AETC AIDS Education & Training Center Program Southeast

From Prescription to Patient:

Navigating Barriers to HCV Treatment Initiation

Autumn Bagwell, PharmD, BCPS
Vanderbilt Specialty Pharmacy

Objectives

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

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

Disclosure

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

Outline

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

Outline

- **The problem:**
  - **HCV treatment financial burden**
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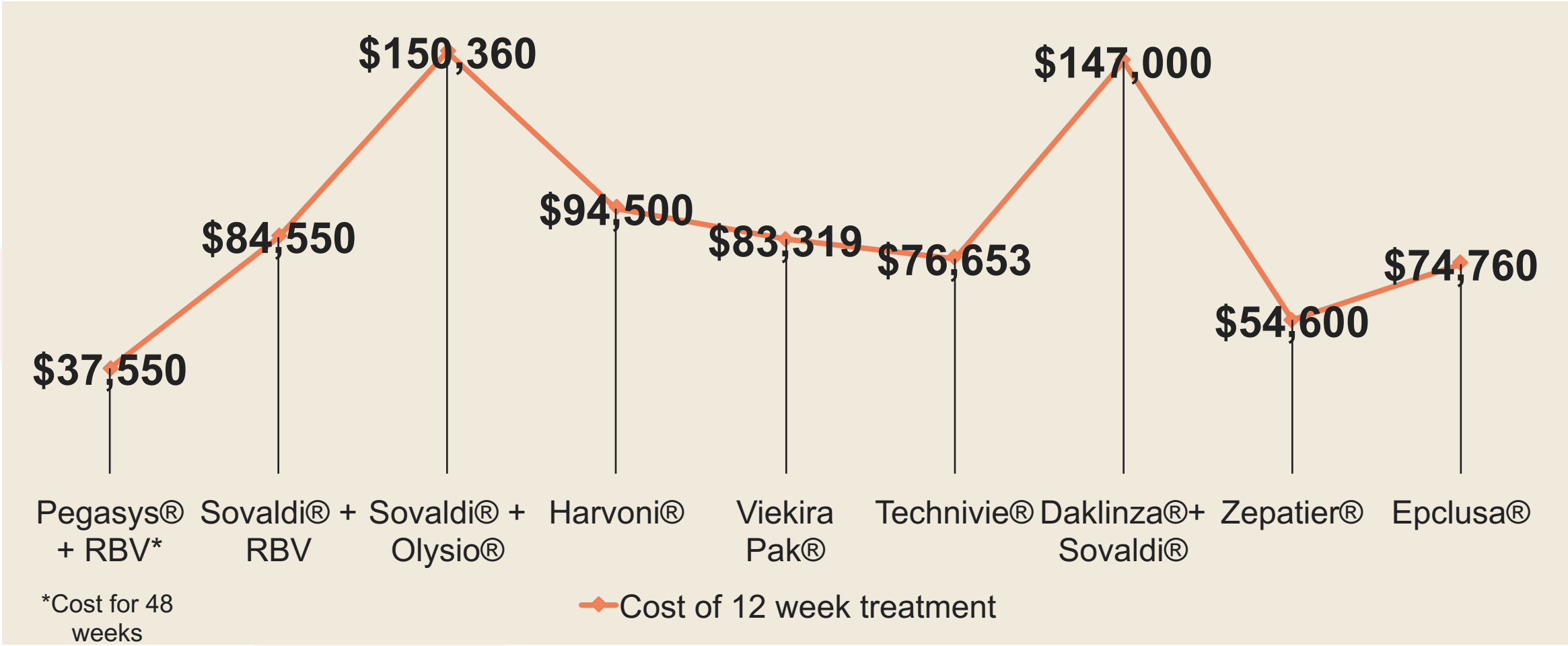
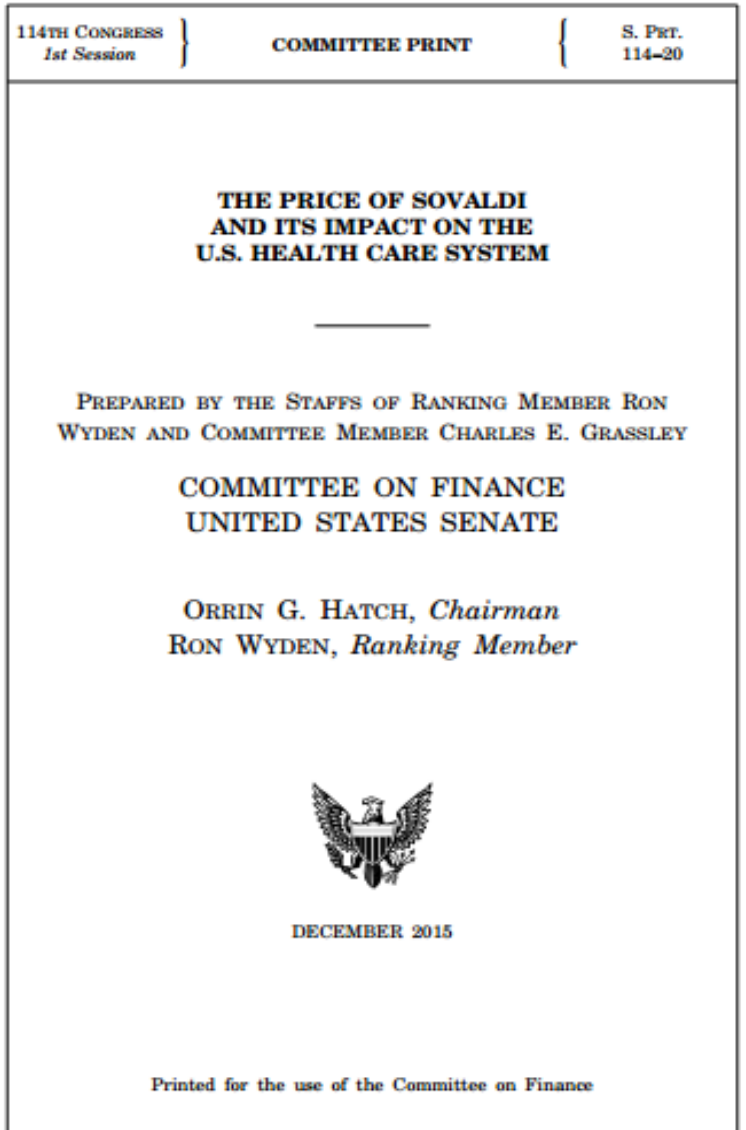
Cost of HCV Treatment



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

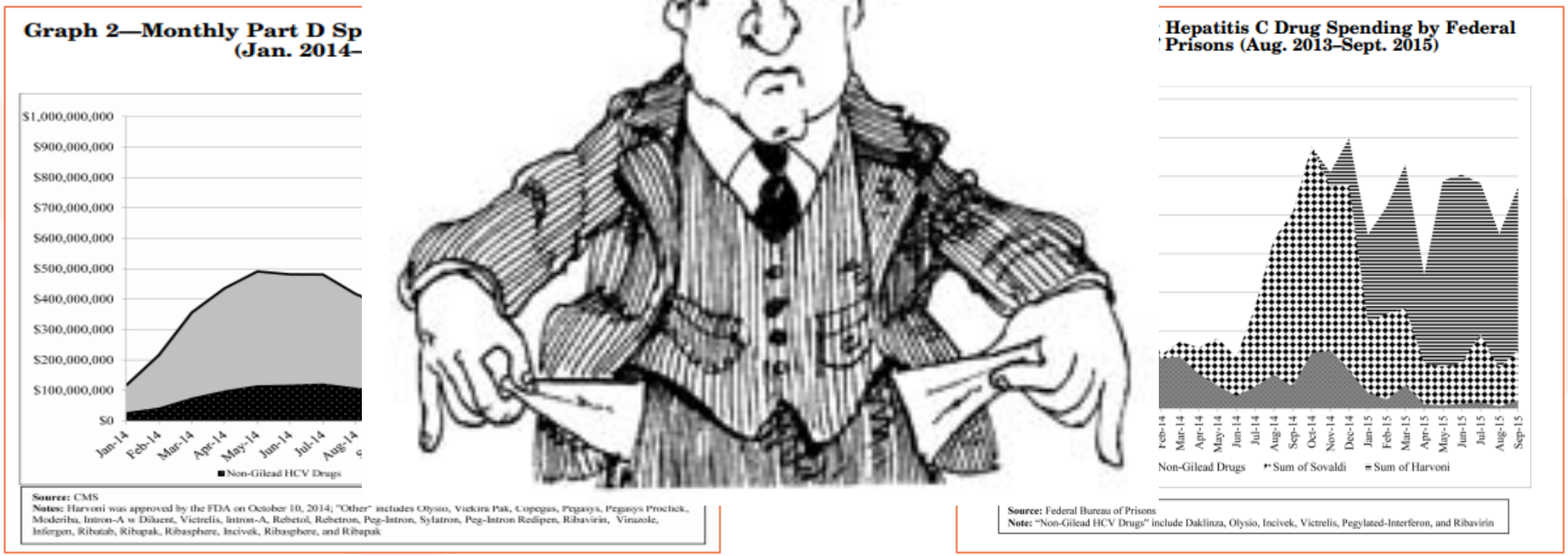
ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

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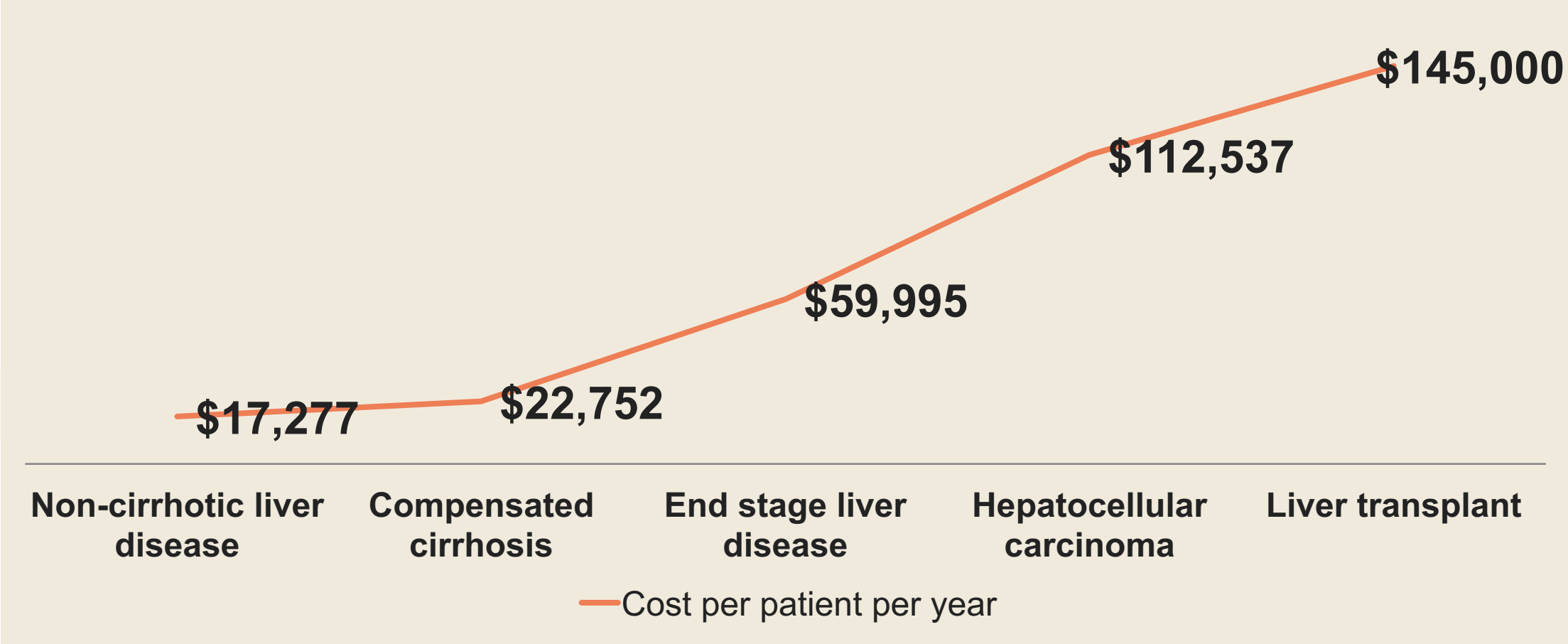
The same pill that costs $1,000 in the U.S. sells for $4 in India

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

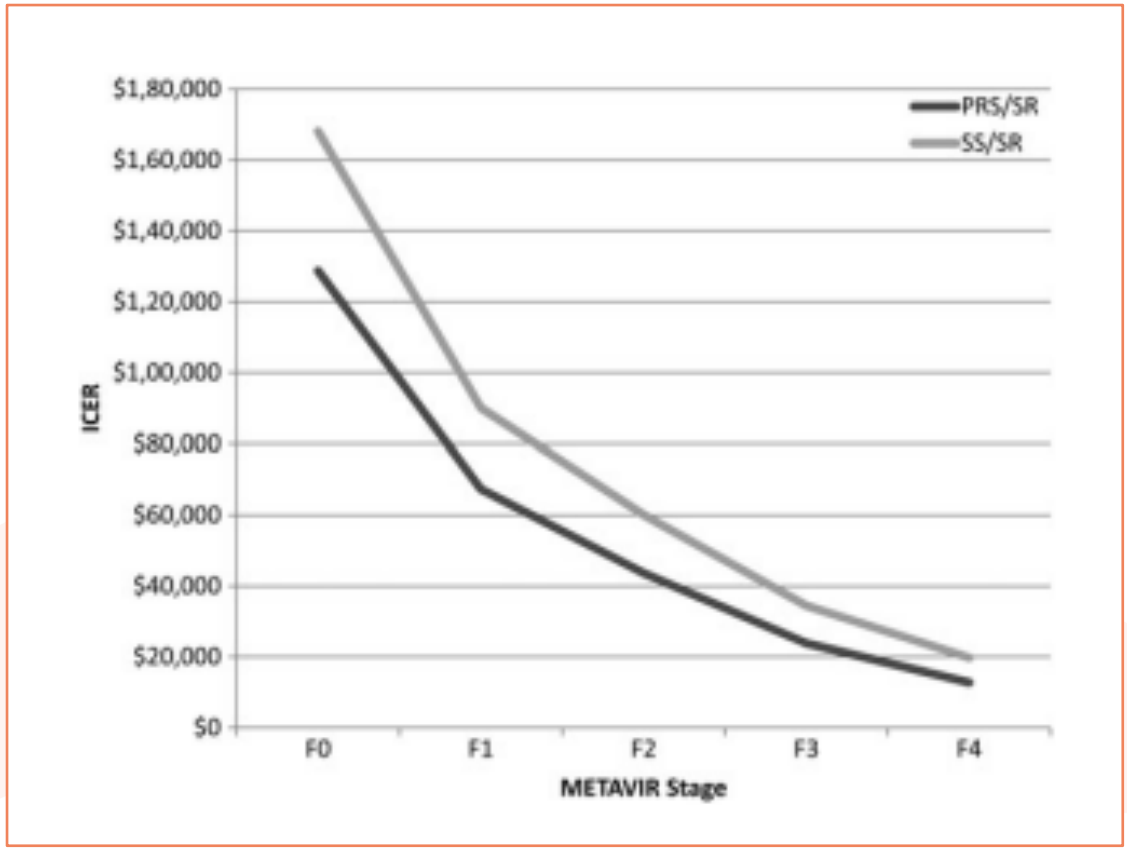
Chahal, Harinder S., et al. "Cost-effectiveness of early treatment of hepatitis C virus genotype 1 by stage of liver fibrosis in a US treatment-naive population." *JAMA internal medicine* 176.1 (2016): 65-73.

The Cost-effectiveness, Health Benefits, and Financial Costs of New Antiviral Treatments for Hepatitis C Virus

David B. Rein,[1] John S. Wittenborn,[1] Bryce D. Smith,[2] Danielle K. Liffmann,[1] and John W. Ward[2]

[1]Public Health Department, NORC at the University of Chicago, and [2]Division of Viral Hepatitis, Centers for Disease Control and Prevention, Atlanta, Georgia

- Compared among treatment regimens
- Cost-effectiveness of Harvoni and Viekira Pak:
  - $25,000 per QALY gained compared to PegIFN/RBV/SOF
  - $32,000 per QALY compared to no treatment



Rein DB, Wittenborn JS, Smith BD, Liffmann DK, Ward JW. The cost-effectiveness, health benefits, and financial costs of new antiviral treatments for hepatitis C virus. Clin Infect Dis. 2015;61(2):157-68.

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: NM

- Young female
- HIV/HCV coinfection on Triumeq
- Genotype 6
- Treatment naïve
- Stage F0 to F1 fibrosis
- Household income: $21,000 for family of 3
- Tenncare insurance

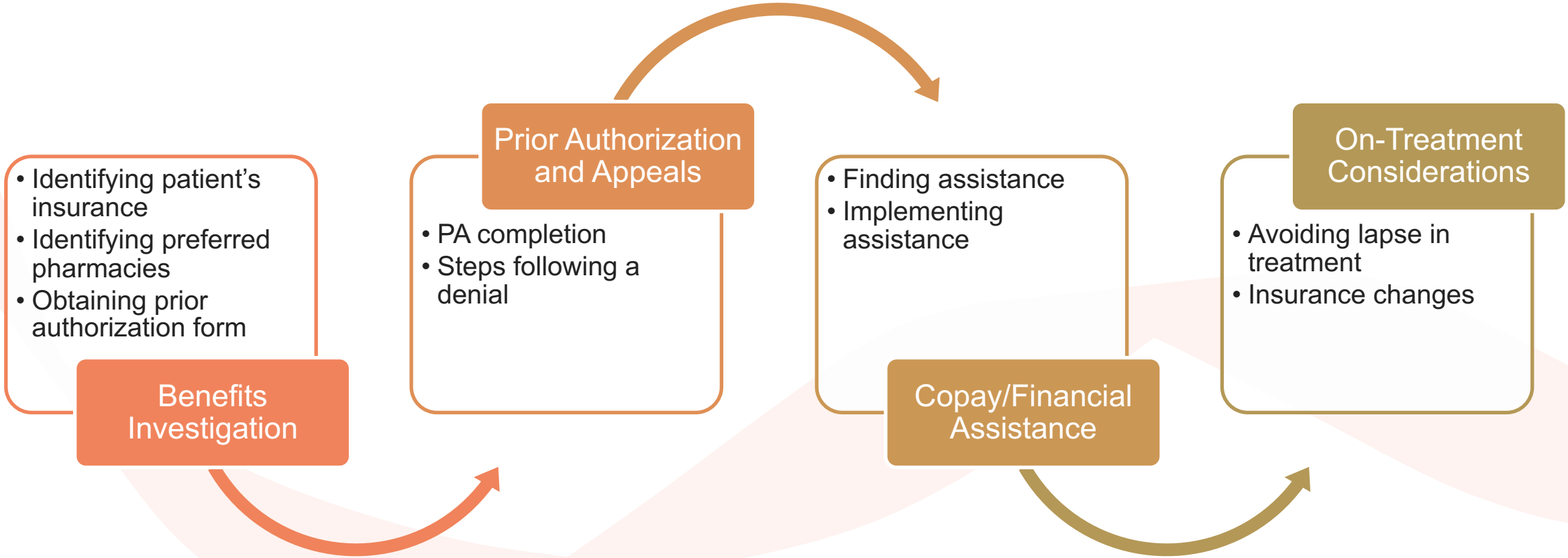
Patient Case 2: TM

- Older male
- HIV/HCV coinfection on Descovy, Prezista, Norvir, and Tivicay
- Genotype 3
- Cirrhosis
- OptumRx insurance

Patient Case 3: JL

- Middle aged male
- HIV/HCV coinfection on Triumeq
- Genotype 1a
- F0 fibrosis
- Express Scripts insurance

The Insured


Benefits Investigation
• Identifying patient's insurance
• Identifying preferred pharmacies
• Obtaining prior authorization form
Prior Authorization and Appeals
• PA completion
• Steps following a denial
Copay/Financial Assistance
• Finding assistance
• Implementing assistance
On-Treatment Considerations
• Avoiding lapse in treatment
• Insurance changes

Benefits Investigation

- Goals:
  1. Determine insurance eligibility
     - Do they have **active** prescription insurance?
     - Who is the pharmacy benefits manager (PBM)?
  2. Identify preferred pharmacies
     - Do they have to fill with a certain pharmacy?
     - Is there a penalty to fill with patient's preferred pharmacy?
  3. Obtain prior authorization (PA) form
     - Phone PAs are usually not effective and lead to immediate denial (*in general, for now*)

Benefits Investigation

- Steps for providers:
  - If you have a preferred pharmacy → send them the prescription
    - Pharmacies can run benefits claims
  - Discuss patient with designated support staff

Benefits Investigation

- Steps for designated staff:
  1. Obtain prescription processing information
     - Check patient's chart or ask patient about their local pharmacy
     - Call patient for prescription processing information
  2. Obtain eligibility and requirements for HCV therapy
     - Call pharmacy line from prescription insurance plan
       - Preferred pharmacy and any penalties or fill limits for using patient-preferred pharmacy
       - Deductible
       - Out of pocket expense
       - PA requirements → transferred to PA department
       - Request PA form faxed to office

Prior Authorization

- Steps for designated staff:
  - Fax Option:
    - Call prescription insurance prior authorization department (obtained from eligibility check)
    - Complete PA paperwork
    - Fax back to insurance
  - Electronic Option:
    - Covermymeds.com
      - All paperwork completed online

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: NM

Print Form | Reset Form

TennCare Prior Authorization Form

Harvoni®

Access this PA form at https://tenncare.magellanhealth.com/portal/docs/Prior_Authorization_Forms/TennCare_Harvoni_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 - 322 - | FAX NUMBER: 615 - 343 -

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 or highest risk for disease progression
- Daily dose of one tablet per day
- Chronic Hepatitis C, Genotype 1
- Usage per FDA package insert
- Must have a contraindication or clinically significant drug-drug interaction with the preferred agent
- Patient has been evaluated for potential clinically significant drug interactions

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.
- Patient alcohol abuse consumption tests and/or urine toxicology test dates are > 14 days from the date of the PA request.
- Patient has decompensated cirrhosis
- Patient will be receiving concomitant therapy with a hepatitis protease inhibitor
- Patient has previously received treatment with sofosbuvir and/or ledipasvir
- 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 & attach documentation of lab values****

Laboratory Documentation		
Baseline HCV RNA level	10557665	12/2/15
Week 4 HCV RNA level		
Week 12 HCV RNA level		

Magellan HEALTH SERVICES

TennCare Prior Authorization Form

Harvoni®

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 for which this drug is being requested?
   - ☐ Chronic Hepatitis C, genotype 1, Continue to Question #2
   - ☒ Other Genotype 6
2. For females: Is the patient pregnant? ☐ Yes ☒ No
3. Is the patient's Creatinine clearance greater than 30 ml/minute? ☒ Yes ☐ No
4. Does the patient have End-stage renal disease? ☐ Yes ☒ No
5. Please check if the patient has any of the following. If yes, documentation must be attached.
   - ☐ Liver biopsy showing Metavir score of F3/F4
   - ☐ Fibrotest (FibroSure) score of ≥ 0.59
   - ☐ Ultrasound based transient elastography (Fibroscan) score ≥ 9.5 kPa
   - ☐ Fibrosis-4 index (FIB-4) > 3.25

   US w/ elastography consistent with F0-F1 disease
6. Please check if the patient has any of the following. If yes, documentation must be attached.
   - ☐ Essential mixed cryoglobulinemia with end organ manifestations
   - ☐ Proteinuria
   - ☐ Nephrotic Syndrome
   - ☐ Membranoproliferative glomerulonephritis
7. Has the patient had prior treatment for Chronic Hepatitis C with a protease inhibitor? ☐ Yes ☒ No
   - If yes, attach documentation of current positive HCV RNA
   - If no, go to question 9
8. Has the patient had prior treatment with sofosbuvir and/or ledipasvir? ☐ Yes ☒ No
9. Is the patient actively participating in illicit substance or alcohol abuse?(If Yes, Skip to Question#14) ☐ Yes ☒ No
10. Confirmation patient is not participating in illicit substance or alcohol abuse by one the following methodologies is attached:
    - Validated screening instruments for current substance abuse (examples include NIDA's drug screening tool) **AND** alcohol abuse (examples include: Alcohol Use Disorders Identification Test (AUDIT C), CAGE alcohol screen); **OR**
      - Acceptable alcohol consumption tests: serum gammaglutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests (within 14 days of this request); **AND** ☒ Yes ☐ No
      - Urine toxicology screen results including substances tested, results of testing and date tested (within 14 days of this request)

      NIDA, CAGE, AUDIT, UDS attached

    The prescriber should submit clinical rationale for treatment continuation for positive tests that are false positives and not thought to be due to a relapse in alcohol or substance abuse.
11. Does the patient have a past history of illicit substance or alcohol abuse?
    - If yes, attach confirmation that the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of Chronic Hepatitis C treatment ☐ Yes ☒ No
12. Has the patient been free of substance abuse for the previous 6 months? ☒ Yes ☐ No
13. Has the patient been free of alcohol abuse for the previous 6 months? ☒ Yes ☐ No

This facsimile transmission contains legally privileged and confidential information intended for the person identified below. If you have received this transmission in error, please immediately notify us by telephone and return the original message to TennCare Pharmacy Program, c/o Magellan Health Services, 1st Floor South, 14100 Magellan Plaza, Maryland Heights, MO 63043. Distribution, reproduction or any other use of this transmission by any party other than the intended recipient is strictly prohibited.

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Magellan HEALTH SERVICES

TennCare Prior Authorization Form

Harvoni®

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

14. Does the patient have decompensated cirrhosis, defined as a Child-Pugh score of greater than 6 (Class B or C)? ☐ Yes ☒ No

15. Does the patient have a diagnosis of compensated cirrhosis? ☐ Yes ☒ No

16. Please check the box corresponding to the specialty of the prescribing physician:
- ☐ Gastroenterologist
- ☐ Hepatologist
- ☒ Infectious Disease Specialist
- ☐ Other _____

17. Is the requesting physician a TennCare provider with a Medicaid ID? ☒ Yes ☐ No

18. Does the patient have a reason they cannot take the preferred agent? ☒ Yes ☐ No

19. If yes, what is the reason:

Viekira Pak is not indicated for HCV genotype 6 infection.

20. Is the patient taking any of the following potentially interacting medications?
- Acid Reducing Agents: antacids, PPIs, H2Blockers
- Antiarrhythmics: digoxin
- HIV Antiretroviral combinations including tenofovir Truvada - will be transitioned pending Harvoni approval
- HCV products: simeprevir
- Anticonvulsants: carbamazepine, phenytoin, phenobarbital, oxcarbazepine ☒ Yes ☐ No
- Antimycobacterials: rifabutin, rifampin, rifapentine
- HIV medications: tipranavir/ritonavir, cobicistat/elvitegravir/emtricitabine/tenofovir
- Herbal Supplements: St John's wort
- HMG-CoA Reductase Inhibitors: rosuvastatin

20. If treatment experienced, please list ALL previous hepatitis C regimens this patient has received:

Treatment-naive

21. Which of the following best describes the patient prior to this course of treatment for hepatitis C?

☒ Treatment naive

☐ Treatment experienced

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TennCare Prior Authorization Form

Harvoni®

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

Please note any other information pertinent to this PA request: Patient with HCV genotype 6 infection and is treatment-naive. She is of child-bearing age therefore would like to treat at this time to prevent further disease progression and possible infection transmission. _____ is at high risk of hepatic disease progression given HIV coinfection

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

Cody Chastain, IAS — 12-7-15

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 2: TM

OPTUMRx®

Please note: All information below is required to process this request
Mon-Fri: 5am to10pm Pacific / Sat: 6am to 3pm Pacific
For real time submission 24/7 visit www.OptumRx.com and click Health Care Professionals
OptumRx • M/S CA 106-0286 • 3515 Harbor Blvd. • Costa Mesa, CA 92626

Epclusa® Prior Authorization Request Form

DO NOT COPY FOR FUTURE USE. FORMS ARE UPDATED FREQUENTLY AND MAY BE BARCODED

Member Information (required)

Member Name:
Insurance ID#:
Date of Birth:
Street Address:
City: Jackson | State: TN | Zip:
Phone:

Provider Information (required)

Provider Name: Cody Chastain
NPI#: | Specialty: Infectious Disease
Office Phone:
Office Fax: 615-875-06666
Office Street Address: 1211 21st Ave South Suite 102A
City: Nashville | State: TN | Zip: 38301

Medication Information (required)

Medication Name: Epclusa
Strength: 400-100mg | Dosage Form: tablet
☐ Check if requesting brand
☐ Check if request is for continuation of therapy
Is the physician supplying the medication? ☐ Yes ☒ No
Directions for Use: 1 daily

Clinical Information (required)

*** Medical record documentation (e.g., chart notes, laboratory values) must be faxed-in along with this request ***

What is the diagnosis for which the medication is being prescribed?
☒ Chronic Hepatitis C (genotype: 3) ☐ Other, please list:
Is Epclusa being prescribed by or in consultation with one of the following?
☐ Hepatologist ☐ Gastroenterologist ☒ Infectious Disease Specialist
☐ HIV Specialist certified through the American Academy of HIV Medicine

Document all of the following that apply:
Is the patient currently on Epclusa? ☐ Yes ☒ No

Does the patient have cirrhosis? ☒ Yes ☐ No

Does the patient have decompensated liver disease? ☐ Yes ☒ No

Will the patient be taking Epclusa with ANY of the following? *(Select all that apply)*
☐ Sovaldi (sofosbuvir) ☐ Olysio (simeprevir) ☐ Ribavirin ☐ Other:

Has the patient experienced contraindication, intolerance or treatment failure (defined as viral relapse, breakthrough while on therapy, or non-responder to therapy) with ANY of the following? *(Select all that apply)*
☐ Peginterferon ☐ Harvoni ☐ Zepatier ☐ Incivek ☒ No Previous Hepatitis C Treatment (Treatment-Naïve)
☐ Olysio ☐ Ribavirin ☐ Victrelis ☐ Sovaldi ☐ Daklinza ☐ Other:

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review? Patient with cirrhosis and GT3 HCV infection, complicated by HIV infection. Epclusa x 12weeks is the AASLD/IDSA recommended regimen (over DAKV/SOF/RBV x 24weeks). Thank you!

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-800-711-4555.
This form may be used for non-urgent requests and faxed to 1-800-853-3844.

PATIENT CASE 3: JL

PRIOR AUTHORIZATION REQUEST

Harvoni

PATIENT Name & DOB

Address -

ID: Name - Cody Chastain

Address - 1211 21st Ave South, Nashville TN 37212

Phone/Fax # -

ID# :

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A Please answer the following questions

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

1. X Yes θ No Is the indication genotype 1 or genotype 4 hepatitis C virus? ***(If 'Yes', please specify below)***
   - X Genotype 1
   - θ Genotype 4
2. θ Yes X No Will the patient be using Harvoni in combination with any other DAAs (direct acting antivirals such as Victrelis, Incivek, Olysio, Sovaldi, Viekira Pak) (not including ribavirin)?
3. θ Yes X 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, and patients who have not completed a course of therapy due to an adverse reaction or for other reasons.*
4. θ Yes X No Is the patient's life expectancy less than 12 months due to non-liver related comorbidities?
5. θ Yes X No Does the patient have **chronic hepatitis C and HCC (hepatocellular carcinoma) and is awaiting liver transplant?**

*If **"yes"** to question 5 please answer questions **6-8** if the request if for a new start*
*OR **8-10** if the request is for a continuation of therapy*
If **"no"** to question 5 proceed to question 11

6. θ Yes θ 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?
7. θ Yes θ No Is the patient treatment naïve? ***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.*
8. θ Yes θ No Does the patient have cirrhosis?
9. θ Yes θ No How many weeks of Harvoni has the patient received? Please list:_____Weeks
10. θ Yes θ No Has the patient been previously treated for HCV?
11. θ Yes X No Does the patient have **recurrent HCV post-liver transplantation?**

Continued on Page 2

Continued from Page 1

*If "yes" to question 11 please answer questions **12-14** if the request is for a new start*
*OR **14-16** if the request is for a continuation of therapy*
If "no" proceed to question 17

12. θ Yes θ 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?
13. θ Yes θ No Is the patient treatment-naïve for recurrent HCV? ***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.*
14. θ Yes θ No Does the patient have cirrhosis?
15. θ Yes θ No How many weeks of Harvoni has the patient received? Please list:_____Weeks
16. θ Yes θ No Has the patient previously been treated for their recurrent HCV?
17. X Yes θ No Does the patient have **chronic hepatitis C?**

*If **"yes"** to question 17 please answer questions **18-24** if the request is for a new start*
*OR **20-25** if the request is for a continuation of therapy*

18. X Yes θ No Is Harvoni prescribed by, or in consultation with, one of the following prescribers: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician?
19. θ Yes X No Does the patient have advanced fibrosis?
20. X Yes θ No Is the patient treatment naïve? ***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.*
21. θ Yes X No Does the patient have cirrhosis?
22. θ Yes X No Is the patient's baseline HCV RNA less than 6 million IU/mL?
23. θ Yes X No Has the patient been previously treated with a Sovaldi-containing regimen (note: this does not include Harvoni)?
24. θ Yes X No Has the patient been previously been treated for HCV with PR (pegylated interferon [Pegasys, Peg-Intron] and ribavirin) with or without a protease inhibitor for HCV (such as Incivek, Vicrelis, or Olysio)?
25. θ Yes θ No How many weeks of Harvoni has the patient received? Please list:_____Weeks

Continued on Page 3

PRIOR AUTHORIZATION REQUEST

Harvoni

PATIENT	Name & DOB -	D:	Name - Cody Chastain
	Address		Address - 211 21st Ave South Nashville TN 37232
			Phone/Fax # -

Continued from Page 2

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

Patient with GT 1a HCV, complicated by HIV coinfection, placing him at high risk for fibrosis progression. Harvoni is compatible with his current HIV ART.

SECTION B Physician Signature

Cody Chastain 1AB — PHYSICIAN SIGNATURE

9-9-16 — DATE

FAX COMPLETED FORM TO: 1 877-329-3760

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

If you have any questions regarding your patient's plan drug limits you may call us at: 800-753-2851

Patient Case 3: JL
APPROVED!

EXPRESS SCRIPTS®
Medicare (PDP)
4700 North Hanley Street Suite B
St Louis, MO 63134

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

Case ID:

Patient:
Patient DOB:
Plan Name: EXPRESS SCRIPTS MEDICARE
Plan ID (PBP Code): 114

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

September 15, 2016

Dear Dr. CHASTAIN:

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

If you have any questions, please call us at 1.800.935.6103, 24 hours a day, 7 days a week (including holidays). (TTY users should call 1.800.716.3231.)

Sincerely,

Coverage Review Department
Express Scripts

APPROVED!- Now what?

- Pharmacy should run a test claim
  - Ensure approval
  - Determine copay
- Determine if patient qualifies copay assistance
  - Medicaid: does not qualify for assistance → copay $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 1: NM Denied

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:
First Name:
Last Name:
Date of Birth:

MEDICATION INFORMATION:

Name: HARVONI
Strength: 90MG-400MG
Dosage Form: TABLET

MEDICAL PROVIDER:

Name: CODY CHASTAIN
Address 1: 1161 21ST AVE S
Address 2:
City State Zip: NASHVILLE, TN 372320012

PHARMACY PROVIDER:

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

OUTCOME OF CLINICAL REVIEW OF REQUEST

Prior Authorization Status: Denied
Date of Review: 12/07/2015
Prior Authorization Begin Date: 12/07/2015
Prior Authorization End Date: 12/07/2015

Approval in TennCare requires a specific Genotype of 1.

Also required is medical/lab documentation showing fibrosis corresponding to a Metavir fibrosis score of at least 3 or documentation showing patient at the highest risk for severe complications.

The patient does not meet the criteria for approval of this medication. The request has been denied to allow pursuit of the appeal process. The patient will receive an official denial letter, complete with instructions regarding the appeal process, if applicable.

Patient Case 2: TM Denied

Department of Health and Human Services
Centers of Medicare & Medicaid Services

Form Approved
OMB No. 0938-0976

Important: This notice explains your right to appeal our decision. Read this notice carefully. If you need help, you can call one of the numbers listed on the last page under "Get help & more information."

Notice of Denial of Medicare Prescription Drug Coverage

07/15/2016

Request Reference #: 77057

Member ID:

Your request was denied

We have denied coverage or payment under your Medicare Part D benefit for the following prescription drug or drugs that you or your prescriber requested: EPCLUSA

Why did we deny your request?

We denied this request under Medicare Part D because:

EPCLUSA is not on the drug list (formulary). Your plan does not cover this drug unless you have previously tried and failed drugs covered on the formulary that are clinical alternatives for your condition OR if your doctor submits documentation to indicate that these other drugs are not clinically appropriate to treat your condition.

Epclusa is denied because it is not a covered drug. You need to first try Sovaldi plus Daklinza therapy. OR there are specific medical reason(s) why the alternative medication is not appropriate to treat your medical condition.
Reviewed by: KMN, Pharm.D.

Denied- Now What?

- Steps for designated staff:
  - 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.)

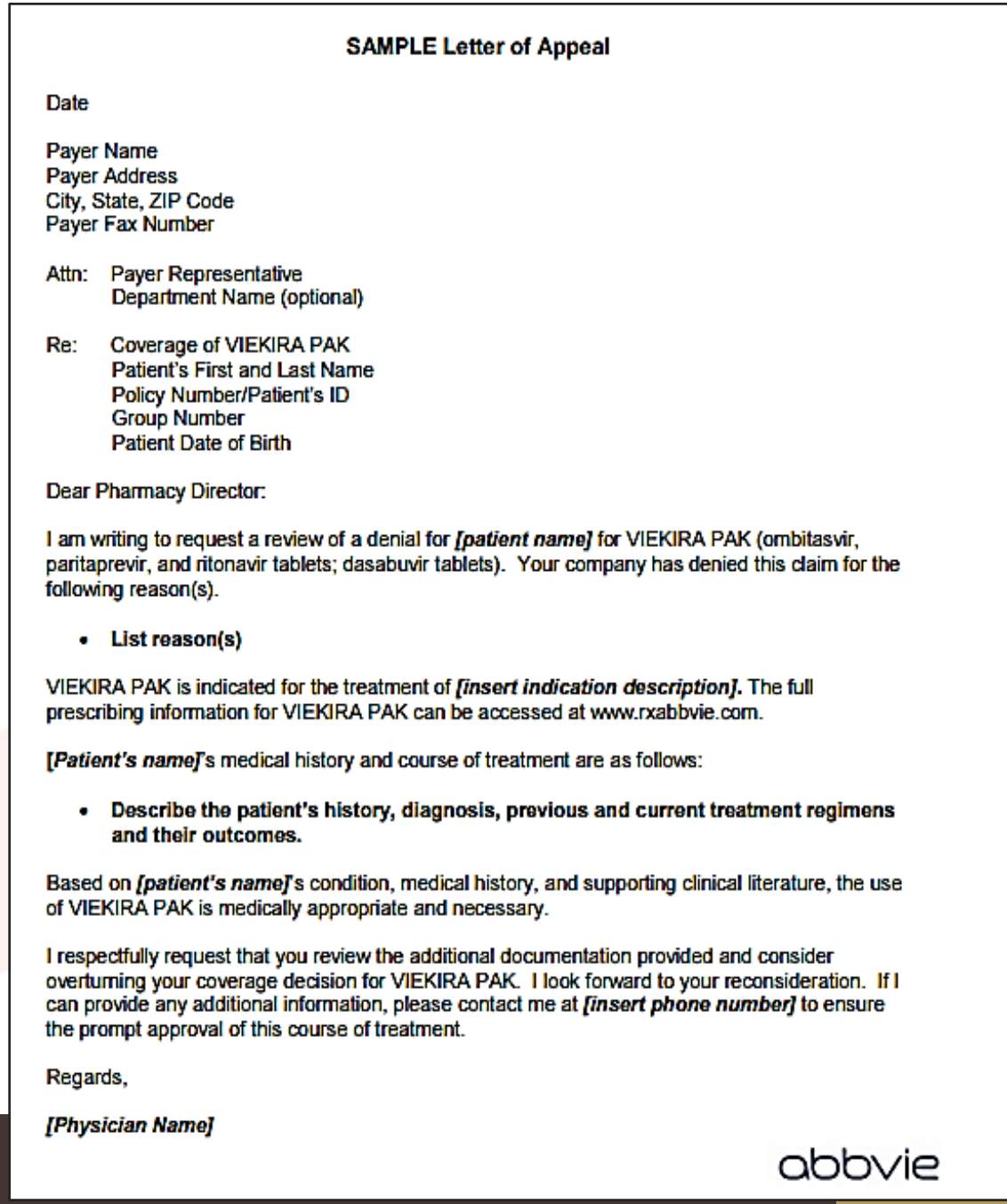
Denied- Now What?

- Steps for provider:
  - Write appeal letter
  - 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

PATIENT CASE 1: NM APPEAL

NM Appeal

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

- Guideline recommendations and support

Vanderbilt University Medical Center, Division of Infectious Diseases

1211 21st Ave. South
Medial Arts Building, Suite 102A
Nashville, TN 37232
Phone: 615-936-1174 Fax: 615-343-1103

December 9th, 2015

To Whom It May Concern:

I am contacting you on behalf of my patient Mrs. .)OB Member ID# Case ID# She has been prescribed a 12 week course of dual direct acting antiviral therapy containing ledipasvir/sofosbuvir (Harvoni™) for her chronic hepatitis C (HCV) infection. She has a history of chronic HCV infection (genotype 6) with stage F0-F1 fibrosis as shown on abdominal ultrasound dated February 11th, 2015 and is naïve to previous HCV treatment. She has evidence of active viral infection as shown by viral load of 10,551,665 IU/mL December 2nd, 2015. **Her HCV is complicated by HIV, placing her at risk for more rapid progression of fibrosis.** Additionally, she is of child-bearing age. Therefore **treatment of her HCV infection is imperative to eliminate the risk of mother to child transmission.**

The AASLD and IDSA Society released Hepatitis C Treatment Guidelines that were recently updated on October 22nd, 2015, and recommend treatment for all individuals infected with HCV with very few caveats. Prior to this most recent update, the guidelines panel classified patients with **HIV coinfection as "high priority to treat owing to high risk for complications"** (Class I, Level B). In this update, the need to treat patients with HIV co-infection regardless of current fibrosis stage is still highlighted. This is due to multiple studies showing accelerated fibrosis progression and death following decompensation in this population (Konerman, 2014); (Pineda, 2005); (Merchante, 2006); (Terrault, 2012). In the Swiss HIV cohort, waiting to treat HCV at Metavir fibrosis stages F3 and F4 resulted in 2- and 5-times higher liver-related mortality, respectively when compared with treating at Metavir stage F2 (Zahnd, 2015). Additionally, the updated guidelines recommend that patients with HIV/HCV co-infection should be treated for a minimum of 12 weeks regardless of baseline HCV viral load. These guidelines can be viewed in their entirety at http://hcvguidelines.org.

NM 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

The regimen of ledipasvir/sofosbuvir (Harvoni™) was recently approved for genotype 6 and in patients co-infected with HIV on November 12th, 2015. The updated approval of Harvoni for genotype 6 was based on the open-label ELECTRON-2 trial in which **96% of patients (24/25) with genotype 6 infection who were treatment-naive or previously-treated with or without cirrhosis achieved an SVR12 after treatment with Harvoni x12 weeks.** Additionally, **96% of patients in the ION-4 trial evaluating Harvoni in patients co-infected with HIV/HCV achieved an SVR12.** Viekira Pak is not an option for this patient as it has not been approved for genotype 6 infection.

In summary, it is recommended that [redacted] HCV be treated now for the aforementioned reasons in order to avoid additional potential morbidity, mortality, and costs associated with worsening liver function. She has demonstrated great adherence to HIV therapy with repeated undetectable viral loads, making her an ideal candidate for HCV therapy. The 12 week course of the requested ledipasvir/sofosbuvir (Harvoni™) is efficacious and approved for treatment in this population. Eradication of the virus now is optimal in order to prevent progression of her liver disease and associated complications, including hepatic decompensation, hepatocellular cancer, liver transplantation, and/or death.

I appreciate your review of this request. Please contact me as needed.

Sincerely,

Cody Chastain /AB

Cody Chastain, MD
Infectious Diseases Specialty

Enc: Original PA paperwork, denial letter, HCV genotype, HCV virology lab report, abdominal ultrasound, NIDA, AUDIT, CAGE screenings, urine drug screenings

PATIENT CASE 2: TM APPEAL

TM Appeal

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

- Guideline recommendations and clinical trial data to support use of this regimen

July 20th, 2016

RE: **APPEAL** for velpatasvir/sofosbuvir (Epclusa™)

To Whom It May Concern:

I am contacting you on behalf of my patient Mr. ' ı (DOB Member ID# : Request Reference #: He has been prescribed a 12 week course of dual direct acting antiviral therapy containing sofosbuvir and velpatasvir (Epclusa™) for his hepatitis C (HCV) infection. He has a history of HCV infection (ICD10: B18.2), genotype 3, **with compensated cirrhosis** as shown on ultrasound June 17th, 2016. He is naïve to previous HCV treatment. He has evidence of active viral infection as shown by his viral load of 381,744 IU/mL on January 8th, 2016. was recently denied treatment stating that "Epclusa is not on the drug list (formulary). Your plan does not cover this drug unless you have previously tried and failed drugs covered on the formulary that are clinical alternatives for your condition OR if **your doctor submits documentation to indicate that these other drugs are not clinically appropriate to treat your condition.**" We have submitted such documentation and do believe that Epclusa™ should be provided for this patient as it is currently **AASLD/IDSA Guidelines recommended regimen for patients with genotype 3 HCV infection and cirrhosis and has superior efficacy results, is more cost-effective, provides a shorter treatment duration, and does not require the addition of ribavirin as opposed to the formulary-preferred agent.**

The AASLD/IDSA Hepatitis C Treatment Guidelines, recently updated July 6th, 2016, **recommend treatment of genotype 3 HCV infection with cirrhosis with sofosbuvir/velpatasvir for 12 weeks (Rating: I/A) or daclatasvir/sofosbuvir for 24 weeks with or without ribavirin (Class IIa, Level B).** This updated recommendation is based on the results of the ASTRAL-3 study evaluating sofosbuvir and velpatasvir for 12 weeks in patients with genotype 3 HCV compared to sofosbuvir/ribavirin for 24 weeks. Patients who were **naïve to previous HCV treatment, with cirrhosis had an overall SVR12 rate of 93% on sofosbuvir/velpatasvir**, compared to 73% SVR12 rate of the sofosbuvir ribavirin regimen. **Sofosbuvir/velpatasvir is now preferred in patients with genotype 3 infection and cirrhosis over daclatasvir/sofosbuvir.** In the ALLY-3 study, daclatasvir/sofosbuvir for 12 weeks in patients with genotype 3 infection and cirrhosis, **the SVR12 rate was only 58%.** Therefore, if this regimen is used in this population, there is a recommendation to **extend treatment to 24 weeks with the option of adding ribavirin.** However, **there is limited data regarding efficacy of this extended treatment**, though smaller studies have shown SVR12 rates around 85-90% (Hezode 2015, Leroy 2016). Given these results, sofosbuvir/velpatasvir gained FDA approval and is now the AASLD/IDSA preferred regimen in patients with genotype 3 and cirrhosis such as Mr.

TM 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

The AASLD and IDSA Society Hepatitis C Treatment Guidelines were recently updated July 6th, 2016, and continue to recommend treatment for all individuals infected with HCV with very few caveats. Prior to the guidelines update in October 2015, the panel classified patients with **HIV co-infection as "high priority to treat owing to high risk for complications" (Class I, Level B)**. In this update, the need to treat patients with

HIV co-infection regardless of current fibrosis stage is still highlighted. **This is due to multiple studies showing accelerated fibrosis progression and death following decompensation in this population** (Konerman, 2014); (Pineda, 2005); (Merchante, 2006); (Terrault, 2012). In the Swiss HIV cohort, waiting to treat HCV at Metavir fibrosis stages F3 and F4 resulted in 2- and 5-times higher liver-related mortality, respectively when compared with treating at Metavir stage F2 (Zahnd, 2015). These guidelines can be viewed in their entirety at http://hcvguidelines.org.

The currently regimen has superior efficacy results, is more cost-effective, provides a shorter treatment duration, and does not require the addition of ribavirin as opposed to the formulary-preferred agent. **Given Mr. genotype, coinfection with HIV, and current cirrhotic status place him at a high priority to treat at this time given his increased risk of hepatic decompensation, failure, and hepatocellular carcinoma.**

I appreciate your review of this request. Please contact me as needed.

Sincerely,

Cody Chastain

Cody Chastain, MD
Infectious Diseases Specialty

Enc: denial letters clinic notes, genotype, virology lab report, abdominal ultrasound, AASLD/IDSA Hepatitis C Clinical Treatment Guidelines, ASTRAL-3

TM APPEAL 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

NM

- PA denied → Appeal denied → sent to Legal Solutions Hearing → denied
- Now what?

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 SERVICE(S) (REQUIRED) — *CHECK ALL BOXES THAT APPLY*

☐ Benefits Investigation ☐ Prior Authorization and Appeals Investigation ☐ Patient Assistance Program (PAP) Eligibility Screening

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*

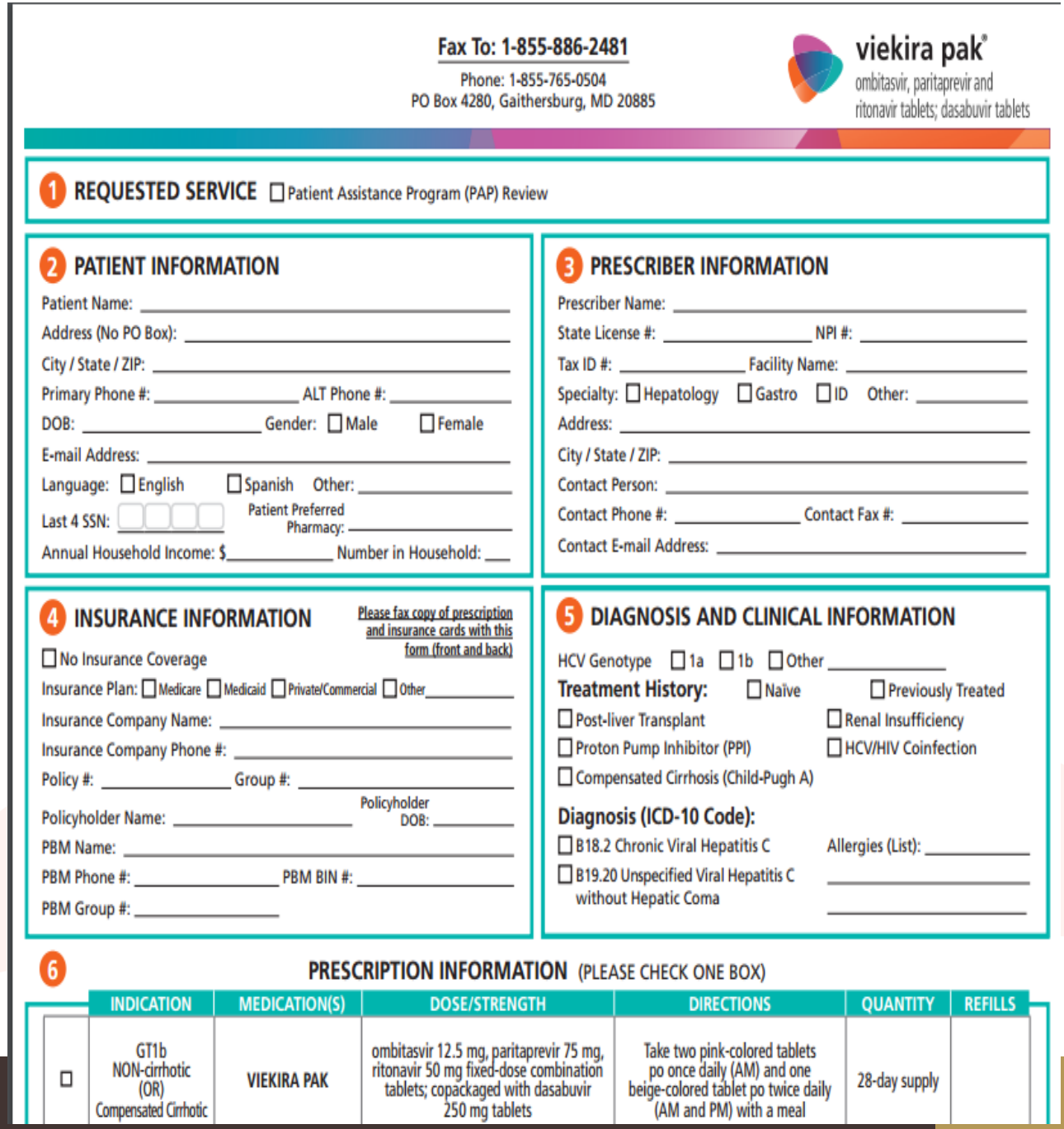
Diagnosis:

ICD-10 code: F Score (Fibrosis Score): ☐ Other:

HCV Genotype ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other: ☐ HCV/HIV-1 Co-infection

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 _____

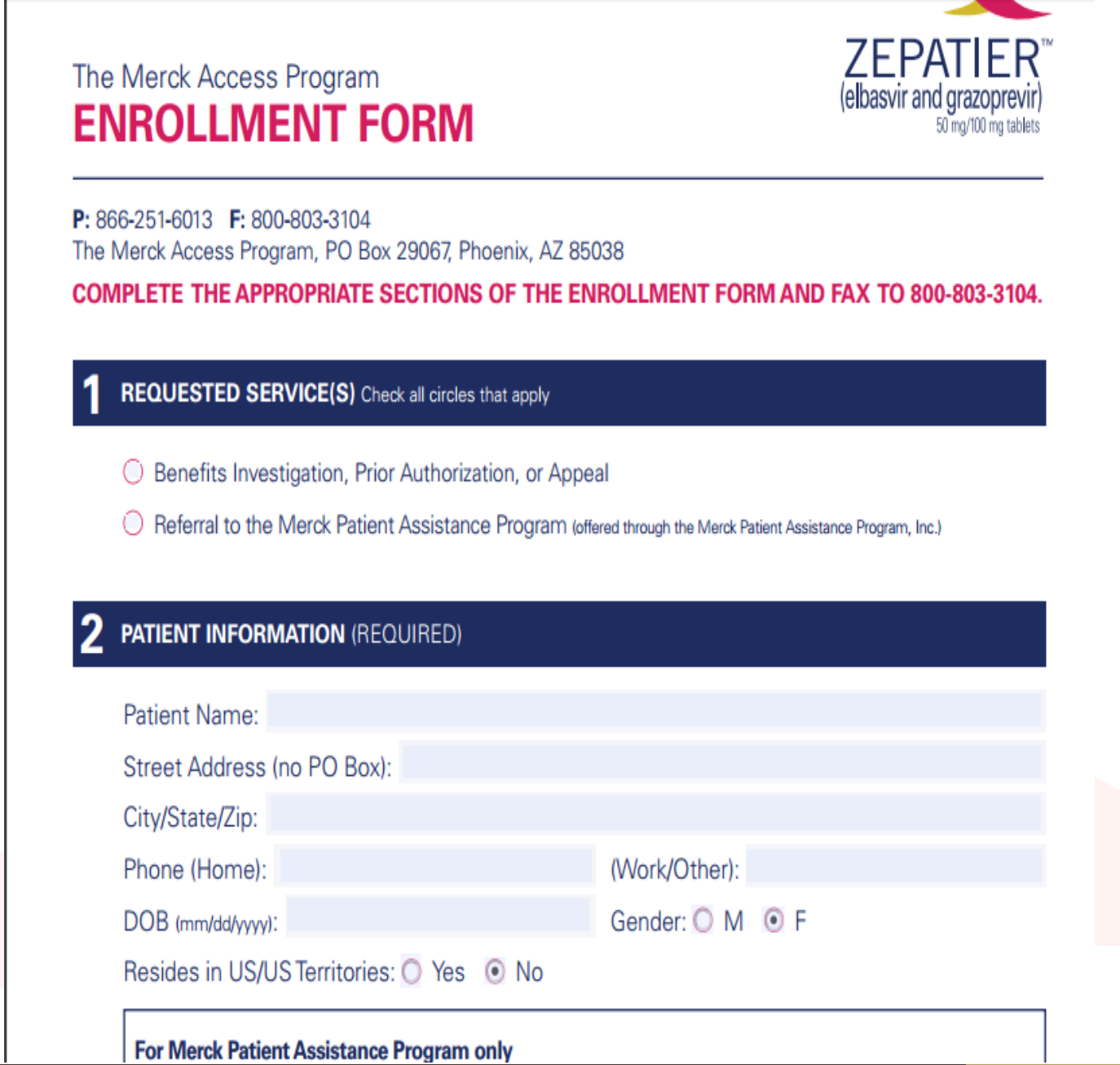
5 PRESCRIPTION INFORMATION (PLEASE CHECK ONE BOX)

	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.)

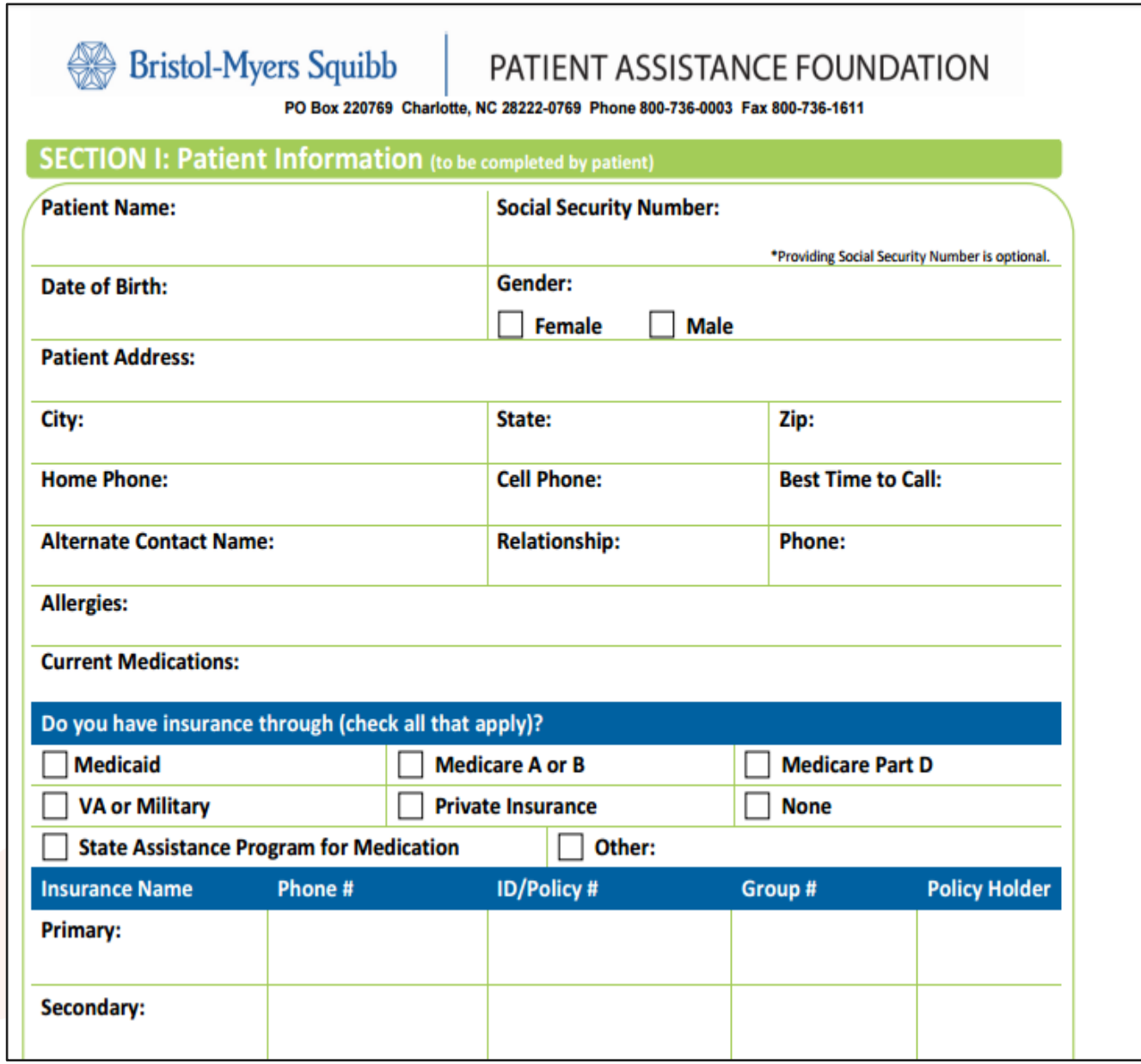
2 PATIENT INFORMATION (REQUIRED)

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 1: NM

NM

- 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

NM

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

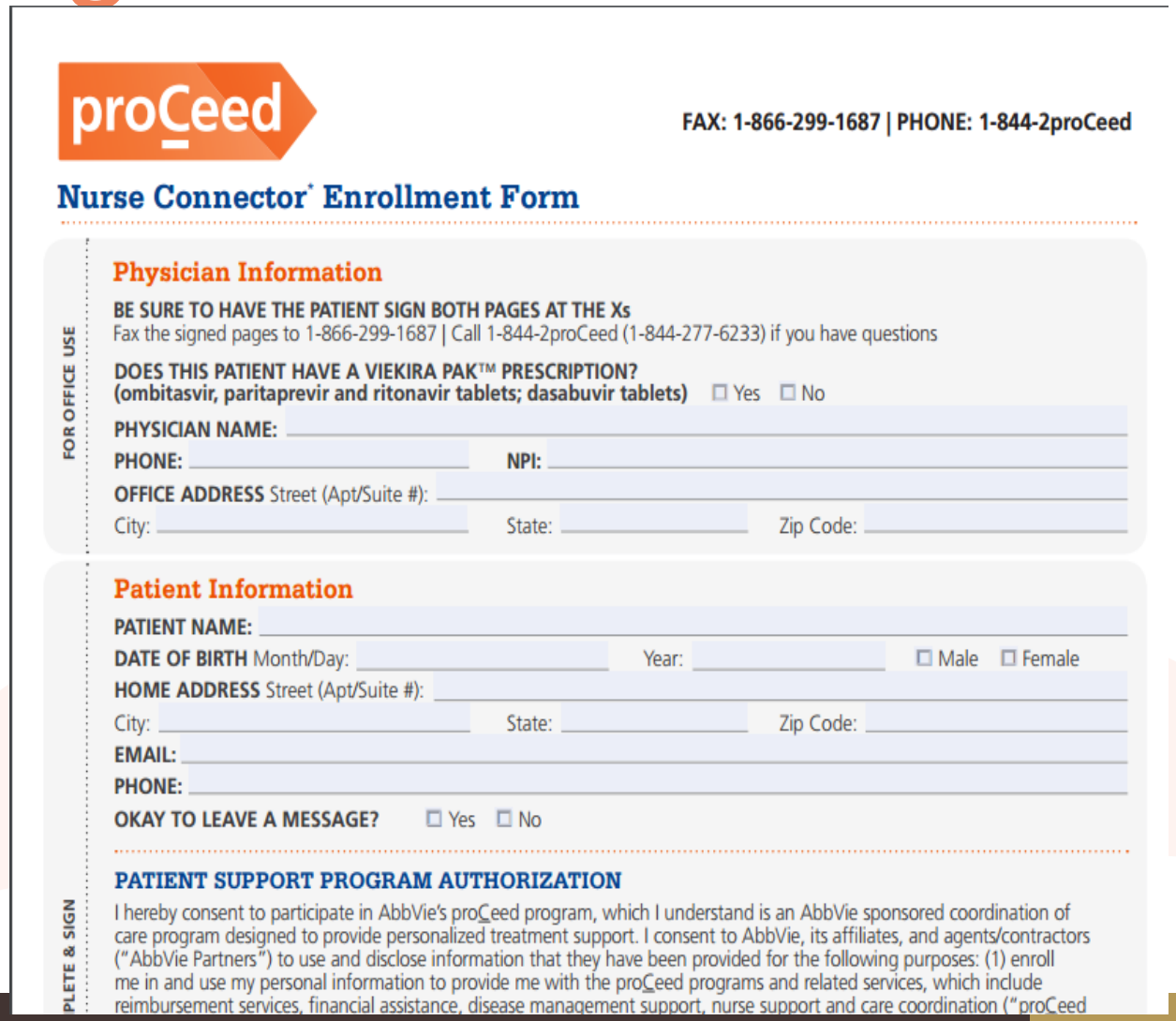
- Prescription faxed to clinic for provider signature
  - Select delivery to provider or patient
- Pharmacy calls patient for delivery information

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 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

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**

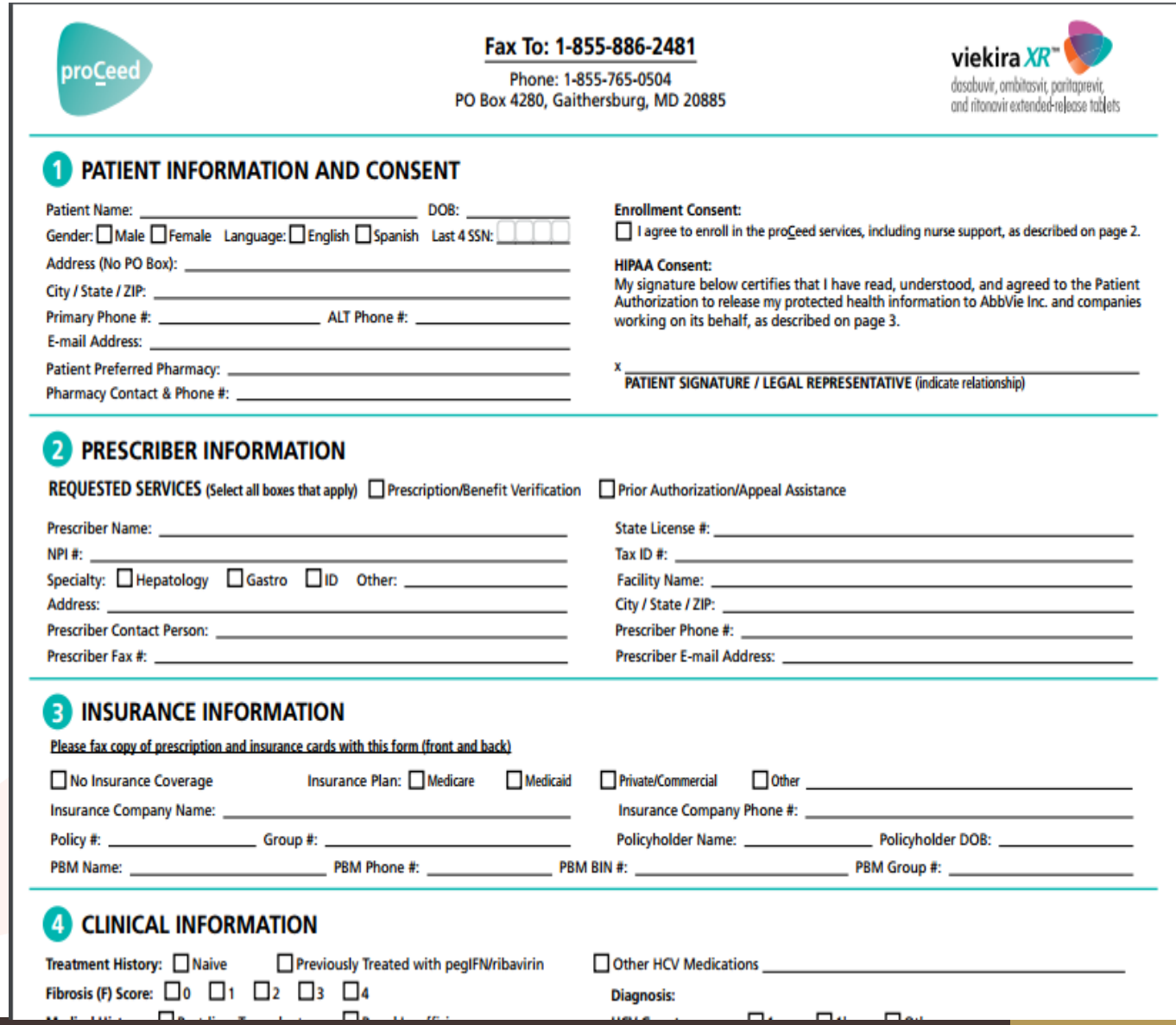
Provider Support: Gilead SupportPath

- 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)

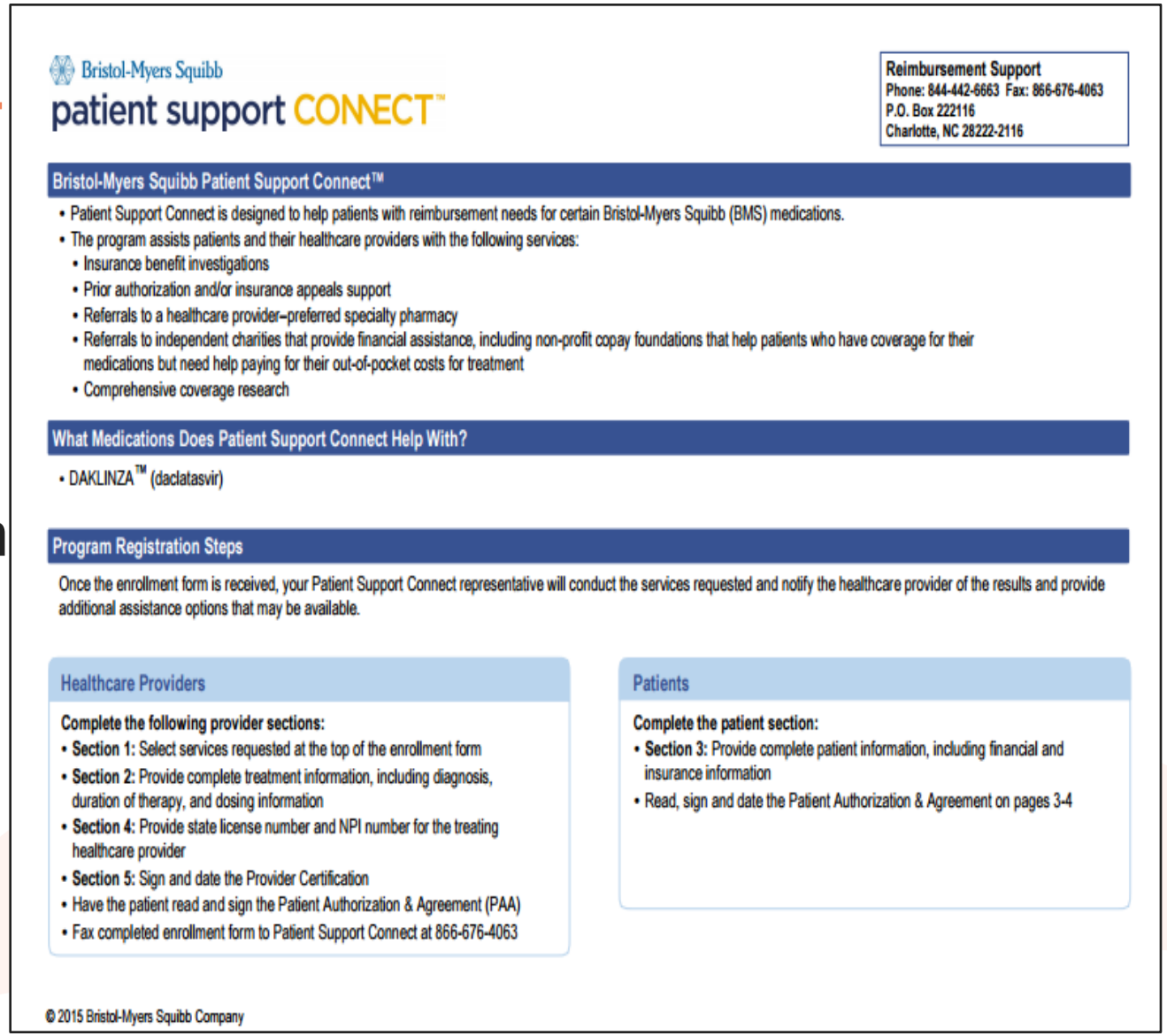
Patient Name:
Street Address (no PO Box):
City/State/Zip:
Phone (Home): (Work/Other):
DOB (mm/dd/yyyy): Gender: ○ M ○ F
Resides in US/US Territories: ○ Yes ○ No

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

Other Access Resources

- 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/

Thank you!

Questions?

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