on US with cirrhotic changes see attached
6. Please check the box corresponding to the specialty of the prescribing physician:
   - [ ] Gastroenterologist
   - [ ] Hepatologist
   - [X] Infectious Disease Specialist
   - [ ] Other: _____
7. Does the patient have a past history of illicit substance or alcohol abuse? (If no, skip to #10) [X] Yes [ ] No
   - 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

   Rehab completion attached.
8. Has the patient been free of substance abuse for the previous 6 months? [X] Yes [ ] No
9. Has the patient been free of alcohol abuse for the previous 6 months? [X] Yes [ ] No last drink >2 years ago
10. For females: Is the member currently pregnant? [ ] Yes [X] No
11. Is the patient's Creatinine clearance greater than 30 ml/minute? [X] Yes [ ] No
12. Does the patient have End-stage renal disease? [ ] Yes [X] No
13. Will the patient be taking in combination with ribavirin? [ ] Yes [X] No
14. For genotype 1 & 4, does the patient have a reason they cannot take the preferred agent? [X] Yes [ ] No



Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Epclusa

Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_Harvoni_PA_Request_Form.pdf

15. If yes, what is the reason:

Patient is on pain medication that would interact with Viekira, placing him at risk for opioid overdose. 2) Patient has cirrhosis (CTP class 6A). Epclusa has superior efficacy with decreased toxicity risk over Viekira (RBV (SVR 12 rates of 99% (120/121) with Epclusa in ASTRAL-1 vs. 95% in TURQUOISE-II with Viekira +RBV for 24 weeks. for 12 weeks

16. For genotypes 5 & 6, does the patient have a reason they cannot take ledipasvir/sofusbuvir? ☐ Yes ☐ No

- If yes, what is the reason:

Please note any other information pertinent to this PA request: Patient with GT1a and cirrhosis. Epclusa is a superior option over the formulary-preferred agent as it is less toxic (FDA warning for use of VIP in cirrhosis), more efficacious in clinical trials (SVR of 99%), and a shorter treatment duration (12 vs. 24 wks). Additionally, Viekira would interact with patient's current medications. Proof of addiction (consult) attached.

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

Cody Chastain, PharmD — 1-11-17

Prescriber Signature (Required) — Date

(By signature, the Physician confirms the above information is accurate and verifiable by patient records.)

Fax This Form to: 866-434-5523

Mail requests to: TennCare Pharmacy Program
c/o Magellan Health Services
1st floor South, 14100 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: Marsha APPROVED!

Document and monitor dates of approval.

EXPRESS SCRIPTS

02/10/2017

Patient:
Physician: Dr. CODY CHASTAIN
Case ID:

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

Date of Request: 02/10/2017 10:09AM
Date of Decision: 02/10/2017

Dear Dr. CODY CHASTAIN:

We've reviewed the information that you provided in support of your patient's request to obtain Harvoni Tablet under his or her plan. As we informed your patient, this request has been approved from 01/11/2017 until 04/07/2017. This coverage eligibility review only determines what is covered under his or her prescription drug plan. This coverage approval does not extend to coverage for the administration of the drug.

In addition to this coverage eligibility review, every prescription will undergo a professional practice and safety review by a pharmacist before it is dispensed. Such review will be limited to information on file and will include drug interactions, allergies, dosing and medical conditions. **If that review identifies safety concerns, the medication might not be dispensed or your patient could receive less than what you prescribed.**

If you have any questions, please call us at 1 877-916-2271, 24 hours a day, 7 days a week (including holidays).

Sincerely,

Coverage Review Department
Express Scripts

Express Scripts manages the prescription benefit for BlueCross BlueShield Tennessee.
BlueCross BlueShield of Tennessee, Inc., an Independent Licensee of the BlueCross BlueShield Association.

BCBSTN_ap2
April 2013

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

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 1st 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 **Contact: 1-855-769-7284**		

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 -Valid for 12 uses -Expires 12 months from 1st redemption	-Resident of US -No state or federally funded programs -Not valid in Massachusetts
Viekira Pak®	$5	https://www.viekira.com/content/pdf/viekira-treatment.pdf		
Technivie®	$5	https://www.viekira.com/content/pdf/viekira-treatment.pdf **Contact:** 1-844-277-6233		

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 -Must activate before 12/31/16 -Program expires 12/31/17 (except in Mass. 6/30/17)	-Resident of US or Puerto Rico -No state or federally funded programs -≥18 years old

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 -Program expires 6/30/17	-Resident of US or Puerto Rico -No state or federally funded programs -≥18 years old

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

Grant Funding

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

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

BACK TO CASES

Patient Case 2: Bill

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:

ID Number: 342972814032
First Name:
Last Name:
Date of Birth:

MEDICATION INFORMATION:

Name: EPCLUSA
Strength: 400-100MG
Dosage Form: TABLET

MEDICAL PROVIDER:

Name: CODY CHASTAIN
Address 1: 1211 21ST AVE S
Address 2: STE 102A
City State Zip: NASHVILLE, TN 372122700

PHARMACY PROVIDER:

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

OUTCOME OF CLINICAL REVIEW OF REQUEST 2014629

Prior Authorization Status: Denied
Date of Review: 10/08/2016
Prior Authorization Begin Date: 10/07/2016
Prior Authorization End Date: 10/07/2016

IMPORTANT:

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.

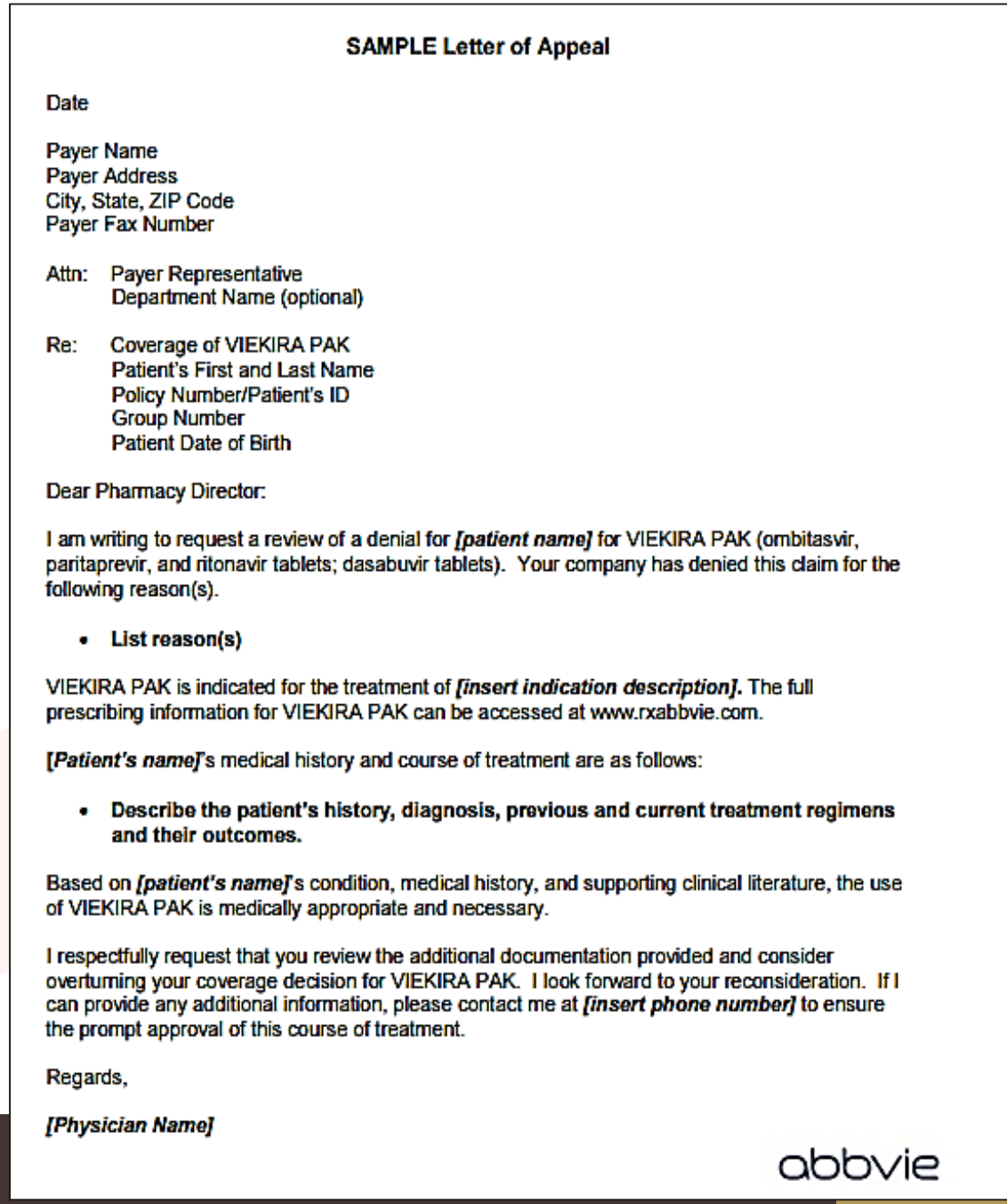
Denied- Now What?

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



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]

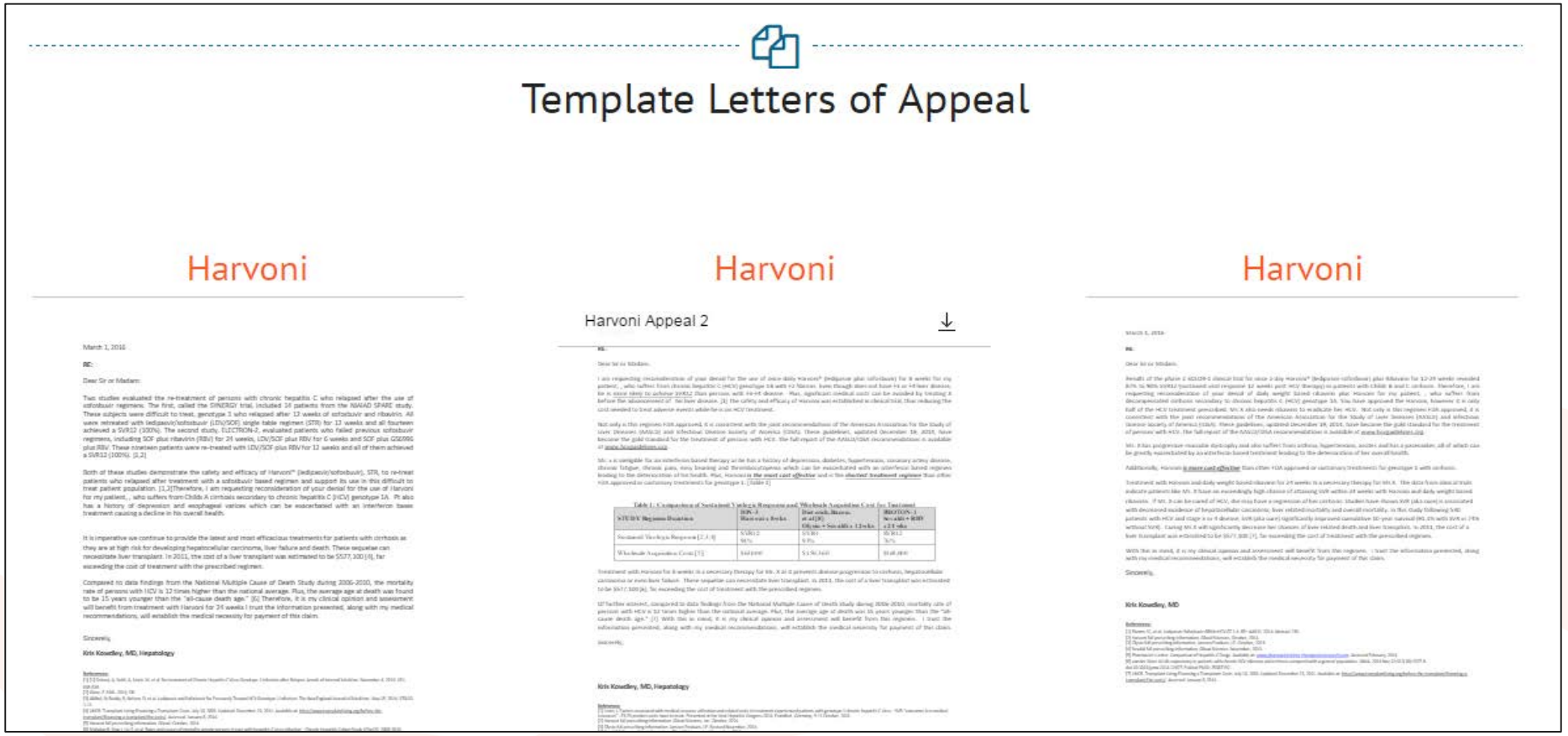
abbvie

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



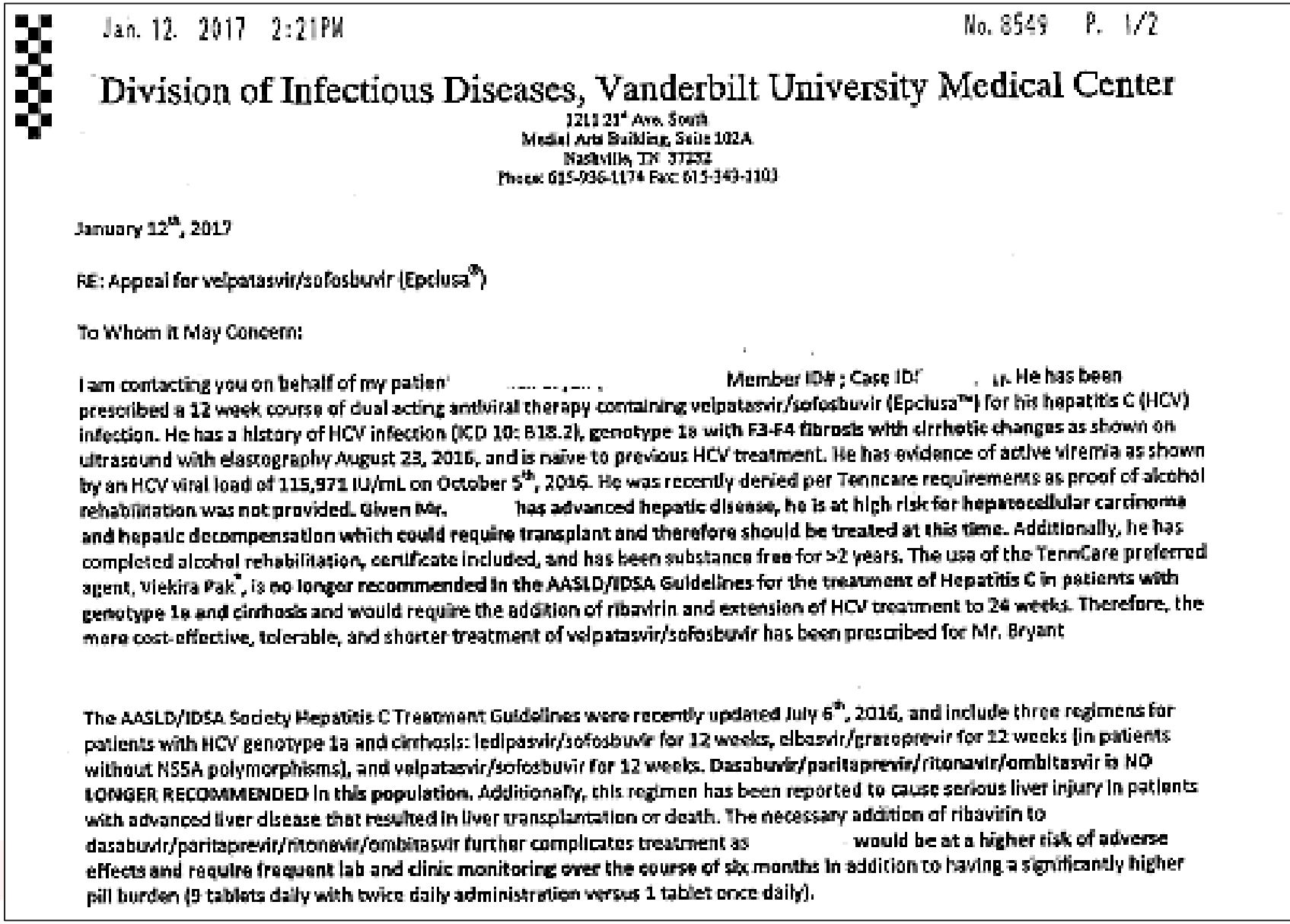
NVHR.org/hepatitis-c-treatment-access

PATIENT CASE 2: BILL APPEAL

Bill Appeal

- Relevant medical history
- Reason for denial
- Summary as to why she should be approved

- Guideline recommendations and support



Jan. 12. 2017 2:21PM No. 8549 P. 1/2

Division of Infectious Diseases, Vanderbilt University Medical Center

1211 21st Ave. South
Medical Arts Building, Suite 102A
Nashville, TN 37232
Phone 615-936-1174 Fax 615-343-1100

January 12th, 2017

RE: Appeal for velpatasvir/sofosbuvir (Epclusa®)

To Whom it May Concern:

I am contacting you on behalf of my patient [redacted] Member ID#: [redacted]; Case ID: [redacted]. He has been prescribed a 12 week course of dual acting antiviral therapy containing velpatasvir/sofosbuvir (Epclusa™) for his hepatitis C (HCV) infection. He has a history of HCV infection (ICD 10: B18.2), genotype 1a with F3-F4 fibrosis with cirrhotic changes as shown on ultrasound with elastography August 23, 2016, and is naive to previous HCV treatment. He has evidence of active viremia as shown by an HCV viral load of 115,971 IU/mL on October 5th, 2016. He was recently denied per Tenncare requirements as proof of alcohol rehabilitation was not provided. Given Mr. [redacted] has advanced hepatic disease, he is at high risk for hepatocellular carcinoma and hepatic decompensation which could require transplant and therefore should be treated at this time. Additionally, he has completed alcohol rehabilitation, certificate included, and has been substance free for >2 years. The use of the TennCare preferred agent, Viekira Pak®, is no longer recommended in the AASLD/IDSA Guidelines for the treatment of Hepatitis C in patients with genotype 1a and cirrhosis and would require the addition of ribavirin and extension of HCV treatment to 24 weeks. Therefore, the more cost-effective, tolerable, and shorter treatment of velpatasvir/sofosbuvir has been prescribed for Mr. Bryant

The AASLD/IDSA Society Hepatitis C Treatment Guidelines were recently updated July 6th, 2016, and include three regimens for patients with HCV genotype 1a and cirrhosis: ledipasvir/sofosbuvir for 12 weeks, elbasvir/grazoprevir for 12 weeks (in patients without NS5A polymorphisms), and velpatasvir/sofosbuvir for 12 weeks. Dasabuvir/paritaprevir/ritonavir/ombitasvir is NO LONGER RECOMMENDED in this population. Additionally, this regimen has been reported to cause serious liver injury in patients with advanced liver disease that resulted in liver transplantation or death. The necessary addition of ribavirin to dasabuvir/paritaprevir/ritonavir/ombitasvir further complicates treatment as [redacted] would be at a higher risk of adverse effects and require frequent lab and clinic monitoring over the course of six months in addition to having a significantly higher pill burden (9 tablets daily with twice daily administration versus 1 tablet once daily).

Bill Appeal

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

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

was prescribed velpatasvir/sofosbuvir over the other AASLD/IDSA Guidelines recommended regimens for the following reasons. Elbasvir/grazoprevir would require additional testing for NS5A resistance which is not clinically necessary at this time. Velpatasvir/sofosbuvir had an SVR12 rate of 99% (n=120/121) in cirrhotics in the ASTRAL-1 trial.Rates of SVR12 were lower with the use of dasabuvir/paritaprevir/ritonavir/ombitasvir plus ribavirin for 24 weeks in the TURQUOISE-II trial at 95%.

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

Sincerely,

Cody Chastain, MD
Infectious Diseases Specialty

CASE 2: BILL APPROVED!

On-Treatment Considerations

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

Outline

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

The Un-Insured and Under-Insured

Patient Assistance Programs (PAP)

- Criteria for approval
- Process of Application

Medication Delivery

- Setting up the first fill
- Patient Support on therapy

Underinsured

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

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

Uninsured

- Manufacture PAP process relatively simple
- All require the following:

Proof of Income	Proof of residency	Household size

• Tax return
• Copy of a disability or Medicare letter
• Social security income statement
• Retirement and/or pension statement
• Pay stub
	• State-issued ID
	• Letter of residency
	  • Rehab
	  • Housing establishment
	  • Caregiver
		• All income from anyone in the house

Proof of Income

- Letter stating income if no other option is available

To Whom It May Concern:

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

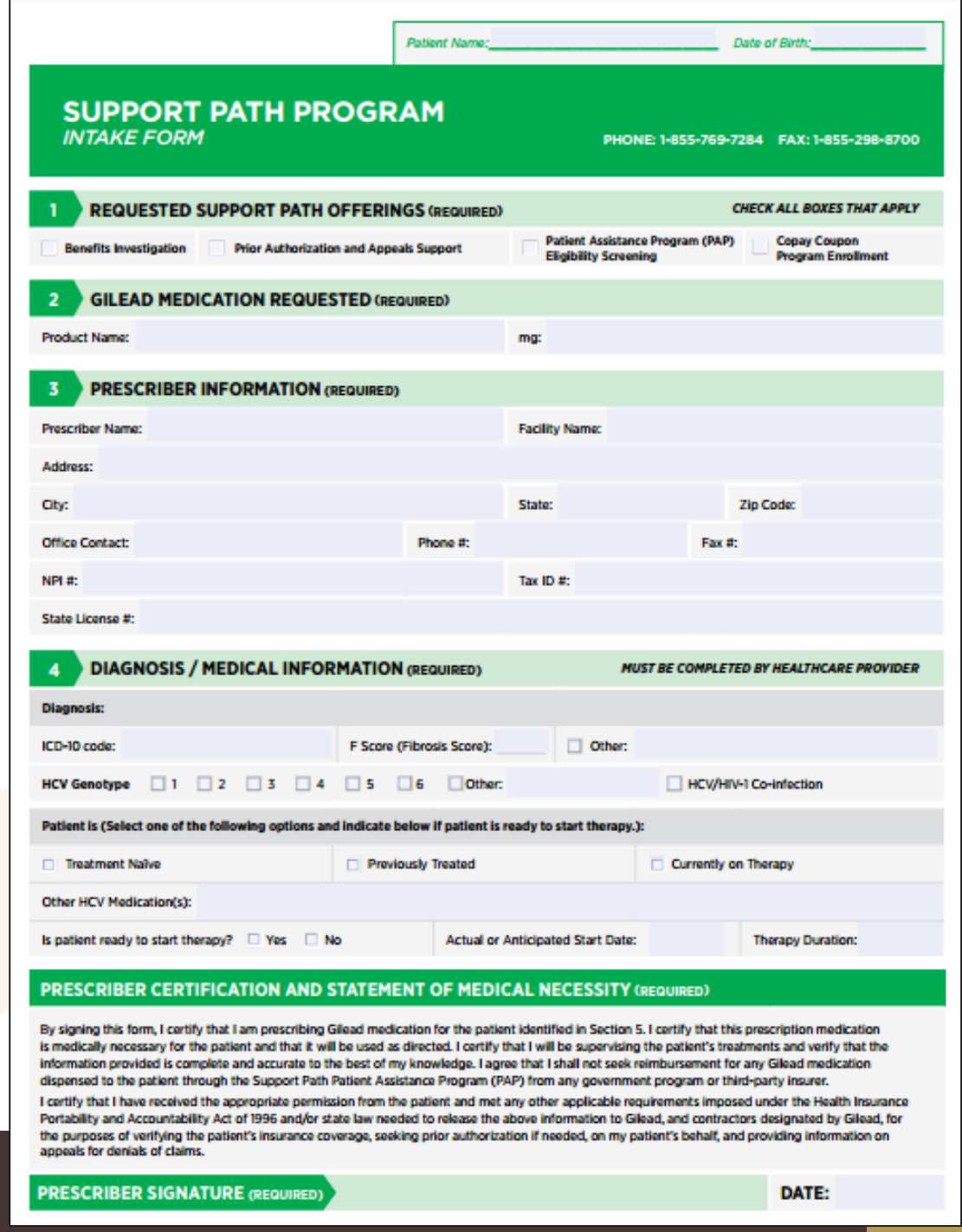
I live with my wife's uncle and do not pay rent at this time. I use food stamps for my meals. Unfortunately I am unable to afford health insurance at this time. I use a Merriweather Lewis discount card for my other medications.

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

Thank you,

PAP: Gilead

- 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:

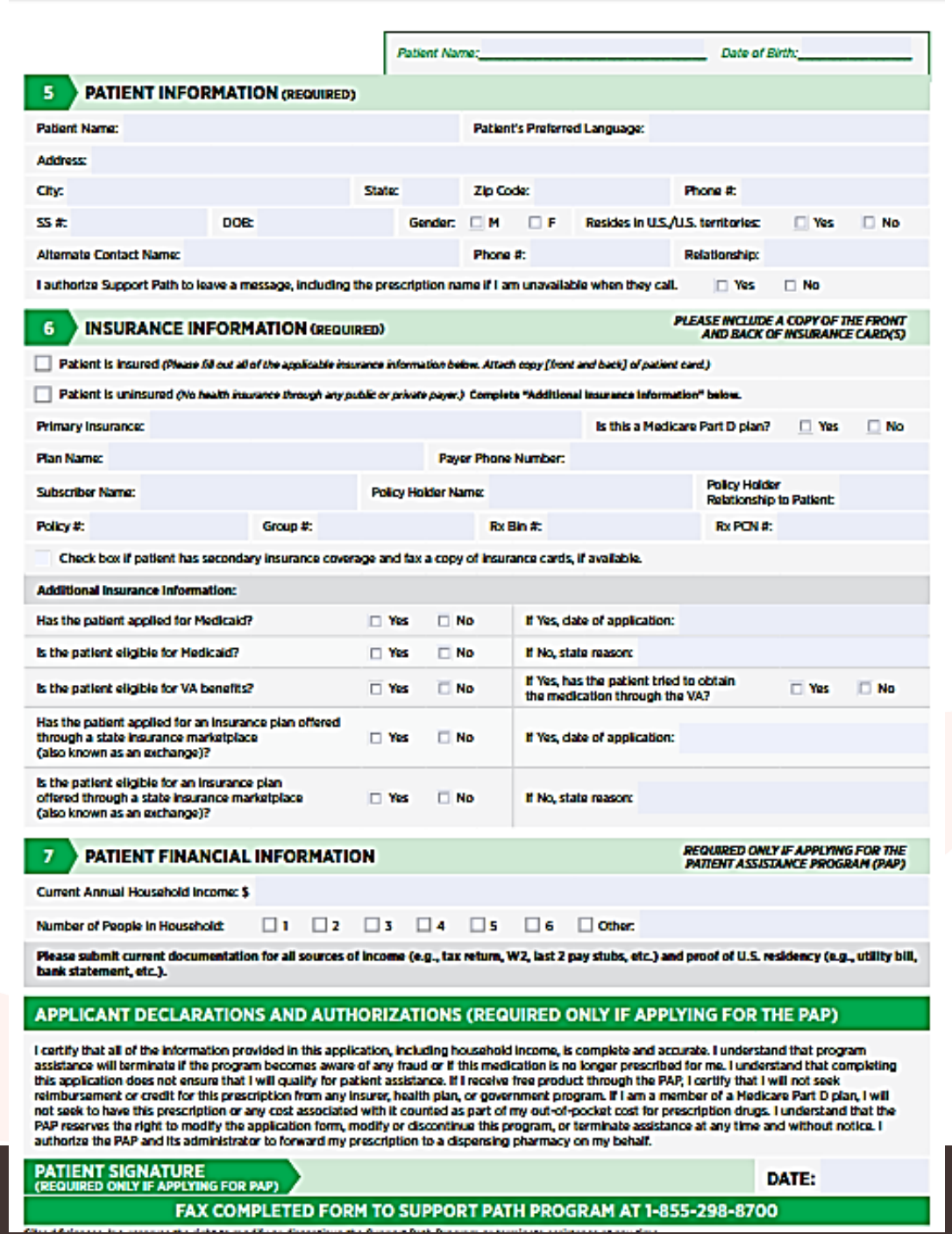
PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY (REQUIRED)

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:**

Patient signature required



Patient Name:_____ Date of Birth:_____

5 PATIENT INFORMATION (REQUIRED)

Patient Name: | Patient's Preferred Language:

Address:

City: | State: | Zip Code: | Phone #:

SS #: | DOB: | Gender: ☐ M ☐ F | Resides in U.S./U.S. territories: ☐ Yes ☐ No

Alternate Contact Name: | Phone #: | Relationship:

I authorize Support Path to leave a message, including the prescription name if I am unavailable when they call. ☐ Yes ☐ No

6 INSURANCE INFORMATION (REQUIRED) *PLEASE INCLUDE A COPY OF THE FRONT AND BACK OF INSURANCE CARD(S)*

☐ Patient is insured *(Please fill out all of the applicable insurance information below. Attach copy [front and back] of patient card.)*

☐ Patient is uninsured *(No health insurance through any public or private payer.)* Complete "Additional Insurance Information" below.

Primary Insurance: | Is this a Medicare Part D plan? ☐ Yes ☐ No

Plan Name: | Payer Phone Number:

Subscriber Name: | Policy Holder Name: | Policy Holder Relationship to Patient:

Policy #: | Group #: | Rx Bin #: | Rx PCN #:

☐ Check box if patient has secondary insurance coverage and fax a copy of insurance cards, if available.

Additional Insurance Information:

Has the patient applied for Medicaid?	☐ Yes ☐ No	If Yes, date of application:	
Is the patient eligible for Medicaid?	☐ Yes ☐ No	If No, state reason:	
Is the patient eligible for VA benefits?	☐ Yes ☐ No	If Yes, has the patient tried to obtain the medication through the VA?	☐ Yes ☐ No
Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	☐ Yes ☐ No	If Yes, date of application:	
Is the patient eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	☐ Yes ☐ No	If No, state reason:	

7 PATIENT FINANCIAL INFORMATION *REQUIRED ONLY IF APPLYING FOR THE PATIENT ASSISTANCE PROGRAM (PAP)*

Current Annual Household Income: $

Number of People in Household: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other:

Please submit current documentation for all sources of income (e.g., tax return, W2, last 2 pay stubs, etc.) and proof of U.S. residency (e.g., utility bill, bank statement, etc.).

APPLICANT DECLARATIONS AND AUTHORIZATIONS (REQUIRED ONLY IF APPLYING FOR THE PAP)

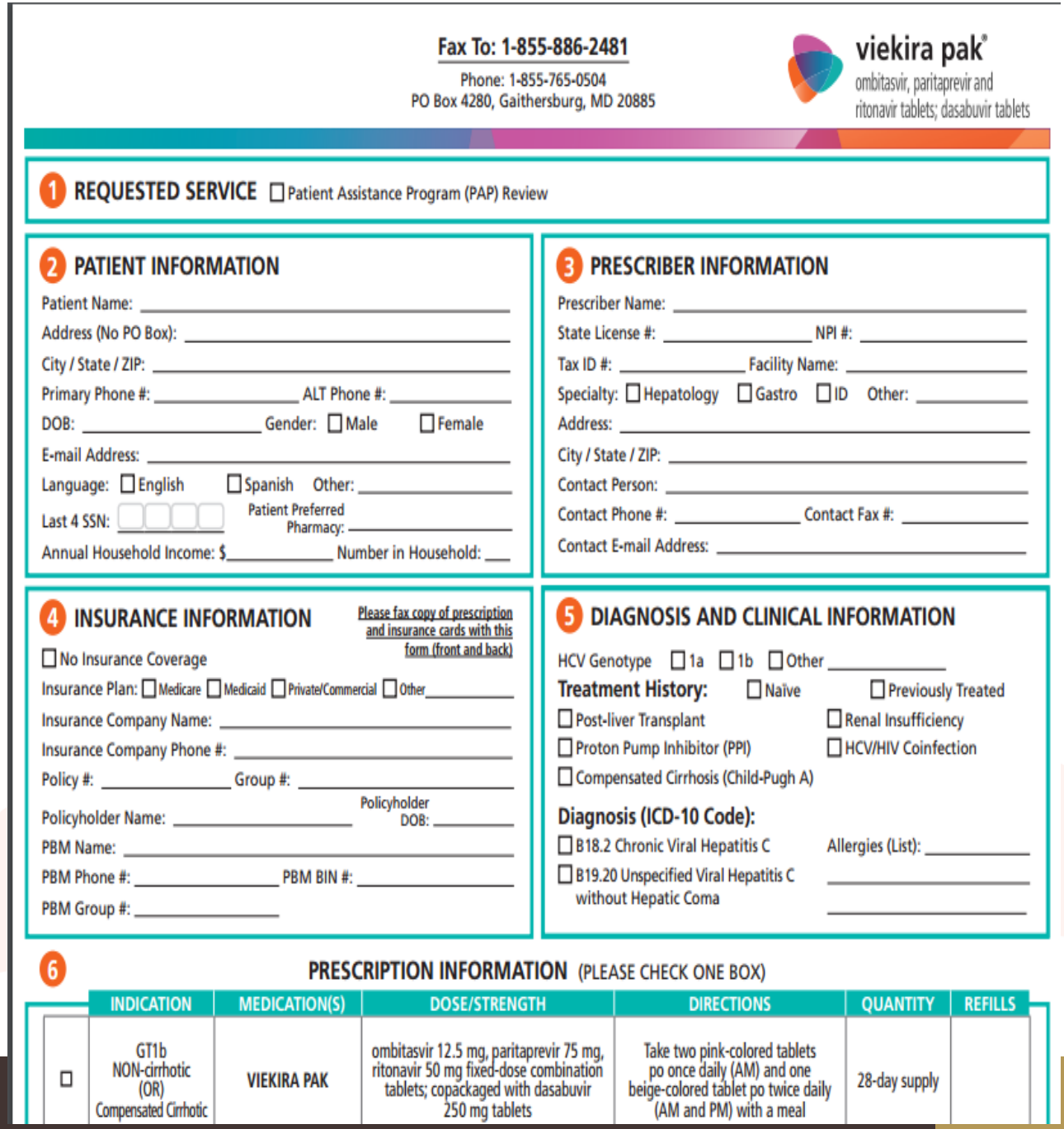
I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if the program becomes aware of any fraud or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. If I receive free product through the PAP, I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this prescription or any cost associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that the PAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize the PAP and its administrator to forward my prescription to a dispensing pharmacy on my behalf.

PATIENT SIGNATURE (REQUIRED ONLY IF APPLYING FOR PAP) **DATE:**

FAX COMPLETED FORM TO SUPPORT PATH PROGRAM AT 1-855-298-8700

PAP: Abbvie Viekira Pak®

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



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

viekira pak®
ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets

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
☐ B19.20 Unspecified Viral Hepatitis C without Hepatic Coma
Allergies (List): _____

6 PRESCRIPTION INFORMATION (PLEASE CHECK ONE BOX)

	INDICATION	MEDICATION(S)	DOSE/STRENGTH	DIRECTIONS	QUANTITY	REFILLS
☐	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 Viekira XR®

- https://www.viekira.com/hcp/access-and-support-resources
- Eligibility:
  - Provide income and household size
  - <$100,000 per year

viekira XR™
dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets

Fax To: 1-855-886-2481
Phone: 1-855-687-7503
PO Box 4280, Gaithersburg, MD 20885

1 PATIENT INFORMATION

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: _____
Shipping Preference (if eligible): ☐ Ship to Patient ☐ Ship to Provider Annual Household Income: $_____ Number in Household (including self): ___
Please include income documentation for your household, such as a copy of your current federal tax return.

2 PRESCRIBER INFORMATION

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 include a 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 DIAGNOSIS AND CLINICAL INFORMATION

HCV Genotype: ☐ 1a ☐ 1b ☐ Other _____
Fibrosis (F) Score: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Treatment History:
☐ Naive ☐ Previously Treated
☐ Other Medications _____
Medical History:
☐ Post-liver Transplant ☐ Renal Insufficiency
☐ Proton Pump Inhibitor (PPI) Use ☐ HCV/HIV Coinfection
☐ Compensated Cirrhosis (Child-Pugh A)
Diagnosis (ICD-10 Code): ☐ B18.2 Chronic Viral Hepatitis C
☐ B19.20 Unspecified Viral Hepatitis C without Hepatic Coma
Allergies (List): _____
Vaccination for Hep A and B: ☐ No ☐ Yes Year _____

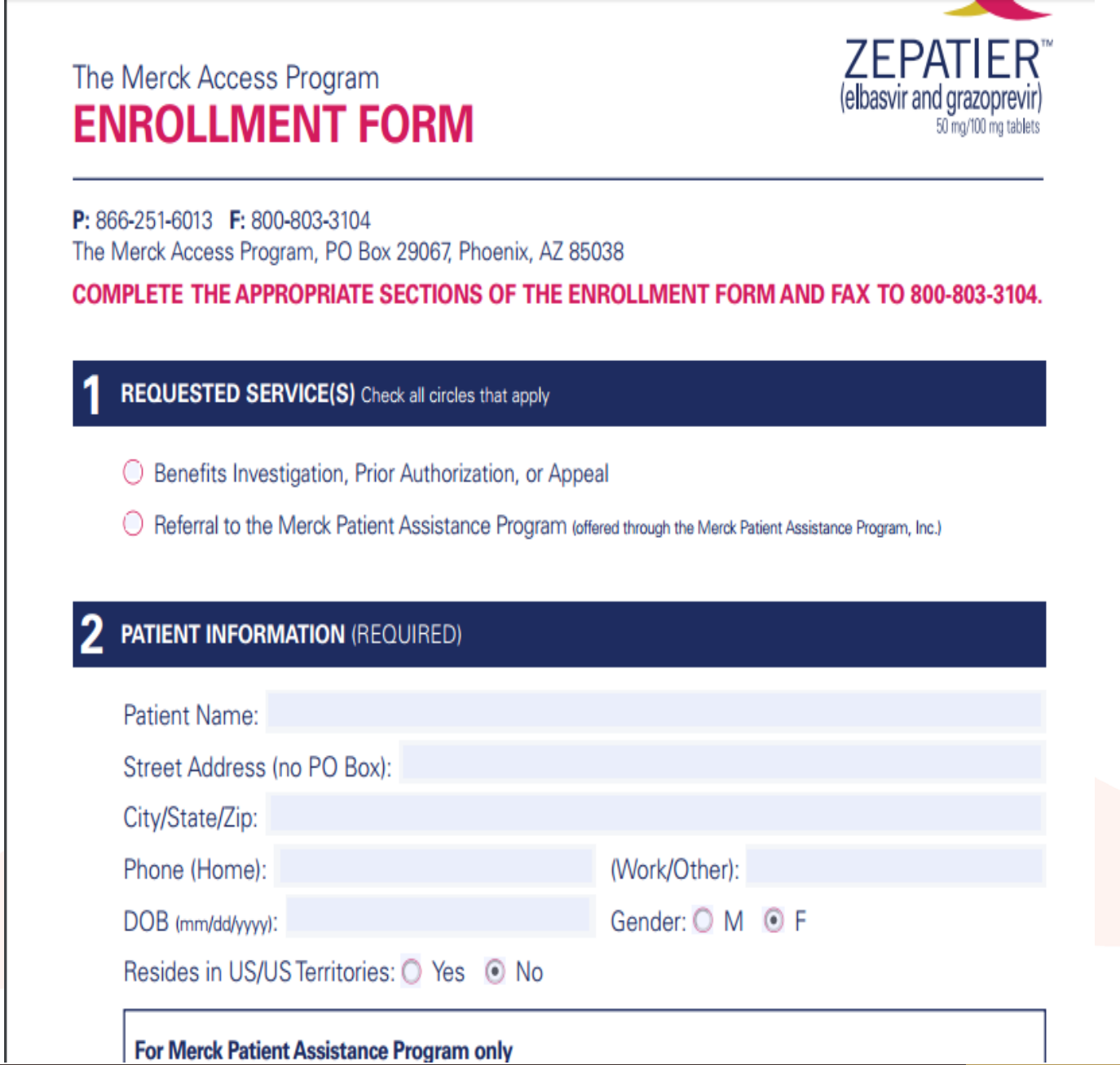
5 PRESCRIPTION INFORMATION (PLEASE CHECK ONE BOX)

	INDICATION	MEDICATION(S)	DOSE/STRENGTH	DIRECTIONS	QUANTITY	REFILLS
☐	GT1b NON-cirrhotic (OR) Compensated Cirrhotic (Child-Pugh A)	VIEKIRA XR	dasabuvir 200 mg, ombitasvir 8.33 mg, paritaprevir 50 mg, ritonavir 33.33 mg	Take three tablets once daily with a meal	28-day supply	
☐	GT1a NON-cirrhotic (OR) Compensated Cirrhotic (Child-Pugh A)	VIEKIRA XR	dasabuvir 200 mg, ombitasvir 8.33 mg, paritaprevir 50 mg, ritonavir 33.33 mg	Take three tablets once daily with a meal	28-day supply	
		Ribavirin	_____mg	Take _____ tabs/caps po AM and _____ tabs/caps po PM	28-day supply	

New York Prescribers, please submit prescription per NY state legal restrictions. For all other states, if not faxed, must be on state-specific form, if applicable.

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.)

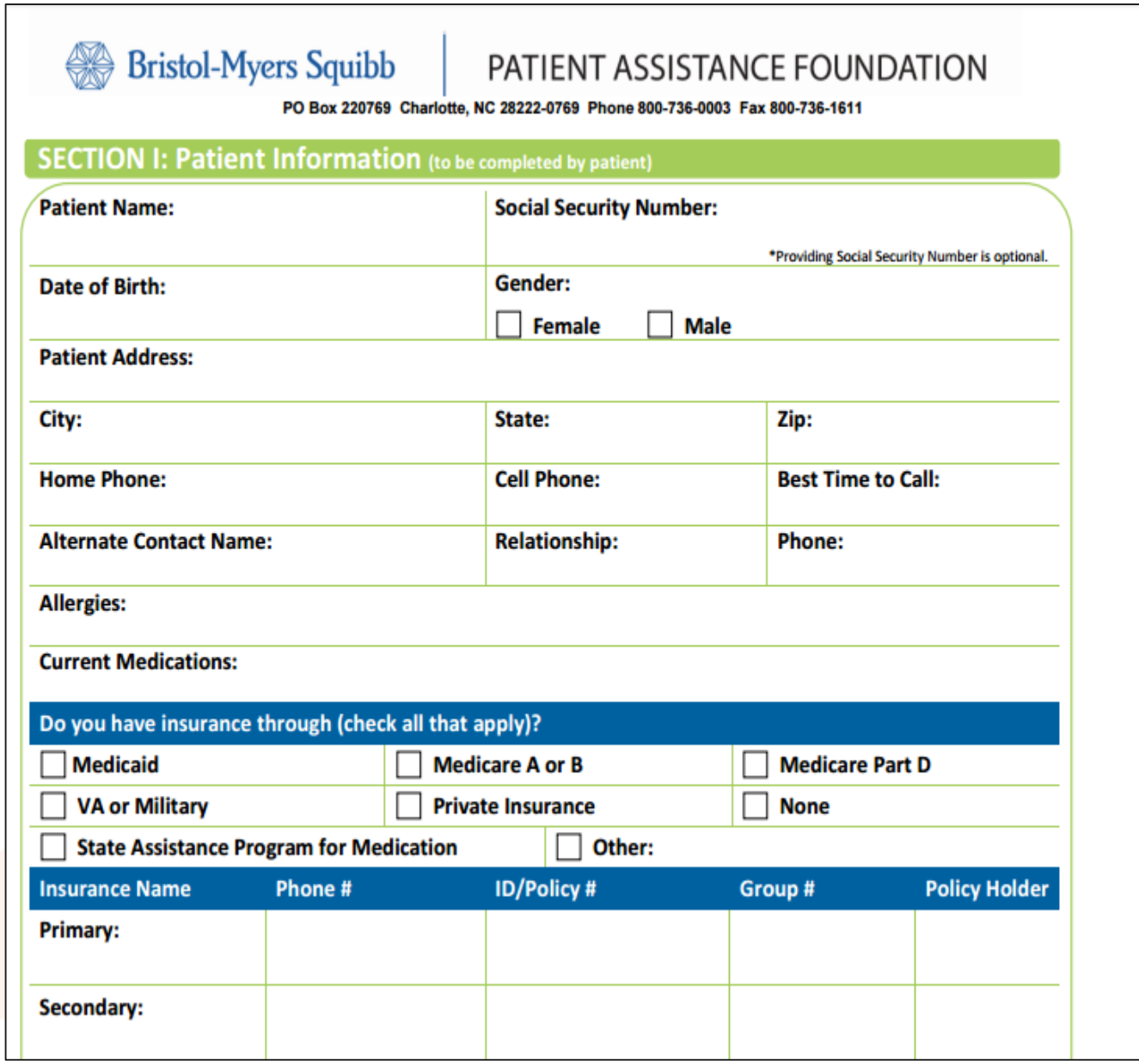
2 PATIENT INFORMATION (REQUIRED)

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

PAP: BMS

- http://www.bmspaf.org/Pages/Home.aspx
- Eligibility:
  - US resident
  - No insurance or 2 appeals denied by insurance or Medicare Part D and ≥3% household income spent on prescriptions costs/year
  - Household income below 300% of FPL
    - $35,640 for one
    - $48,060 for a couple



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: ☐ Female ☐ 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)?

☐ Medicaid	☐ Medicare A or B	☐ Medicare Part D
☐ VA or Military	☐ Private Insurance	☐ None
☐ State Assistance Program for Medication	☐ Other:	

Insurance Name	Phone #	ID/Policy #	Group #	Policy Holder
Primary:				
Secondary:				

BACK TO PATIENT CASE 2: BILL

WHAT IF HE HAD BEEN DENIED?

Bill

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

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

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

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

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

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

Best,

Autumn Bagwell

Autumn Bagwell, PharmD, BCPS

Bill

APPROVED!

GILEAD

Support Path Program

PH: (855) 769-7284
FX: (855) 298-8700

August 15, 2016

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

Re: Patient Assistance Program Enrollment
Service Request Number:

Dear Dr. Cody Chastain:

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

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

Please complete the prescription request form on the following page and fax it to US Bioservices at **855-850-2954**. Once a valid prescription form is received, a pharmacy representative will contact the shipment contact noted on the prescription form to set up shipment.

Please do not hesitate to contact the Support Path Program at 855-769-7284, Monday through Friday between 9:00AM and 8:00PM Eastern Time, with any questions.

Sincerely,

Support Path Program

PAP Medication Delivery

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

Outline

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

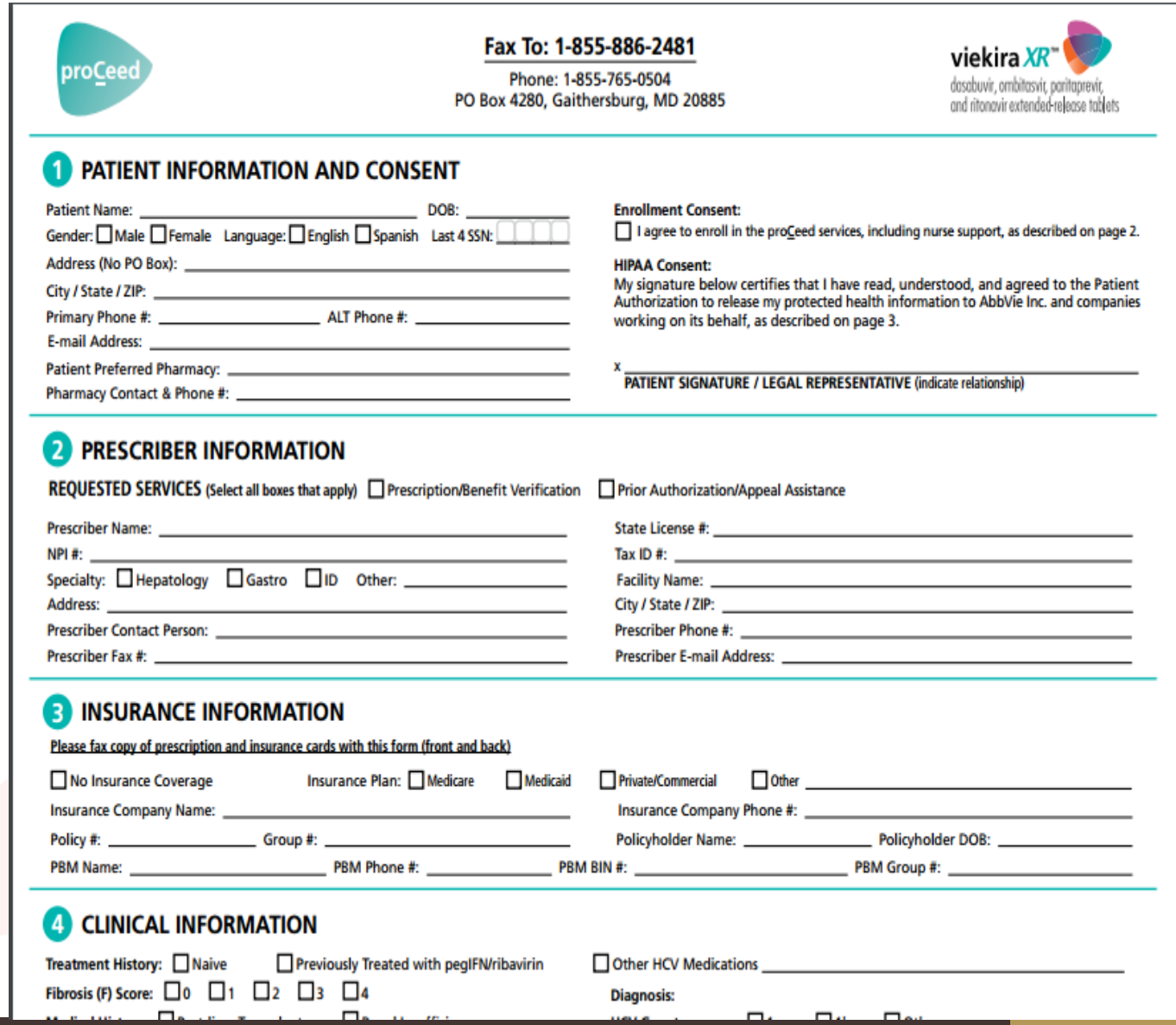
Provider Support: Gilead SupportPath

- Gilead SupportPath iAssist

ePrescription Processing	ePA	Support Path Assistance
• Submit an ePrescription • Confirm patient's insurance • Complete and submit a PA • Send all infromation directly to a pharmacy • Register for the patient education program • Enroll a patient for copay coupon	• Send an online PA without an ePrescription	• Benefits investigation and summary of benefits • Comprehensive PA support • Support for claims appeals and denials • Access to Support Path representatives who work on patient's behalf

Provider Support: Abbvie ProCeed

- Benefits Verification
- PA/Appeal
  - Obtain the appropriate form
  - Track the PA
- Triage prescription to the pharmacy



proCeed

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

viekira XR™
dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets

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: 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

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 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)

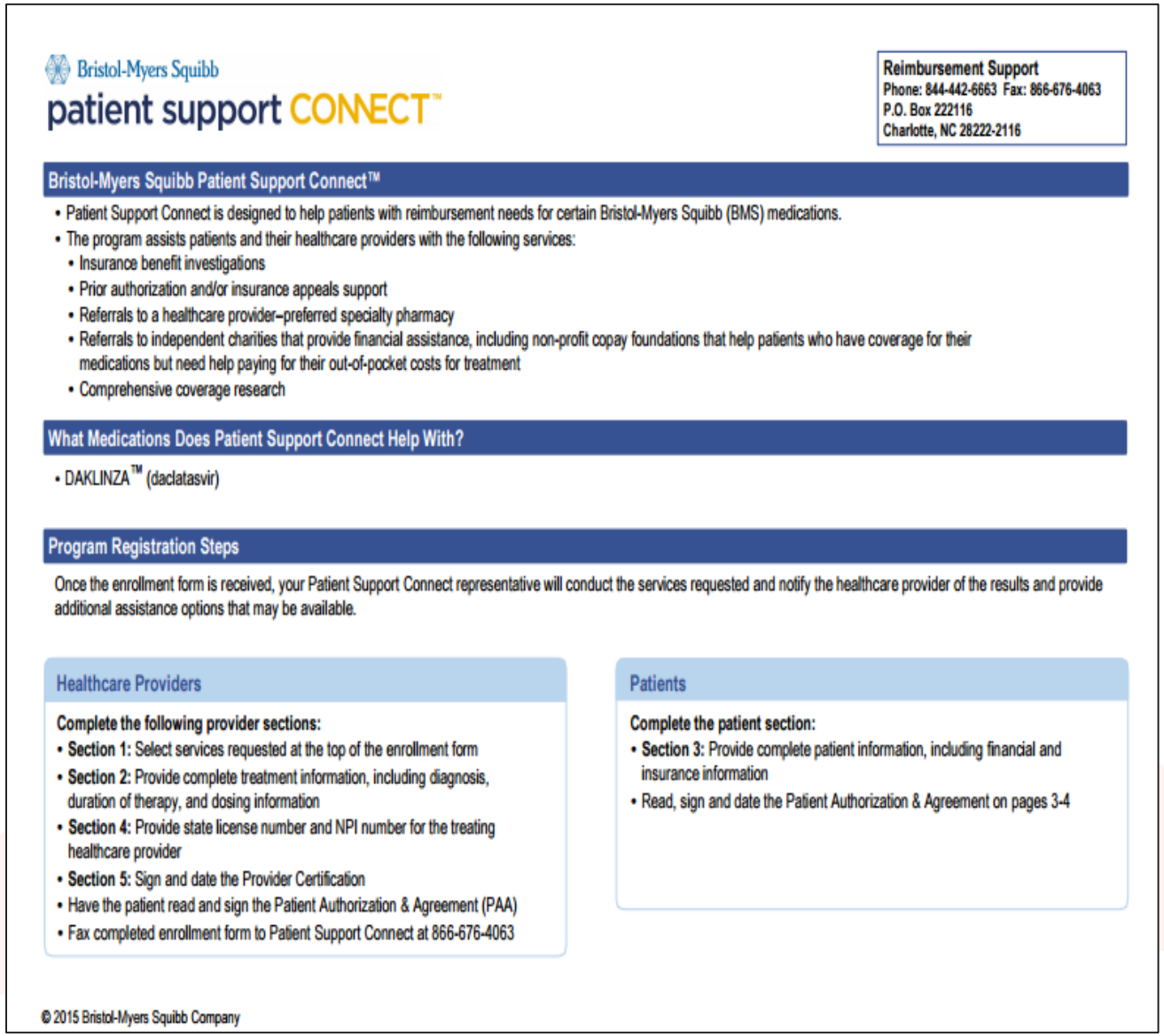
Patient Name:
Street Address (no PO Box):
City/State/Zip:
Phone (Home): (Work/Other):
DOB (mm/dd/yyyy): Gender: ○ M ○ F
Resides in US/US Territories: ○ Yes ○ No

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):

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



Bristol-Myers Squibb

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

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Other Access Resources

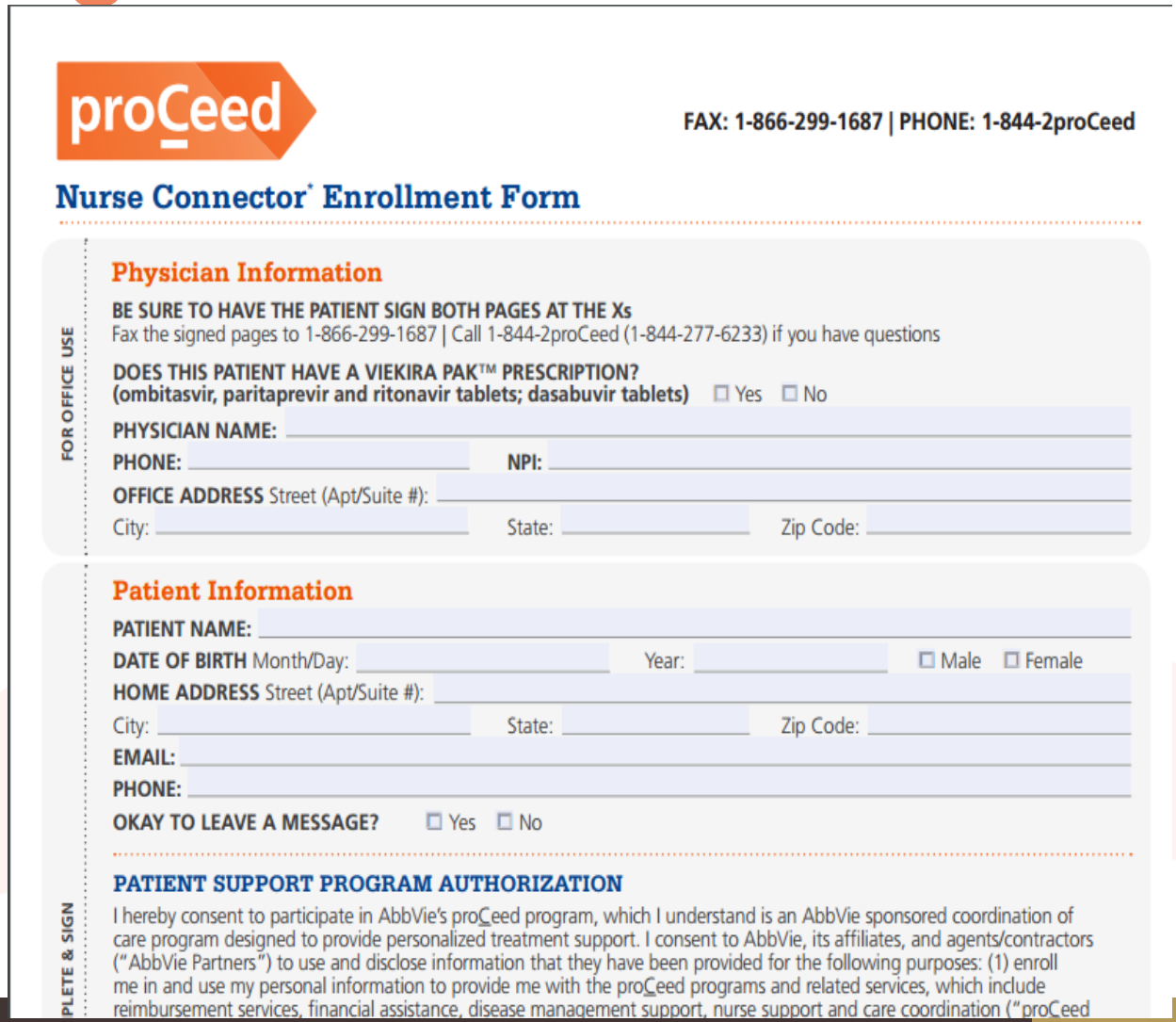
- National Viral Hepatitis Roundtable
  - NVHR.org/hepatitis-c-treatment-acces
- Hepatitis C New Drug Research
  - http://hepatitiscnewdrugresearch.com/hcv-drugs-financial-support.html
- American Liver Foundation
  - http://hepc.liverfoundation.org/resources/what-if-i-need-financial-assistance-to-pay-for-treatment/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

Outline

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

Patient Support through Manufacturers

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



proCeed

FAX: 1-866-299-1687 | PHONE: 1-844-2proCeed

Nurse Connector® Enrollment Form

FOR OFFICE USE

Physician Information

BE SURE TO HAVE THE PATIENT SIGN BOTH PAGES AT THE Xs
Fax the signed pages to 1-866-299-1687 | Call 1-844-2proCeed (1-844-277-6233) if you have questions

DOES THIS PATIENT HAVE A VIEKIRA PAK™ PRESCRIPTION?
(ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) ☐ Yes ☐ No

PHYSICIAN NAME: _____

PHONE: _____ NPI: _____

OFFICE ADDRESS Street (Apt/Suite #): _____

City: _____ State: _____ Zip Code: _____

Patient Information

PATIENT NAME: _____

DATE OF BIRTH Month/Day: _____ Year: _____ ☐ Male ☐ Female

HOME ADDRESS Street (Apt/Suite #): _____

City: _____ State: _____ Zip Code: _____

EMAIL: _____

PHONE: _____

OKAY TO LEAVE A MESSAGE? ☐ Yes ☐ No

PLETE & SIGN

PATIENT SUPPORT PROGRAM AUTHORIZATION

I hereby consent to participate in AbbVie's proCeed program, which I understand is an AbbVie sponsored coordination of care program designed to provide personalized treatment support. I consent to AbbVie, its affiliates, and agents/contractors ("AbbVie Partners") to use and disclose information that they have been provided for the following purposes: (1) enroll me in and use my personal information to provide me with the proCeed programs and related services, which include reimbursement services, financial assistance, disease management support, nurse support and care coordination ("proCeed

Patient Support through Manufacturers

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

Summary

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

Thank you!

Questions?

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