From Prescription to Patient:

Navigating Barriers to HCV Treatment Initiation

Autumn Zuckerman, PharmD, BCPS, AAHIVP, CSP
Vanderbilt Specialty Pharmacy
Vanderbilt University Medical Center

Cody Chastain, MD
Division of Infectious Diseases
Vanderbilt University Medical Center

Disclosures

- Dr. Zuckerman receives grant/research funding from Gilead Sciences, Inc.
- Dr. Chastain receives grant/research funding from Gilead Sciences, Inc.

Objectives

- Describe the financial impact of hepatitis C virus (HCV) on US healthcare
- Identify common restrictions of HCV treatment among payers
- Illustrate successful acquisition of direct acting antiviral (DAA) therapy

Outline

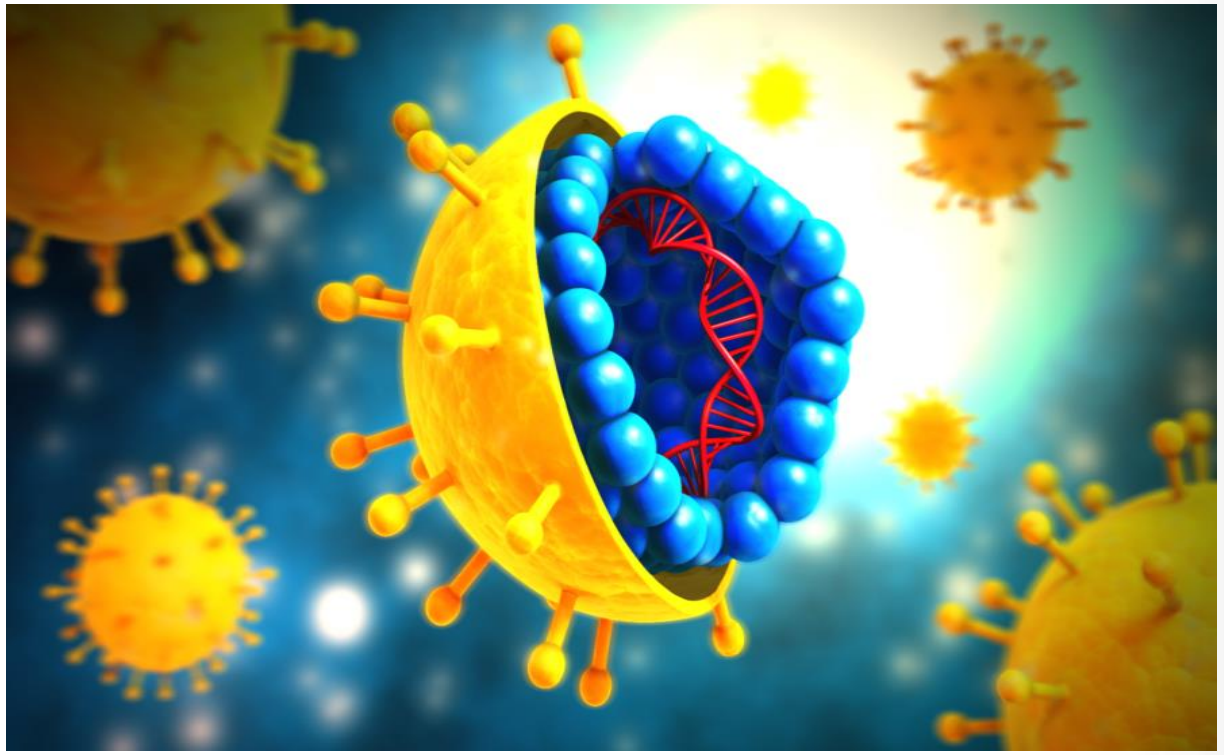
- HCV Review
- HCV and Healthcare Finances
- Navigating the System
  - Patients With Prescription Insurance
  - Patients Without Prescription Insurance
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- Access On the Horizon

Outline

- **HCV Review**
- HCV and Healthcare Finances
- Navigating the System
  - Patients With Prescription Insurance
  - Patients Without Prescription Insurance
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- Access On the Horizon

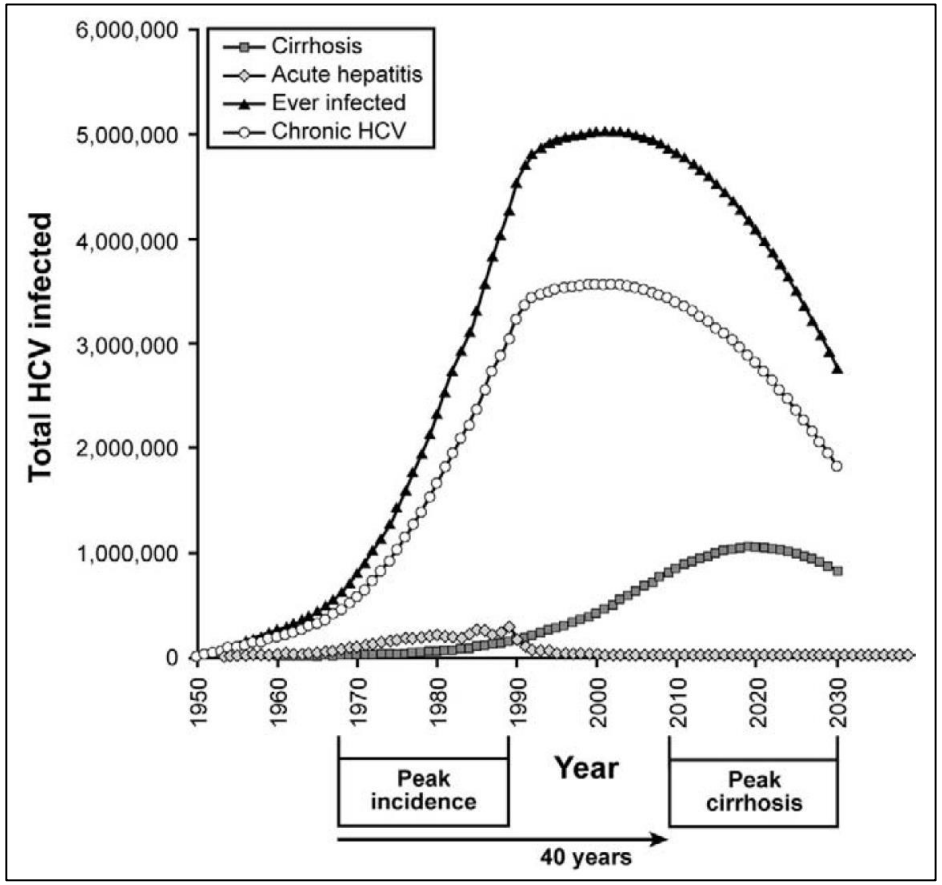
Hepatitis C Virus

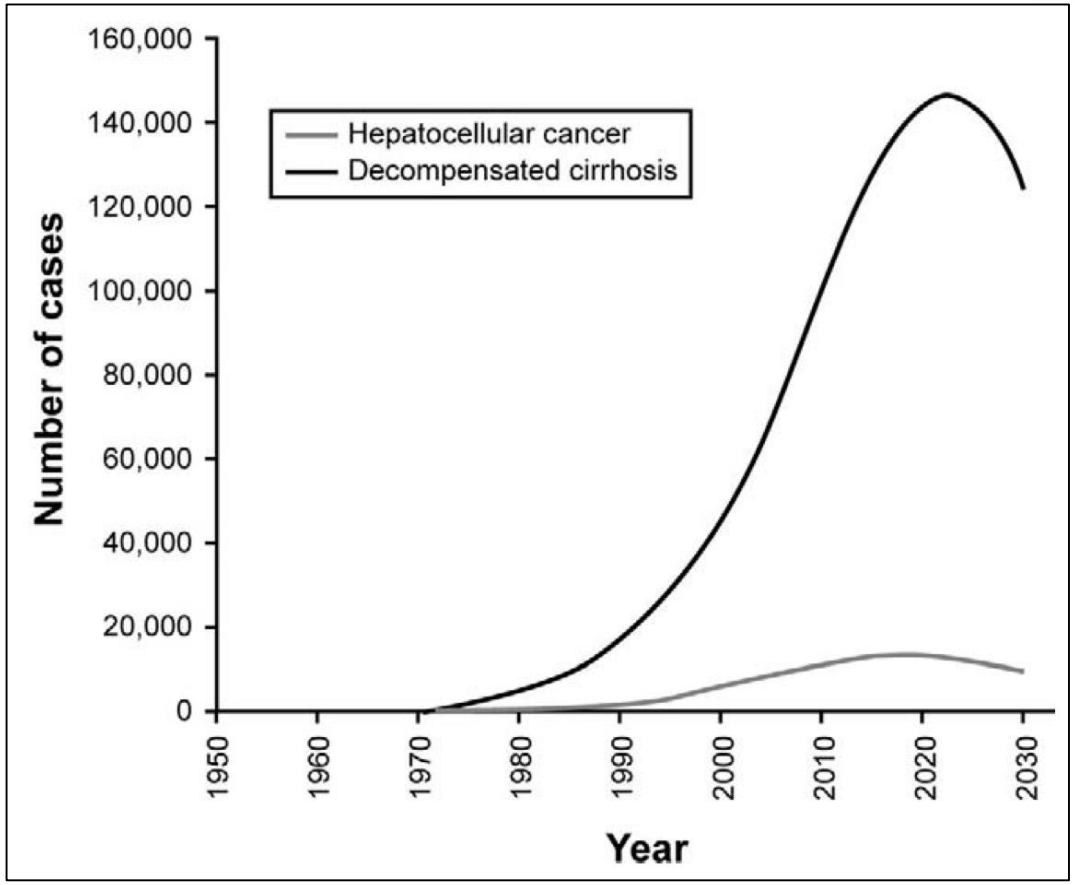
- Single-strand, positive sense RNA flavivirus
- Spread through blood and body fluids
- Predominantly infects and replicates in liver cells
- No latent reservoir



www.cdc.gov

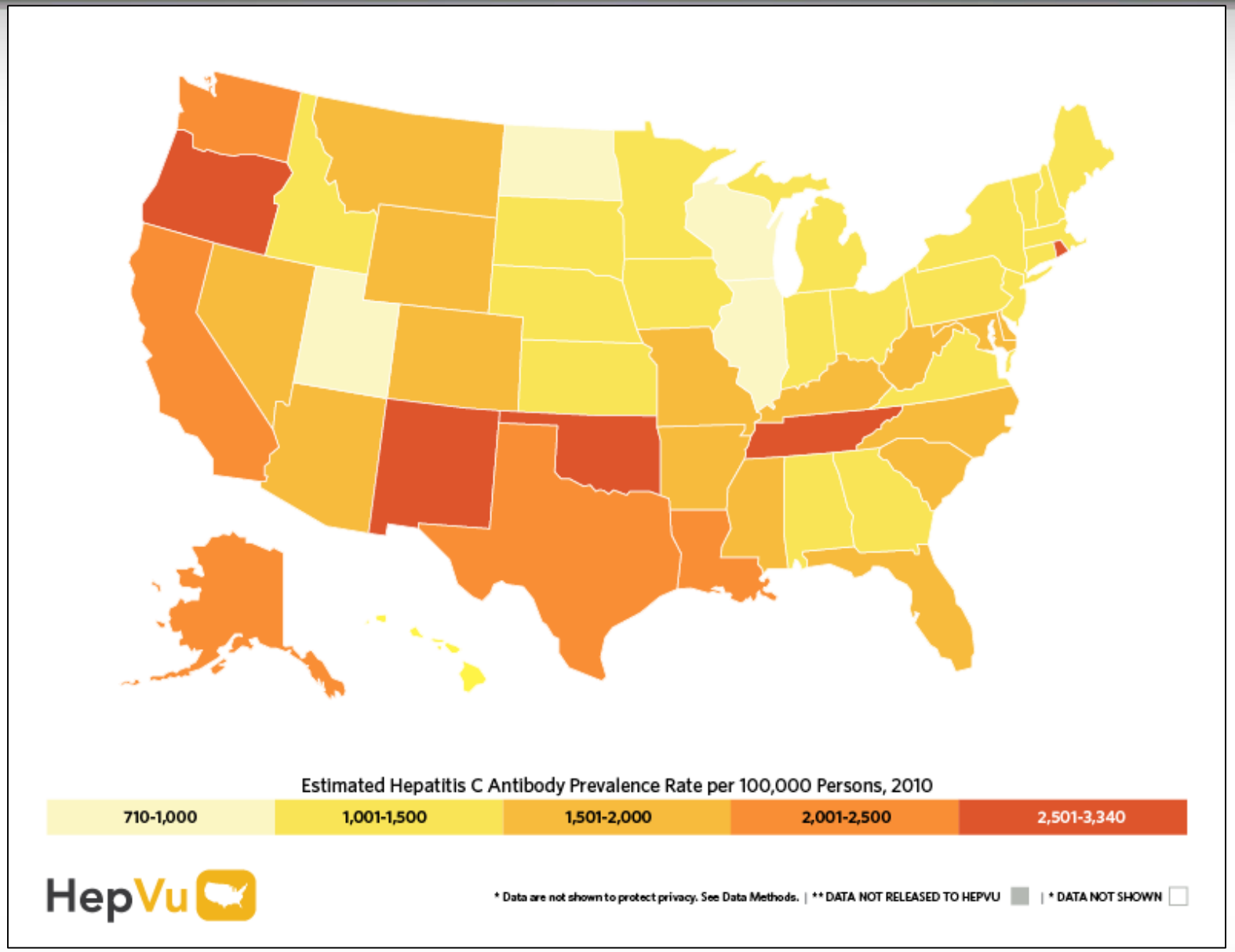
HCV in the US





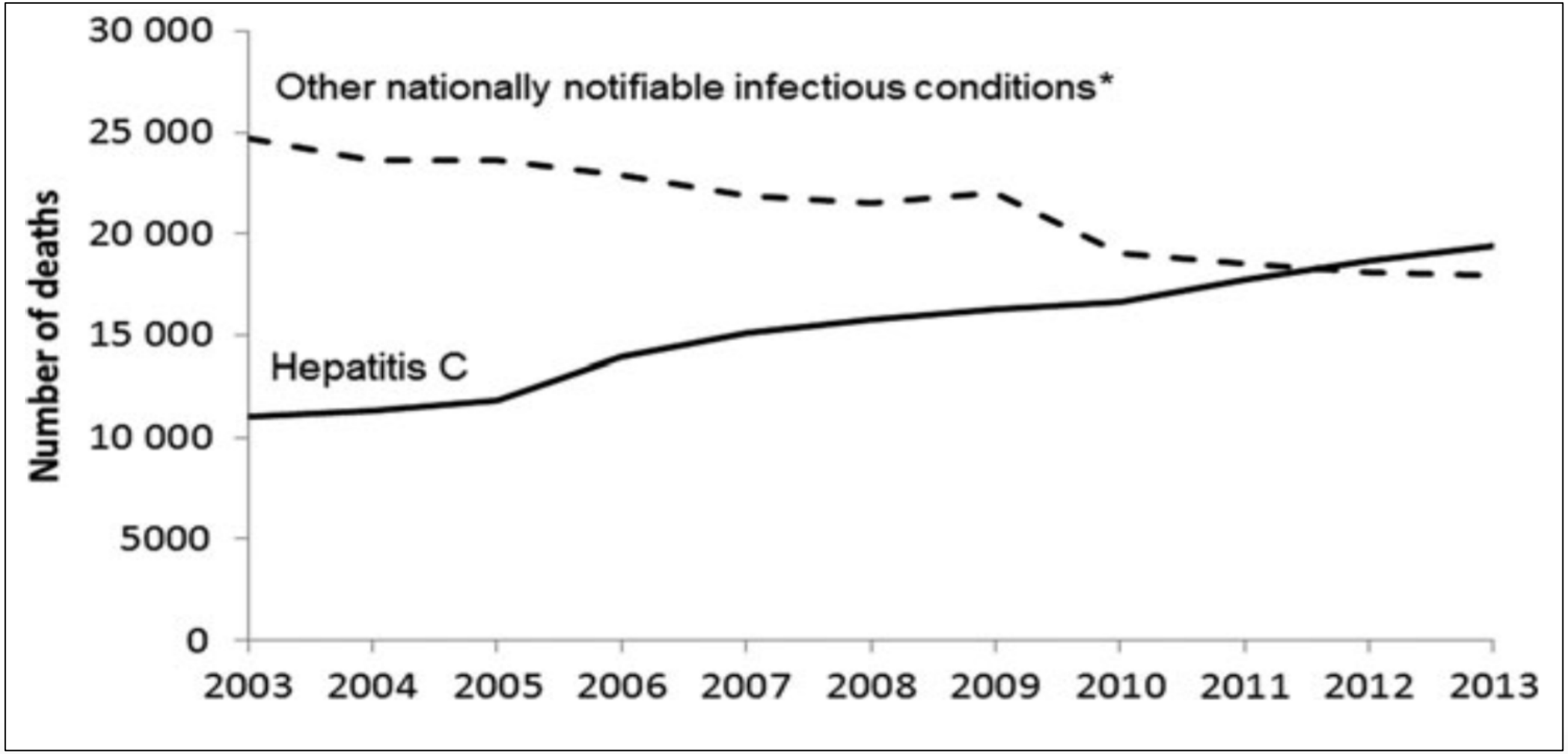
2.7-5.2 million Americans have chronic HCV infection

Davis GL et al. *Gastroenterology* 2010. // Denniston MM et al. *Ann Int Med* 2014. // Chak E et al. *Liver Int* 2011. // Edlin BR et al. Hepatology 2015.



HepVu (www.hepvu.org). Emory University, Rollins School of Public Health.

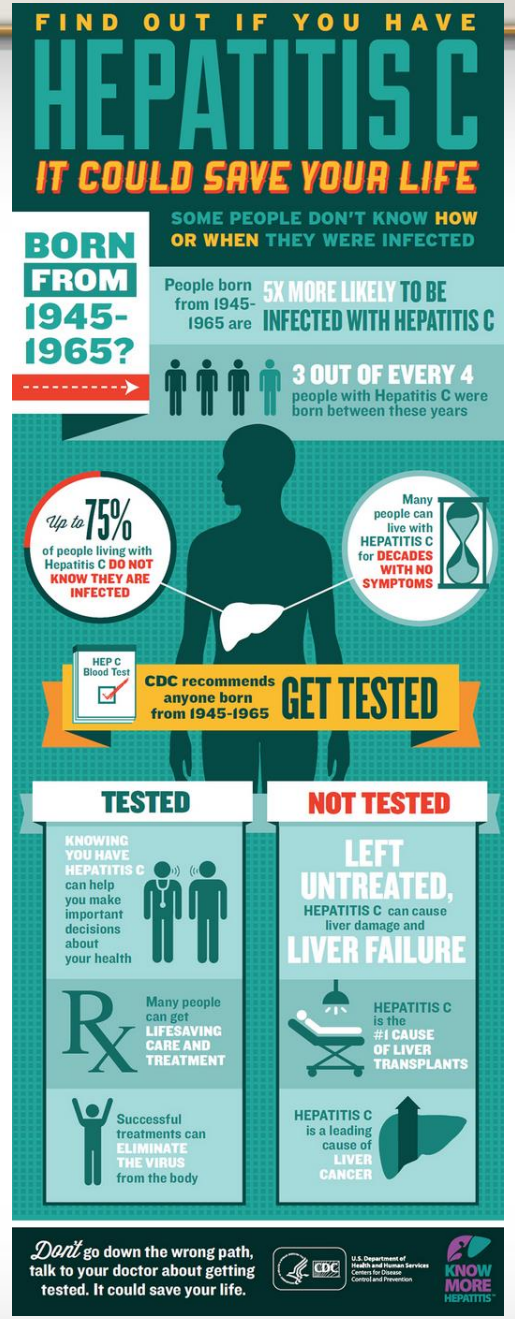
HCV and Mortality in the USA



Ly KN et al. *Clin Infect Dis* 2016.

Who is at Risk for HCV?

- IV drug users
- Tattoo/piercing recipients
- Blood/clotting protein recipients prior to 1992
- Mother-to-child transmission from HCV+ mother
- Hemodialysis patients
- People with HIV
- Occupational exposures
- Born between 1945-1965 (“baby boomer” generation)



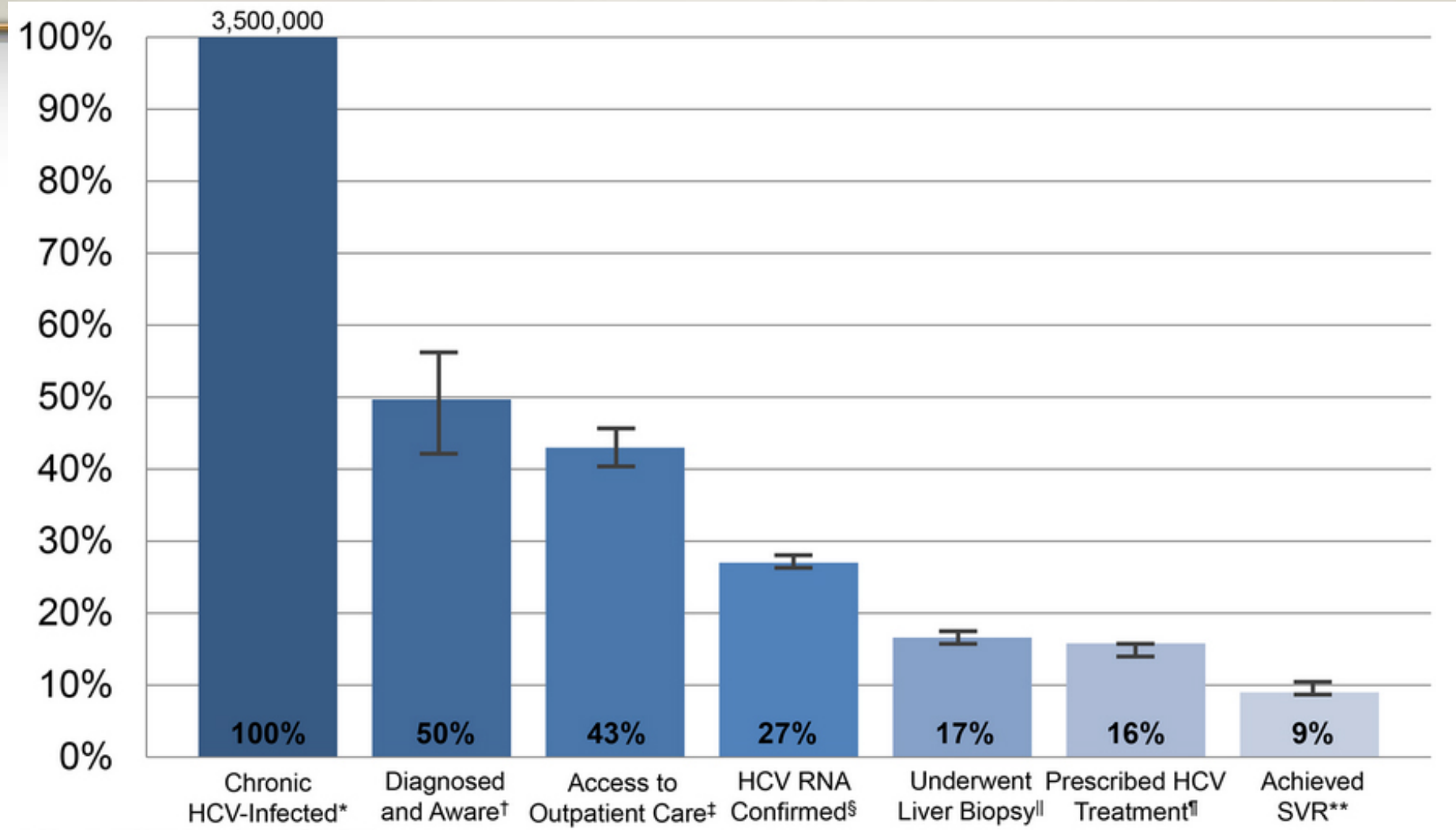
www.cdc.gov/hepatitis/HCV

HCV Screening Indications

- One-time HCV testing recommended for persons born **1945-1965**

Risk behaviors	Risk exposure	Other
• Injection-drug use (current or ever) • Intranasal illicit drug use	• Long-term hemodialysis (ever) • Getting a tattoo in an unregulated setting • Healthcare workers • Children born to HCV-infected women • Prior recipients of transfusions or organ transplants • Ever incarcerated	• HIV infection • Sexually active person about to start HIV PrEP • Unexplained chronic liver disease • Solid organ donors

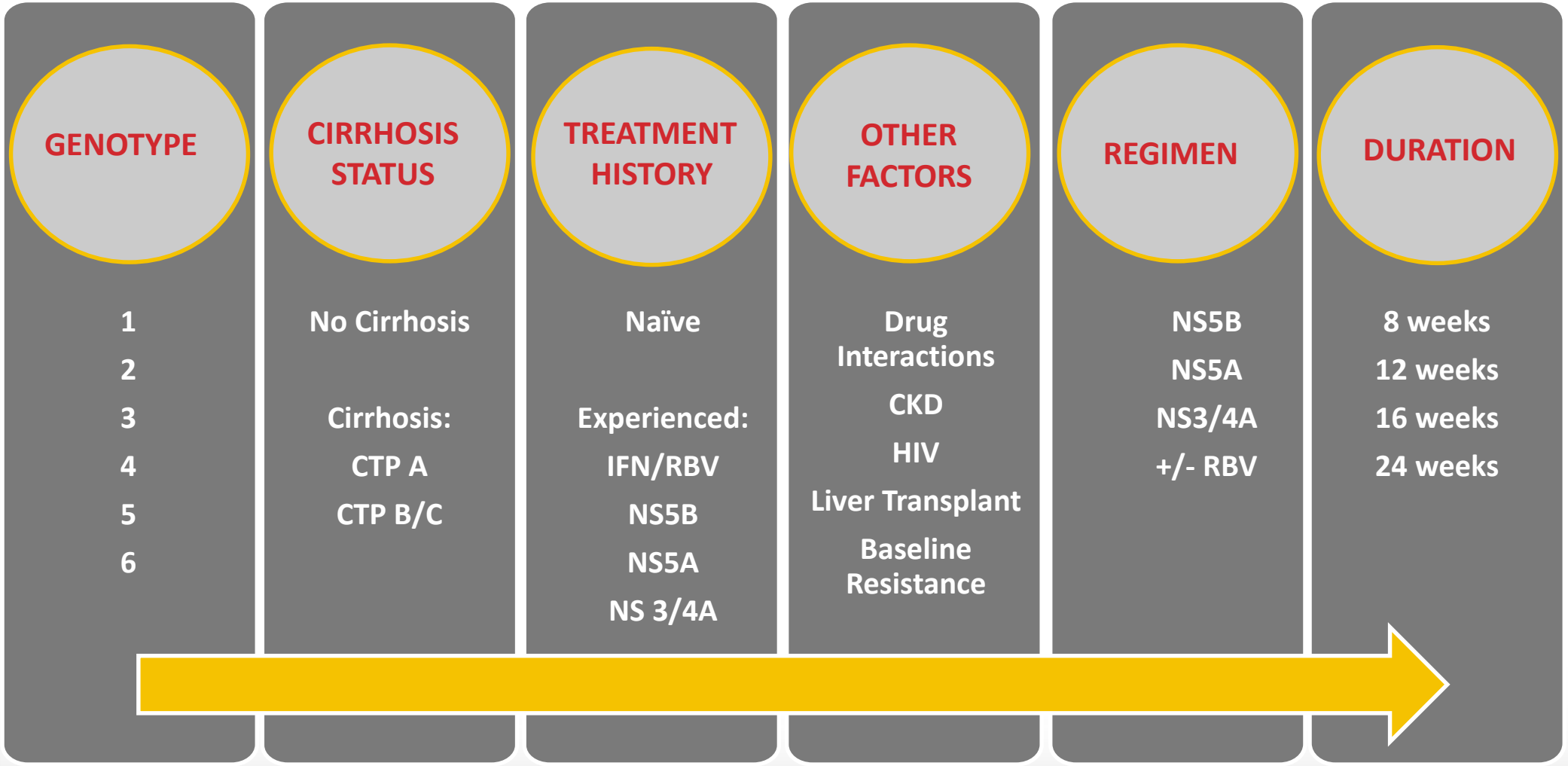
AASLD/IDSA HCV Treatment Guidelines 2018.



* Chronic HCV-Infected; N=3,500,000.
† Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.
‡ Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage with access to outpatient care (86.9%); n=1,514,667.
§ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.
|| Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.
¶ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=555,883.
** Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.
Note: Only non-VA studies are included in the above HCV treatment cascade.

Yehia BR et al. *PLoS One* 2014.

Approach to Treatment Selection



Slide courtesy of Alicia Carver, PharmD

HCV Treatment Options

Non-specific antivirals

- Pegylated interferon-alfa
- Ribavirin

NS3/4A Protease Inhibitors (-previr)

- ~~Telaprevir~~
- ~~Boceprevir~~
- Simeprevir
- Paritaprevir
- Grazoprevir
- Glecaprevir

NS5A Inhibitors (-asvir)

- Ledipasvir
- Ombitasvir
- Daclatasvir
- Elbasvir
- Pibrentasvir
- Velpatasvir

NS5B Inhibitors (-buvir)

- Sofosbuvir
- Dasabuvir

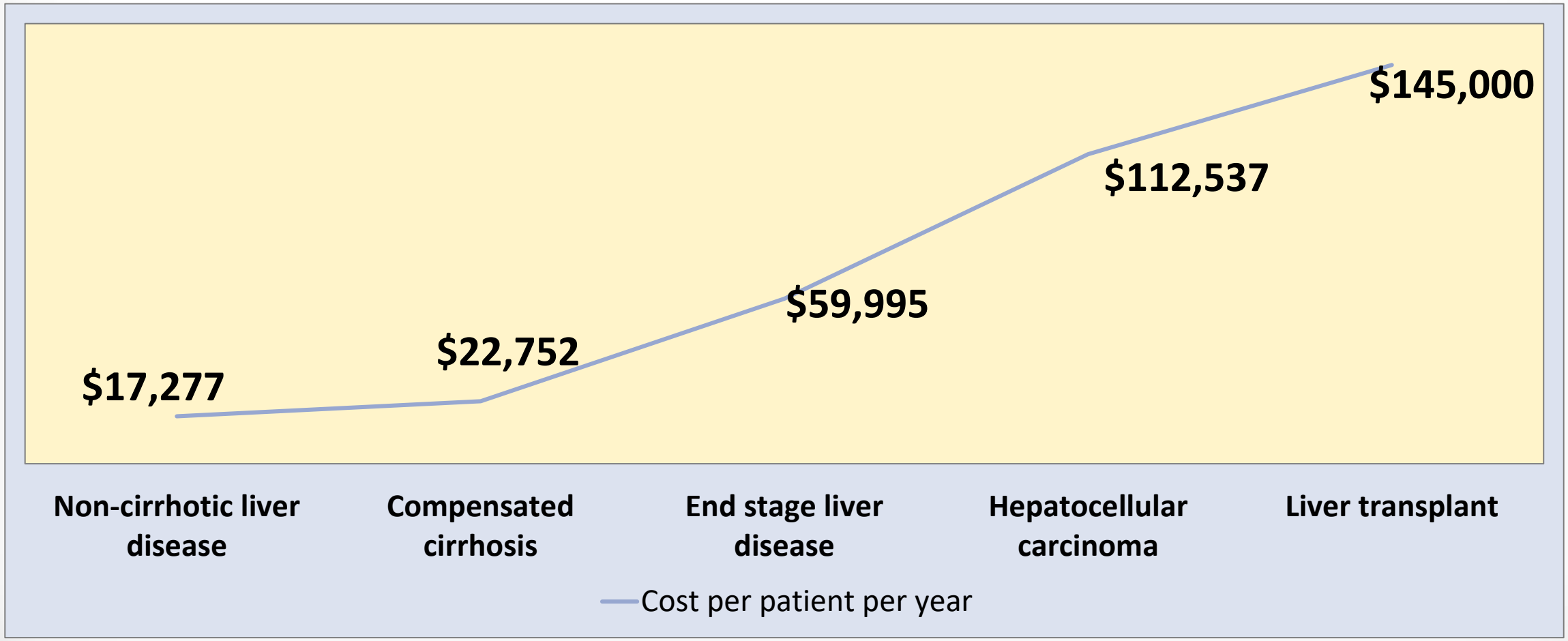
HCV Treatment Options Cont.

BRAND NAME	GENERIC NAME	Manufacturer
Harvoni™	ledipasvir/sofosbuvir (LDV/SOF)	Gilead
Epclusa™	sofosbuvir/velpatasvir (SOF/VEL)	Gilead
Vosevi™	sofosbuvir, velpatasvir, & voxaliprevir (SOF/VEL/VOX)	Gilead
Sovaldi™	sofosbuvir (SOF)	Gilead
Viekira Pak™ and Viekira XR™	dasabuvir, ombitasvir, paritaprevir, & ritonavir (PrOD)	Abbvie
Technivie™	ombitasvir, paritaprevir, & ritonavir (PrO)	Abbvie
Mavyret™	glecaprevir/pibrentasvir (G/P)	Abbvie
Daklinza™	daclatasvir (DCV)	Bristol-Myers Squibb (BMS)
Zepatier™	elbasvir/grazoprevir (EBR/GZR)	Merck
Olysio™	simeprevir (SIM)	Janssen
Copegus™, Ribapak™	ribavirin (RBV)	many

Outline

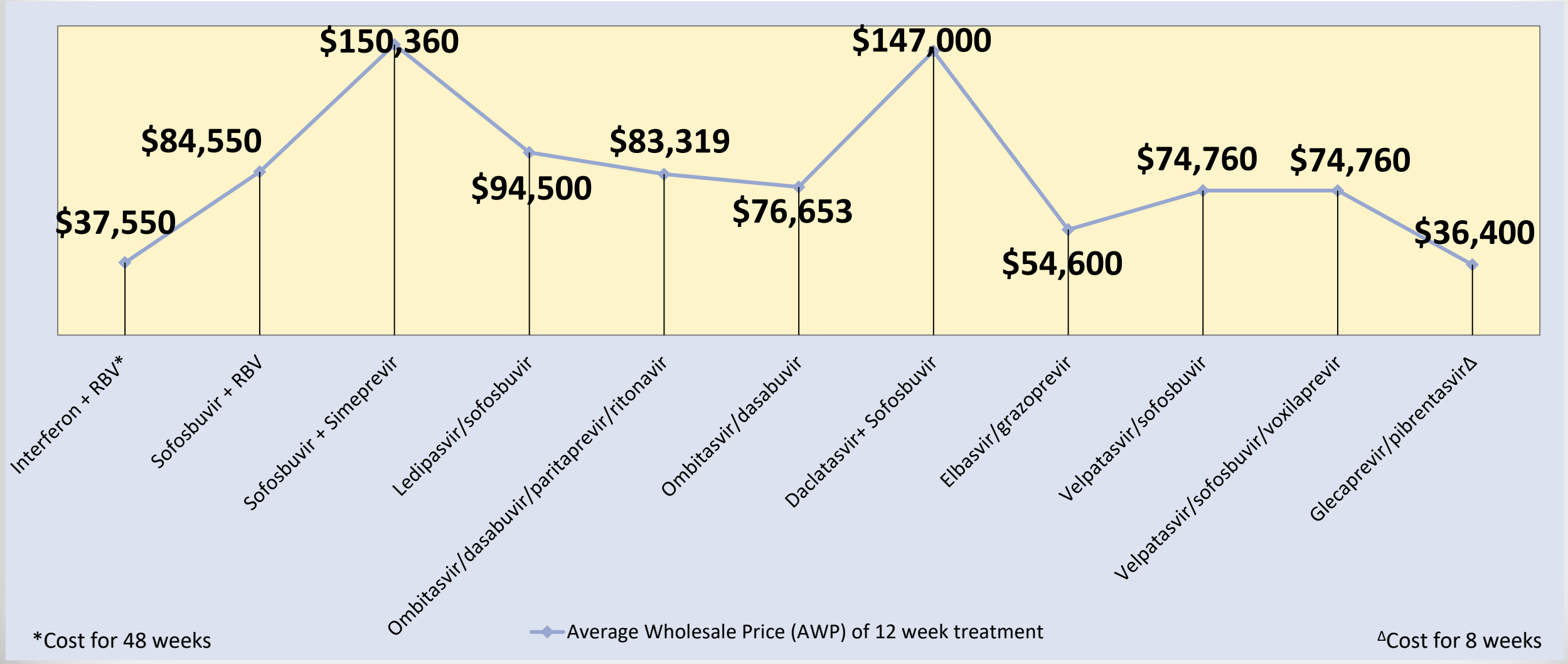
- HCV Review
- **HCV and Healthcare Finances**
- Navigating the System
  - Patients With Prescription Insurance
  - Patients Without Prescription Insurance
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- Access On the Horizon

Cost Due to HCV and Related Care



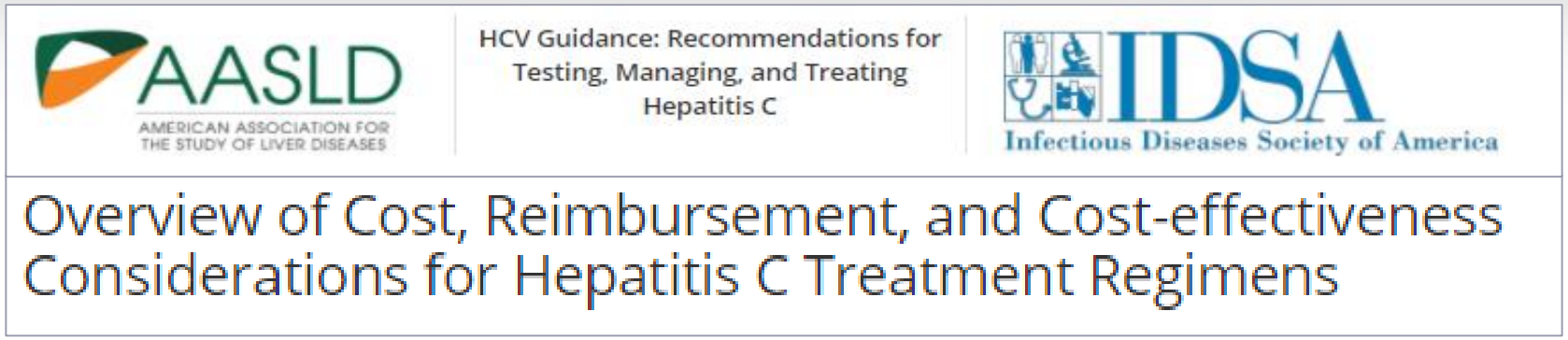
Younossi Z et al. *Dig Liver Dis* 2014.

Cost of HCV Treatment



*Cost for 48 weeks

ΔCost for 8 weeks



- Genotype 1: ICERs from $0 to $31,452 per QALY gained
- Limitations
  - Newer agents
  - Analyzed using WAC pricing
- "..actual current cost of HCV DAAs, competition and negotiated pricing…continue to limit the public health impact of these new therapies"
- "To be clear, this section is informational. As explained below, **actual costs are rarely known.** Accordingly, the HCV Guidance **does not utilize cost-effectiveness** analysis **to guide recommendations at this time.**"

Access Restrictions

- Public and private payer requirements vary by state and program
- All Payers:

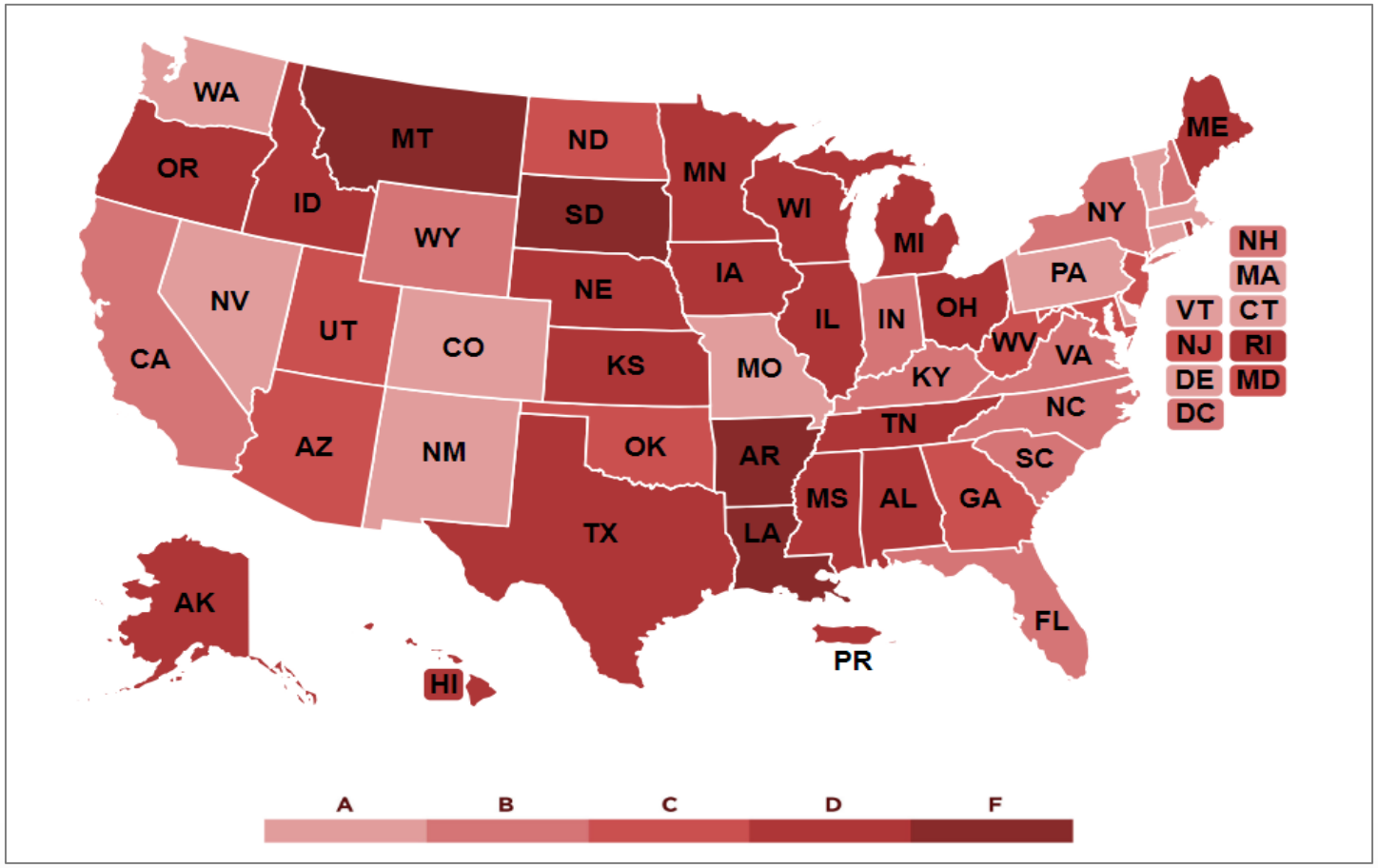
Common

- Fibrosis stage
- Prescriber type
- Substance use

Less Common

- HIV co-infection
- “Once per lifetime”
- Genotype
- Previous adherence requirement
- Specialty pharmacy restriction
- Exclusivity agreements

Hepatitis C State of Medicaid Access



https://stateofhepc.org/

NVHR National Viral Hepatitis Roundtable

CHLPI CENTER for HEALTH LAW and POLICY INNOVATION HARVARD LAW SCHOOL

Outline

- HCV Review
- HCV and Healthcare Finances
- **Navigating the System**
  - **Patients With Prescription Insurance**
  - Patients Without Prescription Insurance
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- Access On the Horizon

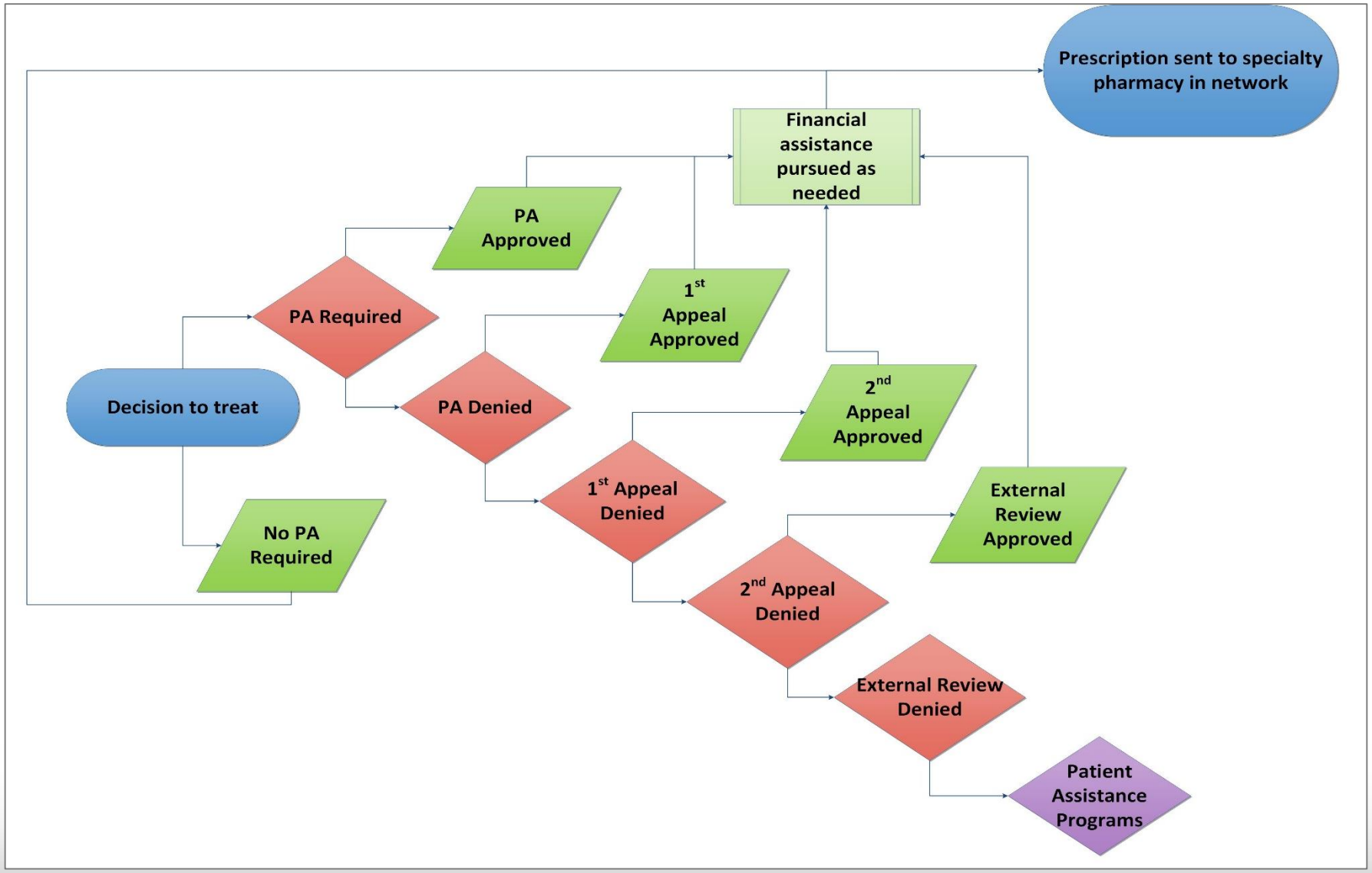
Patient Case 1: Gabriel

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

Patient Case 2: Lucas

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

Insured Medication Access Process



Prior Authorization

Paper/Fax

- Obtain PA application
- Complete PA paperwork
- Gather supporting materials
- Fax to insurance

Electronic

- Covermymeds.com
- All paperwork completed online

Phone

- Primarily used for PA extension

Prior Authorization

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

Patient Case 1: Gabriel

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 GT1a 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 MD — 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 2: Lucas

TN Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_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: Greene

FIRST NAME: Matthew

NPI NUMBER:

DEA NUMBER:

PHONE NUMBER: – –

FAX NUMBER: – –

Is the prescriber a TennCare provider with a Medicaid ID? ■ Yes ☐ No

Is the prescriber a single-patient contract holder for this patient? ☐ Yes ■ No

INSTRUCTIONS TO THE PROVIDER — Please note the following criteria for approval and for denial of 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	2875352 IU/ml	11/01/2017
Week 4 HCV RNA level		
Week 12 HCV RNA level		

TN Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Margret

Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_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 ☒ No
3. Does the patient have a diagnosis of compensated cirrhosis? ☒ Yes ☐ No
4. Is the patient post liver transplant? ☐ Yes ☒ No
5. Please check if the patient has any of the following. If yes, documentation must be attached.
   - [ ] Liver biopsy showing Metavir score of F2-F4
   - [x] Fibrotest (FibroSure) score of ≥ 0.49
   - [x] Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa
   - [x] Fibrosis-4 index (FIB-4) > 1.45
   - [x] Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5
   - [ ] None of the above or not otherwise specified, provide staging: _____
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) ☒ 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 i attached
8. Has the patient been free of substance abuse for the previous 6 months? ☒ Yes ☐ No
9. Has the patient been free of alcohol abuse for the previous 6 months? ☐ Yes ☒ No
10. For females: Is the member currently pregnant? ☐ Yes ☒ No
11. Is the patient's Creatinine clearance greater than 30 ml/minute? ☒ Yes ☐ No
12. Does the patient have End-stage renal disease? ☐ Yes ☒ No
13. Will the patient be taking in combination with ribavirin? ☐ Yes ☒ No
14. For genotype 1 and 4, does the patient have a reason they cannot take the preferred agent? ☒ Yes ☐ No

TN Division of Health Care Finance & Administration | TennCare

Prior Authorization Form

Mavyret

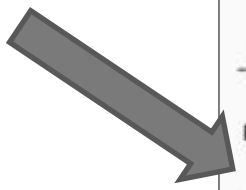
Access this PA form at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_PA_Request_Form.pdf

15. If yes, what is the reason:

Viekira is no longer recommended in GT1a with cirrhosis.

16. For genotypes 5 and 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 HCV and cirrhosis who is naive to treatment. He recently completed alcohol rehab (records attached) and currently lives in a recovery home. He does not use illicit drugs

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

Cody Chastain MD — 11-10-17

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: Gabriel APPROVED!

Document and monitor dates of approval.

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 $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		
Vosevi®	$5	https://www.vosevi.com/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		
Mavyret®	$5	https://www.mavyret.com/ **Contact:** 1-877-628-9738		

Copay Cards: Bristol-Myers Squibb Patient Support CONNECT

Drug	Patient Cost	Copay Card Information	Card Details	Eligibility
Daklinza®	$0	https://bmsdm.secure.force.com/patientsupportconnect/patient **Contact:** 1-844-442-6663	-Max of $5,000 per 28-day supply of 30mg or 60mg tablets OR up to max of $10,000 per 28-day supply of 90mg	-Resident of US or Puerto Rico -No state or federally funded programs -≥18 years old

Copay Cards: Merck

Drug	Patient Cost	Copay Card Information	Card Details	Eligibility
Zepatier®	$5	https://www.merckaccessprogram-zepatier.com/hcp/copay-assistance/ **Contact:** 1-866-251-6013	-Max of 25% of the catalog price per prescription	-Resident of US or Puerto Rico -No state or federally funded programs -≥18 years old

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: Lucas

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: MAVYRET
Strength: 100MG-40MG
Dosage Form: TABLET

MEDICAL PROVIDER:

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

PHARMACY PROVIDER:

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

OUTCOME OF CLINICAL REVIEW OF REQUEST

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

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

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.

MAGELLAN HEALTH SERVICES

Magellan Health Services contracts with TennCare to provide prior authorization services. All prior authorization determinations are based on the information submitted with the request as reviewed in light of Clinical Criteria approved by TennCare. Prior authorization is not a guarantee of payment. Final payment determinations are not made by Magellan Health Services and are affected by the patient's current eligibility status with TennCare. If you have any questions or would like to discuss this request with a clinical pharmacist, please call (866)434-5524. Send return fax documents to (866)434-5523.

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
- Why this regimen
- Patient need for treatment

Relevant overall patient medical history and current condition
- HCV-related history
- Confounding comorbidities
- Any additional health-related concerns

Address denial
- State reason if provided
- Rationale to address each reason for denial
- Why benefits outweigh risks
- Reasoning for regimen
- Appropriateness of therapy despite restrictions

Describe likely outcomes with the treatment
- Cure rates based on clinic trial data
- Morbidity and mortality benefits

Restatement of request for approval
- Final summary of all information and need for treatment

https://www.mavyret.com/hcp/appealing-prescription-coverage

Appeal Supporting Documents

- Any required appeal form from the insurer (if applicable)
- Copy of the denial letter from the insurance company
- Patient's complete medication profile
- Patient's medical profile as warranted
- Relevant lab results, diagnostics, pathology reports, including illicit drug screening results
- Relevant treatment guidelines → underline applicable sections
- Relevant peer-reviewed journal articles
- Relevant clinical trial information

https://www.mavyret.com/hcp/appealing-prescription-coverage

Appeal Support

Template Letters of Appeal

Harvoni

March 1, 2016

RE:

Dear Sir or Madam:

Two studies evaluated the re-treatment of persons with chronic hepatitis C who relapsed after the use of sofosbuvir regimens. The first, called the SYNERGY trial, included 16 patients from the NIAIAD SPARE study. These subjects were difficult to treat, genotype 1 who relapsed after 12 weeks of sofosbuvir and ribavirin. All were retreated with ledigasvir/sofosbuvir (LDV/SOF) single table regimen (STR) for 12 weeks and all fourteen achieved a SVR12 (100%). The second study, ELECTRON-2, evaluated patients who failed previous sofosbuvir regimens, including SOF plus ribavirin (RBV) for 24 weeks, LDV/SOF plus RBV for 6 weeks and SOF plus GS6986 plus RBV. These nineteen patients were re-treated with LDV/SOF plus RBV for 12 weeks and all of them achieved a SVR12 (100%). [1,2]

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

It is imperative we continue to provide the latest and most efficacious treatments for patients with cirrhosis as they are at high risk for developing hepatocellular carcinoma, liver failure and death. These sequelae can necessitate liver transplant. In 2011, the cost of a liver transplant was estimated to be $577,100 [4], far exceeding the cost of treatment with the prescribed regimen.

Compared to data findings from the National Multiple Cause of Death Study during 2006-2010, the mortality rate of persons with HCV is 12 times higher than the national average. Plus, the average age at death was found to be 15 years younger than the "all-cause death age." [5] Therefore, it is my clinical opinion and assessment will benefit from treatment with Harvoni for 24 weeks I trust the information presented, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

Kris Kowdley, MD, Hepatology

References:

Harvoni

Harvoni Appeal 2

RE:

Dear Sir or Madam:

I am requesting reconsideration of your denial for the use of once daily Harvoni® (ledipasvir plus sofosbuvir) for X weeks for my patient, , who suffers from chronic hepatitis C (HCV) genotype 1B with F2 fibrosis. Even though does not have F4 or F4 liver disease, he *is more likely to achieve SVR12* than persons with F0-F4 disease. Plus, significant medical costs can be avoided by treating X before the advancement of his liver disease. [3] The safety and efficacy of Harvoni was established in clinical trial, thus reducing the cost needed to treat adverse events while he is on HCV treatment.

Not only it this regimen FDA approved, it is consistent with the joint recommendations of the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA). These guidelines, updated December 19, 2015, have become the gold standard for the treatment of persons with HCV. The full report of the AASLD/IDSA recommendations is available at www.hcvguidelines.org

Mr. x is ineligible for an interferon based therapy as he has a history of depression, diabetes, hypertension, coronary artery disease, chronic fatigue, chronic pain, easy bruising and thrombocytopenia which can be exacerbated with an interferon based regimens leading to the deterioration of his health. Plus, Harvoni is **the most cost effective** and is the **shortest treatment regimen** than other FDA approved or curtionary treatments for genotype 1. [Table 1]

Table 1: Comparison of Sustained Virologic Response and Wholesale Acquisition Cost for Treatment

STUDY Regimen Duration	DON-3 Harvoni x 8wks	Diet-mich, Hassan, et al [8] Olysio + Sovaldi x 12wks	JHOTON-1 Sovaldi + RBV x 24 wks
Sustained Virologic Response [2,3,4]	SVR12 98%	SVR12 93%	SVR12 76%
Wholesale Acquisition Costs [5]	$63,000	$150,360	$168,000

Treatment with Harvoni for X weeks is a necessary therapy for Mr. X as it prevents disease progression to cirrhosis, hepatocellular carcinoma or even liver failure. These sequelae can necessitate liver transplant. In 2011, the cost of a liver transplant was estimated to be $577,100 [6], far exceeding the cost of treatment with the prescribed regimen.

Of further interest, compared to data findings from the National Multiple Cause of Death study during 2006-2010, mortality rate of persons with HCV is 12 times higher than the national average. Plus, the average age at death was 15 years younger than the "all-cause death age." [7] With this in mind, it is my clinical opinion and assessment will benefit from this regimen. I trust the information presented, along with my medical recommendations, will establish the medical necessity for payment of the claim.

Sincerely,

Kris Kowdley, MD, Hepatology

References:

Harvoni

March 1, 2016

RE:

Dear Sir or Madam:

Results of the phase 2 ION-4 clinical trial for once a day Harvoni® (ledipasvir-sofosbuvir) plus ribavirin for 12-24 weeks revealed 97% to 98% SVR12 (sustained viral response 12 weeks post HCV therapy) in patients with Child A and C cirrhosis. Therefore, I am requesting reconsideration of your denial of daily weight based ribavirin plus Harvoni for my patient, , who suffers from decompensated cirrhosis secondary to chronic hepatitis C (HCV) genotype 1A. You have approved the Harvoni, however it is only half of the HCV treatment prescribed. Mr X also needs ribavirin to eradicate her HCV. Not only is this regimen FDA approved, it is consistent with the joint recommendations of the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA). These guidelines, updated December 19, 2015, have become the gold standard for the treatment of persons with HCV. The full report of the AASLD/IDSA recommendations is available at www.hcvguidelines.org

Mr. X has progressive muscular dystrophy and also suffers from asthma, hypertension, ascites and has a pacemaker, all of which can be greatly exacerbated by an interferon based treatment leading to the deterioration of her overall health.

Additionally, Harvoni is more cost effective than other FDA approved or curtionary treatments for genotype 1 with cirrhosis.

Treatment with Harvoni and daily weight based ribavirin for 24 weeks is a necessary therapy for Mr X. The data from clinical trials indicate patients like Mr. X have an exceedingly high chance of attaining SVR within 24 weeks with Harvoni and daily weight based ribavirin. If Mr. X can be cured of HCV, she may have a regression of her cirrhosis. Studies have shown SVR (aka cure) is associated with decreased incidence of hepatocellular carcinoma, liver related mortality and overall mortality. In the study following 640 patients with HCV and stage 3 or 4 disease, SVR (aka cure) significantly improved cumulative 10-year survival (91.2% with SVR vs 79% without SVR). Curing Mr X will significantly decrease her chances of liver related death and liver transplant. In 2011, the cost of a liver transplant was estimated to be $577,100 [7], far exceeding the cost of treatment with the prescribed regimen.

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

Sincerely,

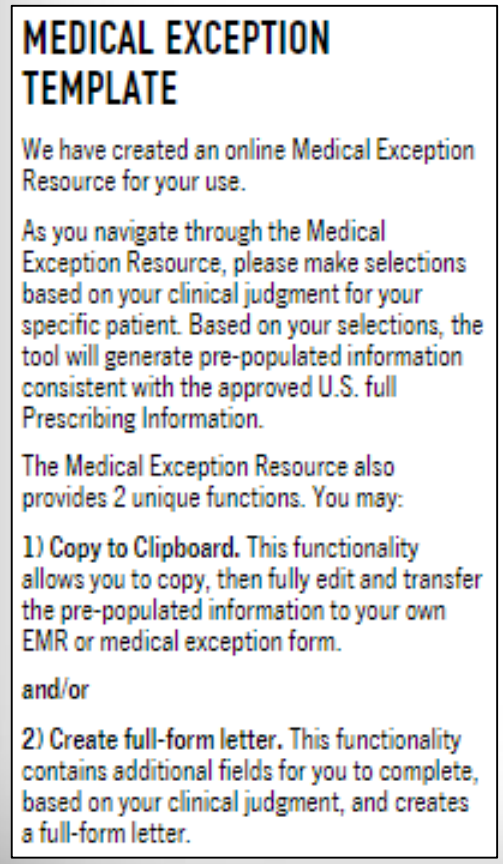
Kris Kowdley, MD

References:

HIVMA/IDSA: http://hcvtreatmentaccess.org/drug-appeals/#section2

Appeal Support

- Mavyret® Medical Exception Request



MEDICAL EXCEPTION TEMPLATE

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

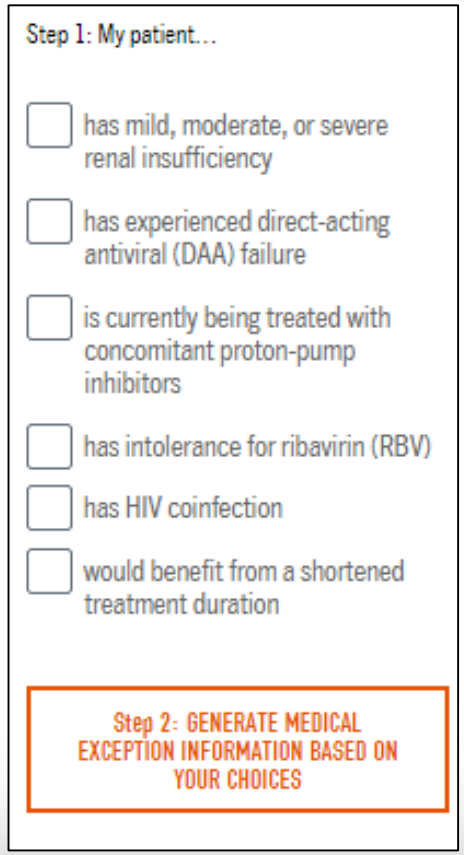
As you navigate through the Medical Exception Resource, please make selections based on your clinical judgment for your specific patient. Based on your selections, the tool will generate pre-populated information consistent with the approved U.S. full Prescribing Information.

The Medical Exception Resource also provides 2 unique functions. You may:

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

and/or

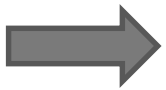
2) **Create full-form letter.** This functionality contains additional fields for you to complete, based on your clinical judgment, and creates a full-form letter.

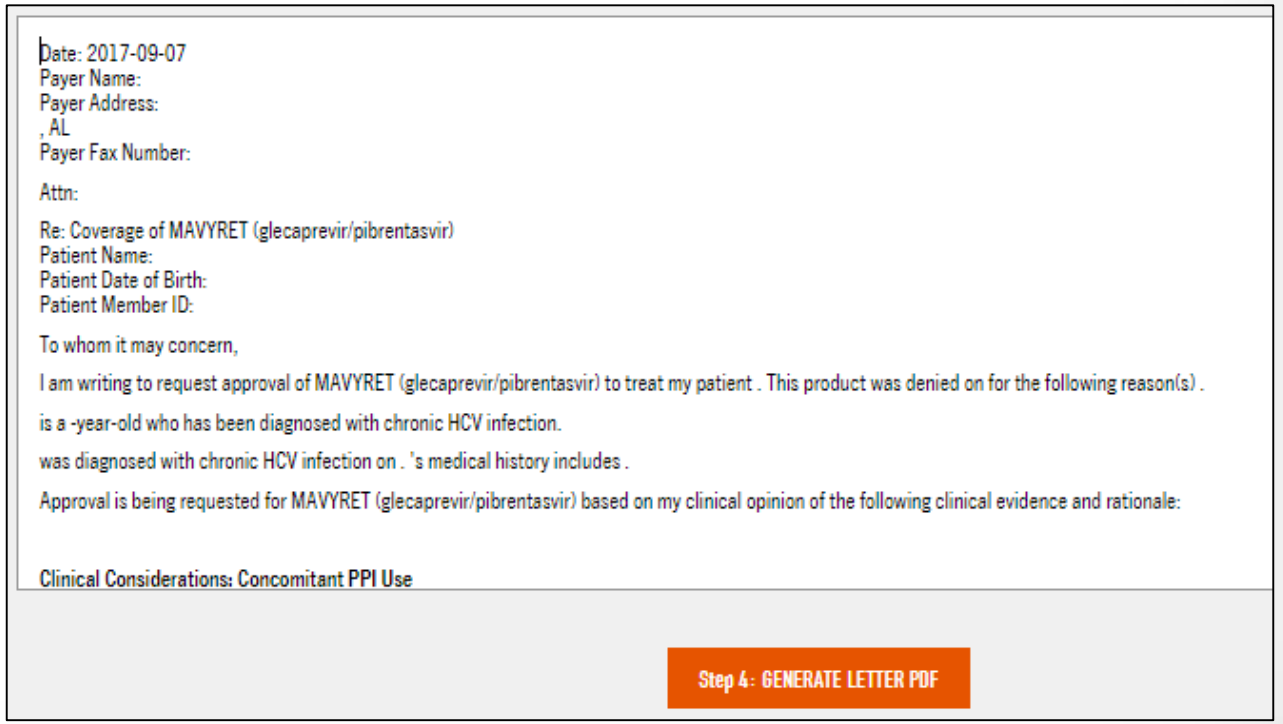


Step 1: My patient…

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

Step 2: GENERATE MEDICAL EXCEPTION INFORMATION BASED ON YOUR CHOICES





Date: 2017-09-07
Payer Name:
Payer Address:
, AL
Payer Fax Number:

Attn:

Re: Coverage of MAVYRET (glecaprevir/pibrentasvir)
Patient Name:
Patient Date of Birth:
Patient Member ID:

To whom it may concern,

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

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

was diagnosed with chronic HCV infection on . 's medical history includes .

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

Clinical Considerations: Concomitant PPI Use

Step 4: GENERATE LETTER PDF

Patient Case 2: Lucas Appeal

Lucas Appeal

- Reason for request
- State denial reason
- Relevant medical history

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

November 15th, 2017

RE: Appeal for glecaprevir/pibrentasvir (Mavyret®)

To Whom It May Concern:

I am contacting you on behalf of my patient Mr. ___ (DOB ___; Member ID# ___; Case ID# ____). He has been prescribed a 12 week course of dual acting antiviral therapy containing glecaprevir/pibrentasvir (Mavyret®) for his hepatitis C (HCV) infection. He has a history of HCV infection (ICD 10: B18.2**), genotype 1a with compensated cirrhosis as evidenced by a CT in October 19th, 2006**, and more recent fibrosis score of 0.84 by Fibrosure testing on 11/1/17. Additionally, an abdominal **ultrasound with elastography revealed F2-F3** fibrosis on 11/6/17. He is naïve to previous HCV treatment and has evidence of active viremia as shown by his viral load of 2,875,352 IU/mL on 11/1/2017. He was recently denied HCV treatment, with no specified rationale other than "does not meet the criteria for approval." **Given Mr. ___'s advanced disease, he is at high risk for hepatocellular carcinoma and hepatic decompensation which could require transplant and therefore should be treated at this time.** He has completed alcohol rehab 1 month ago and currently lives in a recovery home. He has abstained from alcohol use since completion of rehab. **Denial of treatment in this patient with advanced disease due to a history of alcohol abuse places him at high risk for hepatic decompensation. This type of restriction is in direct opposition to CMS guidance (attached) and the Social Security Act and is not applied to other disease states.**

Lucas Appeal

- Address denial

The AASLD/IDSA Hepatitis C Treatment Guidelines recommend patients with chronic HCV infection abstain from alcohol and drug use, but do not exclude these patients from being considered for treatment, specifically stating **"Data are lacking to support exclusion of HCV-infected persons from considerations for hepatitis C therapy based on the amount of alcohol intake or the use of illicit drugs. Based on data from IFN-based treatment, SVR rates among people who inject drugs are comparable to those among people who do not inject drugs."** On the contrary, they recommend treatment for patients with ongoing drug and alcohol use, highlighting the benefit of treating this patient population:

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

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

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

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

Lucas Appeal

- Describe outcome with treatment
- Summary statement
- List inclusions
- References

The AASLD/IDSA Society Hepatitis C Treatment Guidelines were recently updated in September 21st, 2017, and include four regimens for patients with HCV genotype 1a and cirrhosis: ledipasvir/sofosbuvir for 12 weeks, elbasvir/grazoprevir for 12 weeks (in patients without NS5A polymorphisms), glecaprevir/pibrentasvir for 12 weeks, and velpatasvir/sofosbuvir for 12 weeks.

Glecaprevir/pibrentasvir has been prescribed for Mr. ____ based on the results of the EXPEDITION-1 trial in which **99% (n=145) of patients with genotypes 1, 2, 4, 5, and 6 with compensated cirrhosis achieved an SVR12**. Unlike Mr. ___ who is treatment naïve, the one virologic relapse in this study was previously a non-responder to Peg-IFN and ribavirin. Rates of SVR12 were slightly lower with the use of ledipasvir/sofosbuvir for 12 weeks in the ION-1 trial at 97%.

In summary, it is recommended that Mr. ____'s HCV be treated now for the aforementioned reasons in order to avoid additional potential morbidity, mortality, and cost associated with worsening liver function. He is an ideal candidate for treatment given his advanced disease, recent rehabilitation and current housing in a recovery home, and lack of illicit substance use. **The 12 week course of the requested glecaprevir/pibrentasvir is efficacious, follows FDA labeling, and therefore should not be withheld from this patient based on the Social Security Act under section 1927(d)(1) and (2).** Eradication of the virus now is optimal in order to prevent progression of his liver disease and associated complications, including hepatic decompensation, hepatocellular cancer, liver transplantation, and/or death. Patient is at high risk of decompensation if treatment is withheld given portal hypertension seen on ultrasound six months ago.

Sincerely,

Matthew Greene, MD
Infectious Diseases Specialty

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

Case 2: Lucas approved!

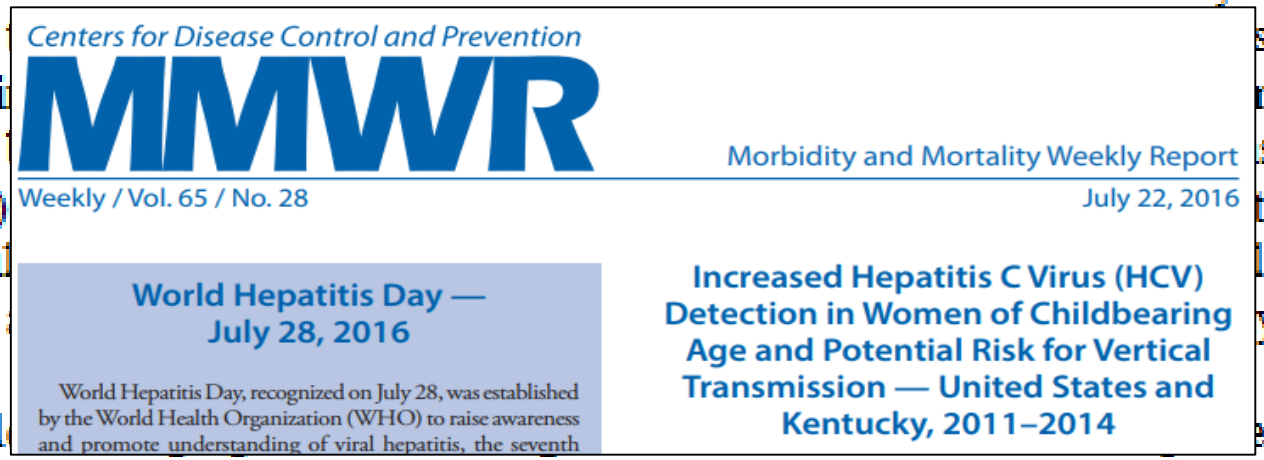
Special Denials

Early fibrosis

- Try to find an additional reason to treat:
  - Cryoglobulinemia
  - Proteinuria, nephrotic syndrome, membranoproliferative glomerulonephritis
  - HIV or HBV coinfection
  - Coexistent liver disease (i.e. NASH)
  - Debilitating fatigue
  - Type 2 Diabetes mellitus
  - Porphyria cutanea tarda
  - Child-bearing age

Child Bearing

The AASLD and IDSA Society released Hepatitis C Treatment Guidelines that were updated in September 2017, and recommend treatment for all individuals infected with HCV with very few caveats. The recommendation t sis is **supported by evidence suggesting that i nay extend the benefits of SVR** including a t s, decreased hepatocellular carcinoma (HCC) this progression occurs, it would likely resul l procedures, laboratory testing, imaging, y at http://hcvguidelines.org.


Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 65 / No. 28

July 22, 2016

World Hepatitis Day — July 28, 2016

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

Increased Hepatitis C Virus (HCV) Detection in Women of Childbearing Age and Potential Risk for Vertical Transmission — United States and Kentucky, 2011–2014

Ms. xxx is of chil es **her at risk for vertical transmission**. Unfortunately, the CDC recently released an MMWR regarding the **drastic increase in HCV among women of childbearing age** and vertical transmission (attached). Treating her HCV at this time would eliminate vertical and household transmission risk.

AASLD/IDSA Guidelines Guidance on Ongoing Alcohol/Illicit Substance Use

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

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

Centers for Medicare/Medicaid Services (CMS) Guidance

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

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

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

Adherence Readiness

- Denial: “Physician/provider asserts that the patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen. The information sent in does not show your patient meets these criteria.”

Psychosocial Readiness Evaluation to Prepare for hepatitis C treatment (PREP-C)

PREP-C Assessment Areas

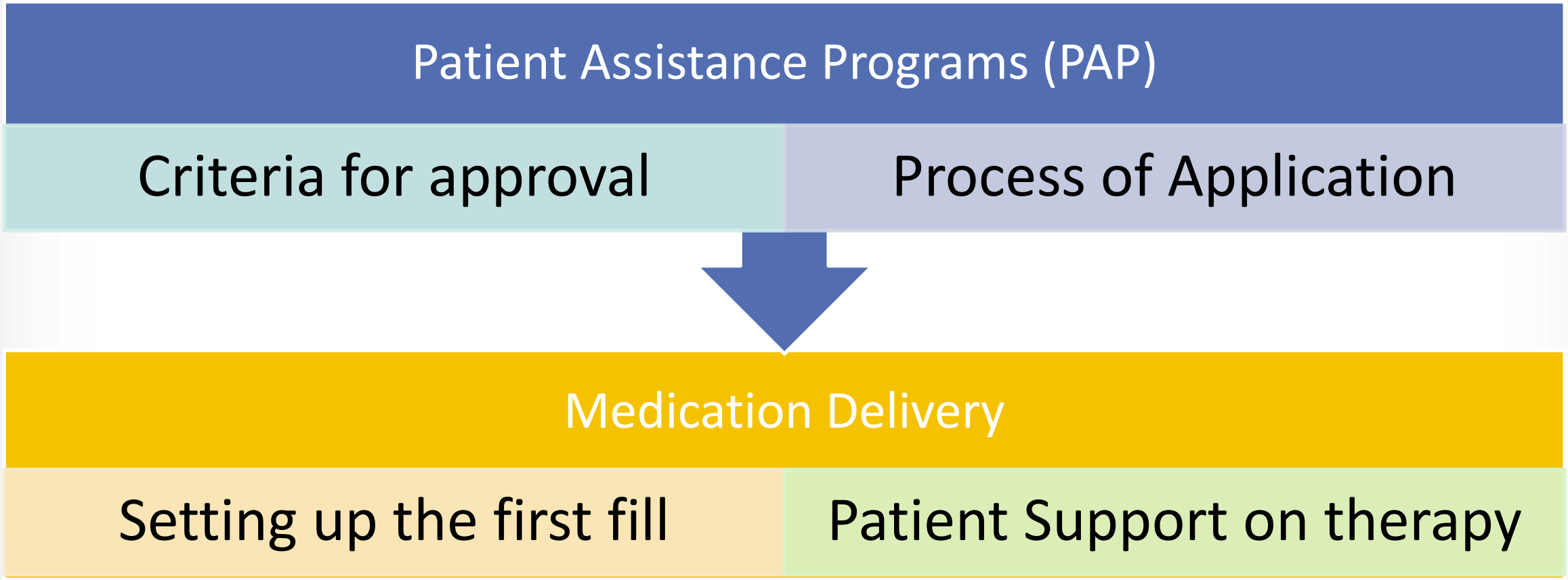
1. **Motivation**: Reasons client wants to begin HCV treatment, concerns about treatment, and importance of treatment.
2. **Information**: Knowledge about HCV treatment and one's own HCV disease status.
3. **Medication Adherence**: Current prescribed medications and adherence to them in prior month.
4. **Self-Efficacy**: Self-confidence about adhering to HCV treatment.
5. **Social Support and Stability**: Stability of financial, housing, and social support resources.
6. **Alcohol and Substance Use**: Alcohol and substance use behaviors and current treatment.
7. **Psychiatric Stability**: Current psychiatric status, previous and current treatment.
8. **Energy Level**: Sleep and fatigue.
9. **Cognitive Functioning**: Perceived difficulty with communication in health care setting, problem-solving ability, and memory.

https://prepc.org/

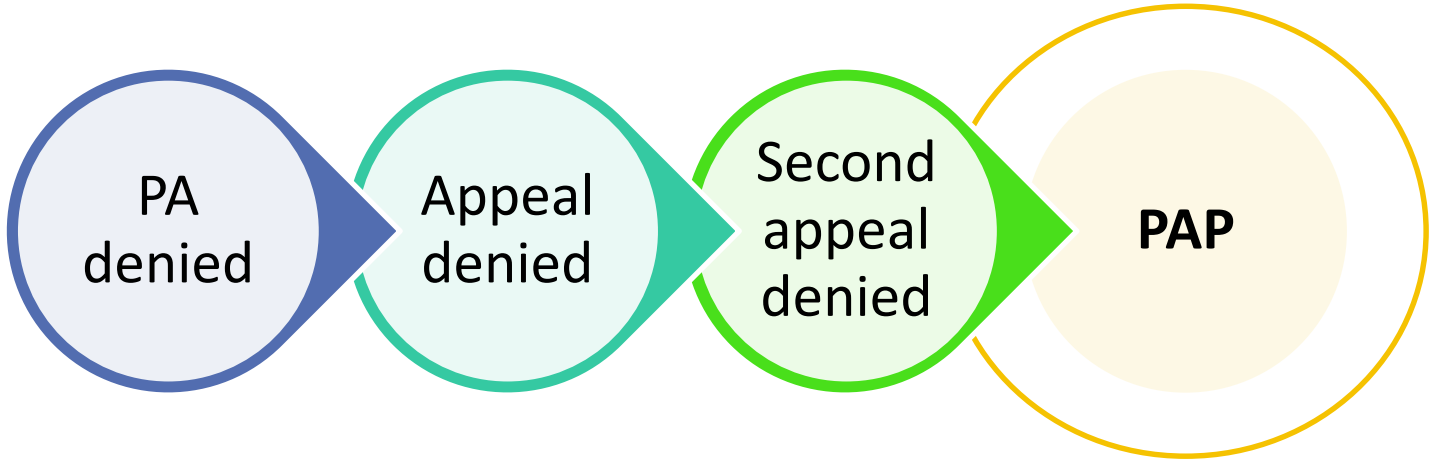
Outline

- HCV Review
- HCV and Healthcare Finances
- **Navigating the System**
  - Patients With Prescription Insurance
  - **Patients Without Prescription Insurance**
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- Access On the Horizon

The Un-Insured and Under-Insured



Underinsured



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

Uninsured

- Often easiest group to get approved!
- Manufacture PAP process relatively simple
- All require the following:

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 **OR**
	• 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
- Proof of residency is similar

To Whom It May Concern:

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

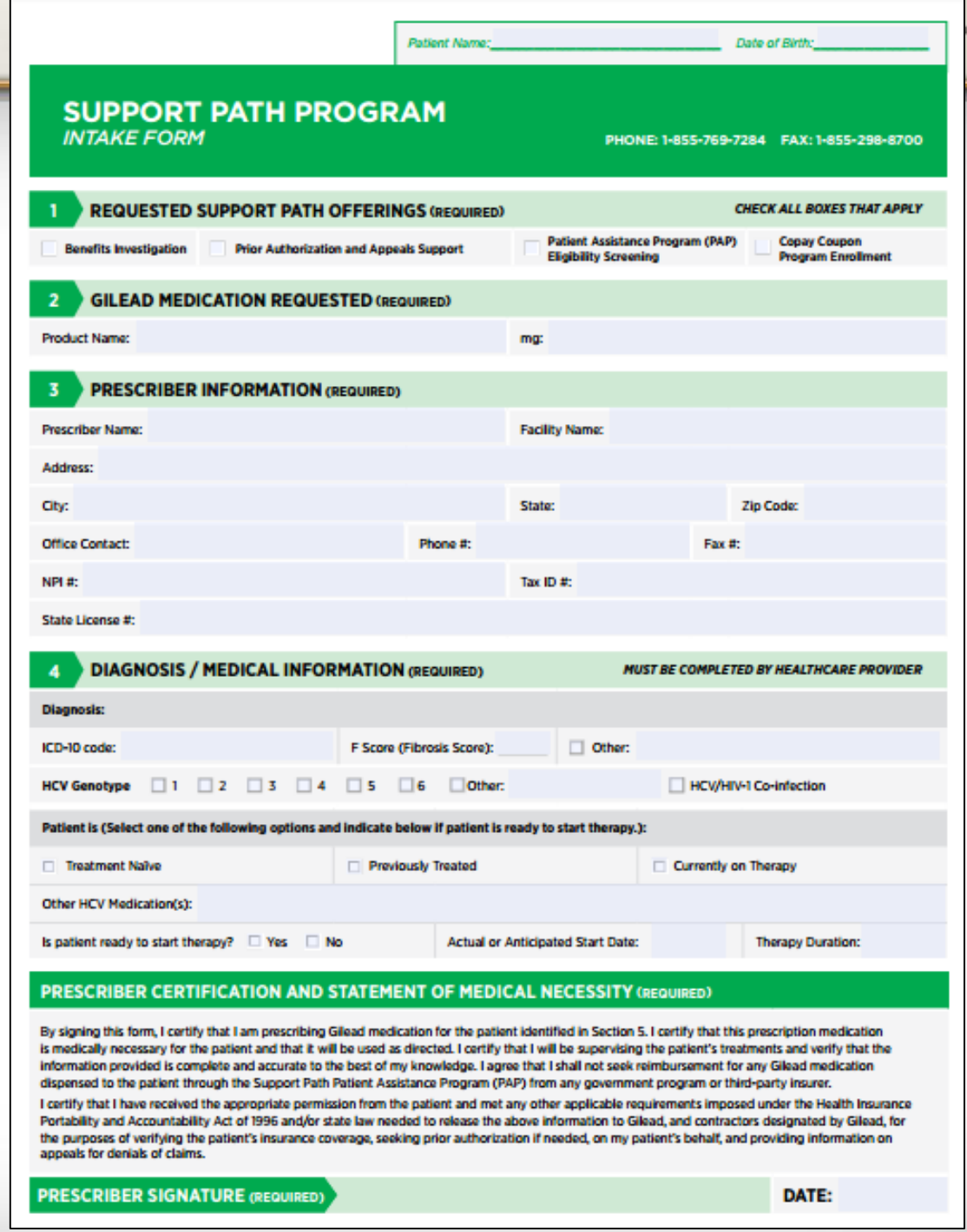
I live with my wife's uncle and do not pay rent at this time. I use food stamps for my meals. Unfortunately I am unable to afford health insurance at this time. I use a Merriweather Lewis discount card for my other medications.

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

Thank you,

PAP: Gilead

- http://www.mysupportpath.com
- Eligibility:
  - Applied and denied for Medicaid and state insurance marketplace
  - Ineligible for VA benefits
  - Provide household income and size



Patient 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:

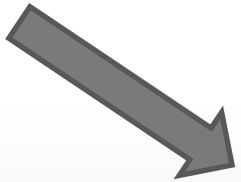
PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY (REQUIRED)

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

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

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

PATIENT TO COMPLETE

PATIENT INFORMATION

Patient Name: _____ DOB: _____

Gender: ☐ Male ☐ Female ☐ Other Language: ☐ English ☐ Spanish ☐ Other: _____

Address (No PO Box): _____

City / State / ZIP: _____

Primary Phone #: _____ ALT Phone #: _____

E-mail Address: _____

PATIENT CONSENT

☐ I would like to receive AbbVie communications about its products, services, or offerings that may be of interest to me.

HIPAA Authorization: My signature below certifies that I have read, understood, and agreed to the HIPAA Authorization on page 2.

PATIENT SIGNATURE/LEGAL REPRESENTATIVE (Indicate relationship) Date

PRESCRIBER TO COMPLETE

PRESCRIBER INFORMATION

Prescriber Name: _____

NPI #: _____

Specialty: ☐ Hepatology ☐ Gastro ☐ ID Other: _____

State License #: _____

Facility Name: _____

Address: _____

City / State / ZIP: _____

Prescriber Contact Person: _____

Prescriber Phone #: _____

Prescriber Fax #: _____

Prescriber E-mail Address: _____

Patient Preferred Pharmacy: _____

Pharmacy Contact & Phone: _____

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

Prescriber, please print name _____ Please sign _____ Date _____

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 3.
Please see full Prescribing Information.

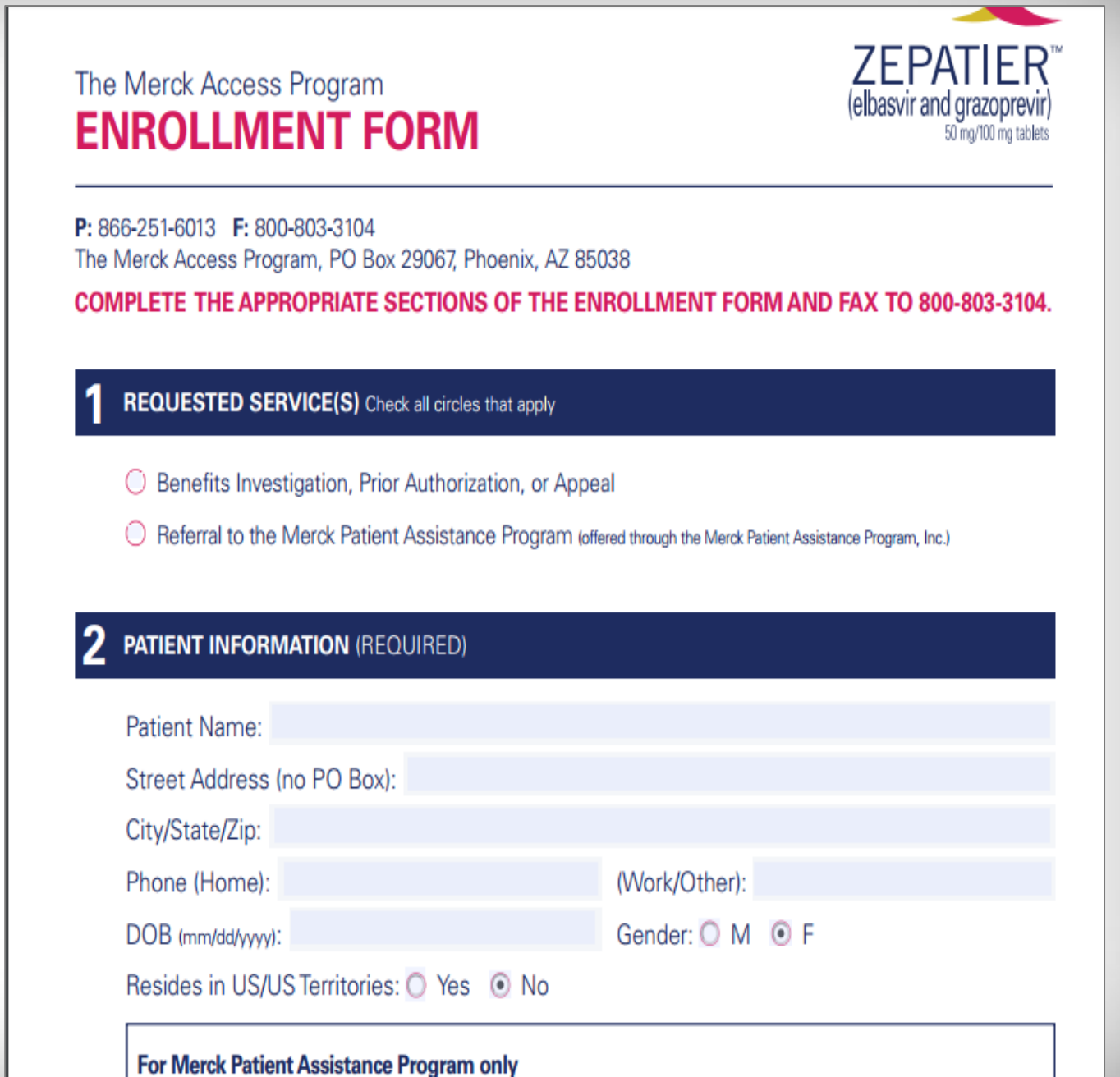
MAVYRET PATIENT SUPPORT

MAVYRET glecaprevir/pibrentasvir

https://www.mavyret.com/content/dam/abbvie-mavyret-brand/enrollment-form.pdf

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

Back to patient case 2: Lucas

What if he had been denied?

Emilia

- 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).

vas 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!

Emilia

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
- Discuss any language barriers with the pharmacy

On-Treatment Considerations

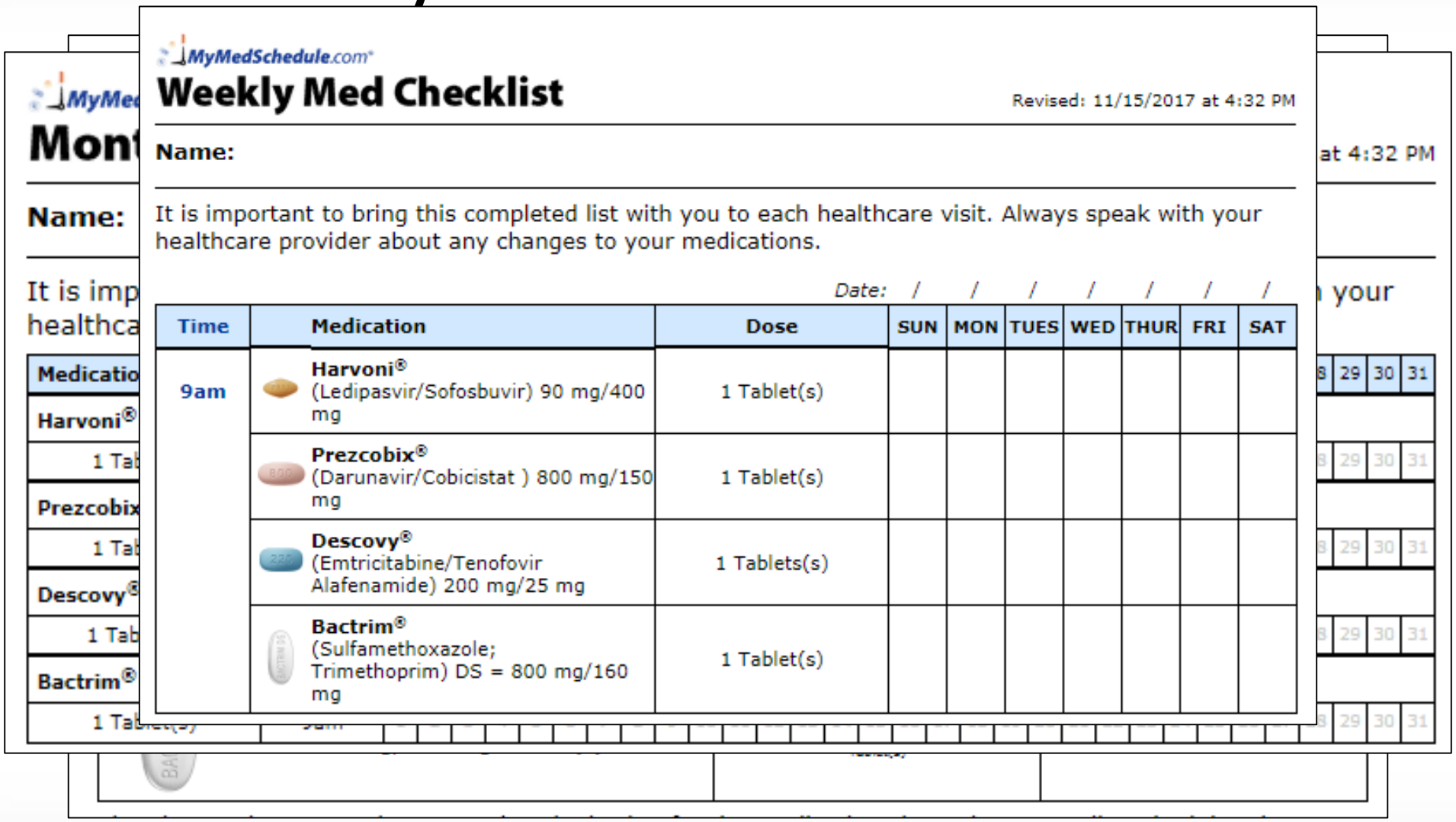
On-Treatment Considerations

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

Ongoing Alcohol/Illicit Substance Use Considerations

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

MyMedSchedule.Com



MyMedSchedule.com

Weekly Med Checklist

Revised: 11/15/2017 at 4:32 PM

Name:

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

Date: / / / / / / /

Time	Medication	Dose	SUN	MON	TUES	WED	THUR	FRI	SAT
9am	**Harvoni®** (Ledipasvir/Sofosbuvir) 90 mg/400 mg	1 Tablet(s)							
	Prezcobix® (Darunavir/Cobicistat) 800 mg/150 mg	1 Tablet(s)							
	Descovy® (Emtricitabine/Tenofovir Alafenamide) 200 mg/25 mg	1 Tablets(s)							
	Bactrim® (Sulfamethoxazole; Trimethoprim) DS = 800 mg/160 mg	1 Tablet(s)							

Outline

- HCV Review
- HCV and Healthcare Finances
- Navigating the System
  - Patients With Prescription Insurance
  - Patients Without Prescription Insurance
- **Tools**
  - **Manufacturer Patient Support**
  - **HCV Treatment Access Resources**
- Access On the Horizon

Priorities at the First Visit

- Educate patients
  - Time requirements for the process
  - Current restrictions and possible barriers to treatment
  - Need for ongoing communication
  - Specialty pharmacy requirement
- Obtain necessary work-up
  - Urine drug screen (based on insurance requirements)
  - Signature for release of information
  - Signature on PAP forms
- Confirm contact information
- Encourage engagement
- Evaluate possible drug interactions

Provider Support: Gilead Support Path

SUPPORT path®

The Gilead Support Path® program is committed to helping you afford your medication every step of the way.

If you need assistance with co-pays or paying for your medication, Support Path is available to help match you to a program that best meets your financial needs based on your circumstances and insurance situation and the eligibility criteria for the programs.

Support Path may be able to help guide you through the process of understanding the type of insurance you have and alternative coverage if needed.

REQUESTED PATIENT SUPPORT PATH OFFERINGS

Please select patient support offerings
CHECK ALL BOXES THAT APPLY

- ☐ **Benefits Investigation**
  Help research and verify specific insurance coverage for Gilead medication
- ☐ **Prior Authorization and Appeals Information**
  Provides information to your doctor if your insurance company requires your doctor to complete a Prior Authorization for your Gilead medication. Provides follow up with health insurers regarding the status of your Prior Authorization request and get updates on information needed.
- ☐ **Patient Assistance Program (PAP) Eligibility Screening**
  If you lack insurance coverage and meet the program criteria, you may be eligible to receive Gilead medication free of charge
- ☐ **Co-Pay Coupon Program Enrollment**
  If you are eligible, Gilead's Co-Pay Coupon may help lower your out-of-pocket costs. Patients enrolled in government prescription drug programs, such as Medicare Part D and Medicaid are not eligible for the co-pay coupon.

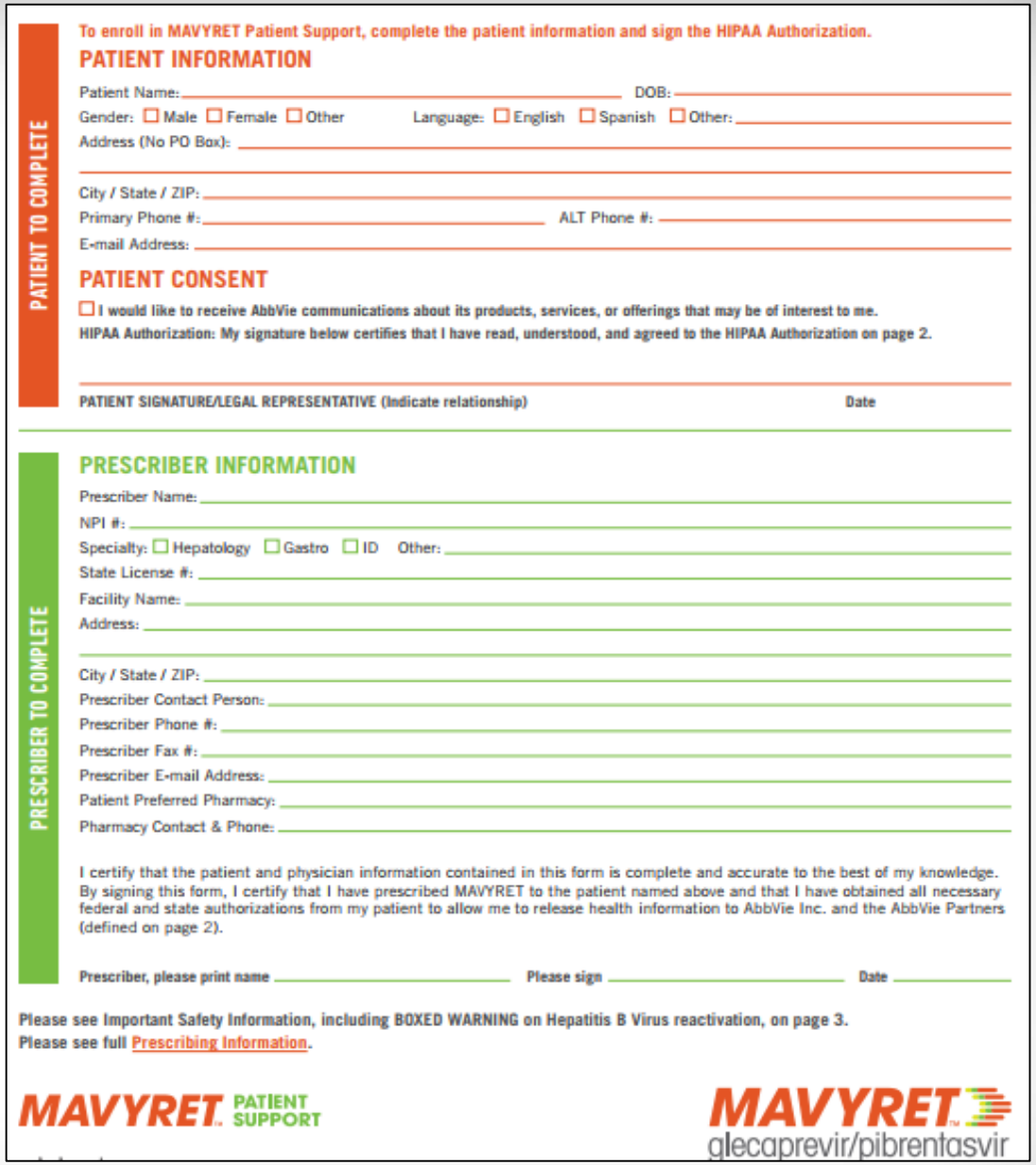
https://supportpathconsent.iassist.com

Provider Support: Gilead Support Path

https://supportpathconsent.iassist.com

PAP: Abbvie

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



PATIENT TO COMPLETE

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

PATIENT INFORMATION

Patient Name: _____ DOB: _____

Gender: ☐ Male ☐ Female ☐ Other Language: ☐ English ☐ Spanish ☐ Other: _____

Address (No PO Box): _____

_____

City / State / ZIP: _____

Primary Phone #: _____ ALT Phone #: _____

E-mail Address: _____

PATIENT CONSENT

☐ I would like to receive AbbVie communications about its products, services, or offerings that may be of interest to me.

HIPAA Authorization: My signature below certifies that I have read, understood, and agreed to the HIPAA Authorization on page 2.

_____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE (Indicate relationship) Date

PRESCRIBER TO COMPLETE

PRESCRIBER INFORMATION

Prescriber Name: _____

NPI #: _____

Specialty: ☐ Hepatology ☐ Gastro ☐ ID Other: _____

State License #: _____

Facility Name: _____

Address: _____

_____

City / State / ZIP: _____

Prescriber Contact Person: _____

Prescriber Phone #: _____

Prescriber Fax #: _____

Prescriber E-mail Address: _____

Patient Preferred Pharmacy: _____

Pharmacy Contact & Phone: _____

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

Prescriber, please print name _____ Please sign _____ Date _____

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 3.

Please see full Prescribing Information.

MAVYRET PATIENT SUPPORT

MAVYRET glecaprevir/pibrentasvir

https://www.mavyret.com/content/dam/abbvie-mavyret-brand/enrollment-form.pdf

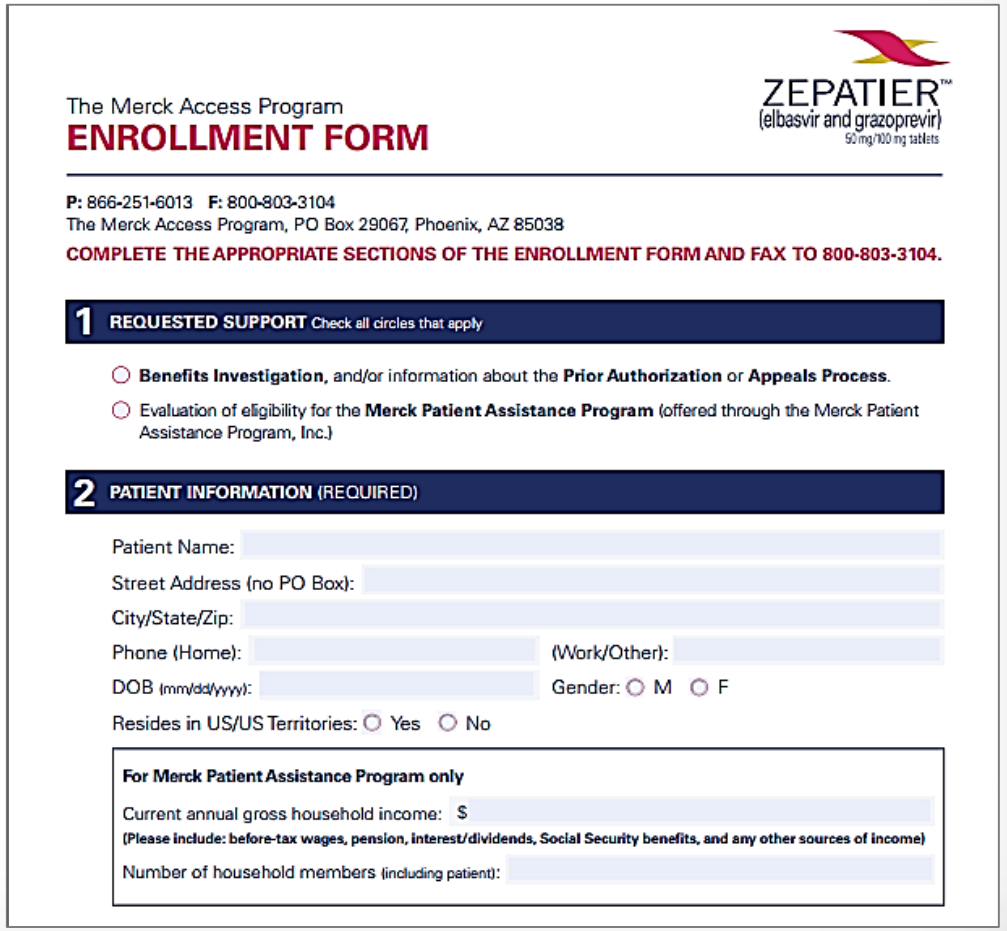
Provider Support: Abbvie

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

https://www.mavyret.com/complete-patient-support

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

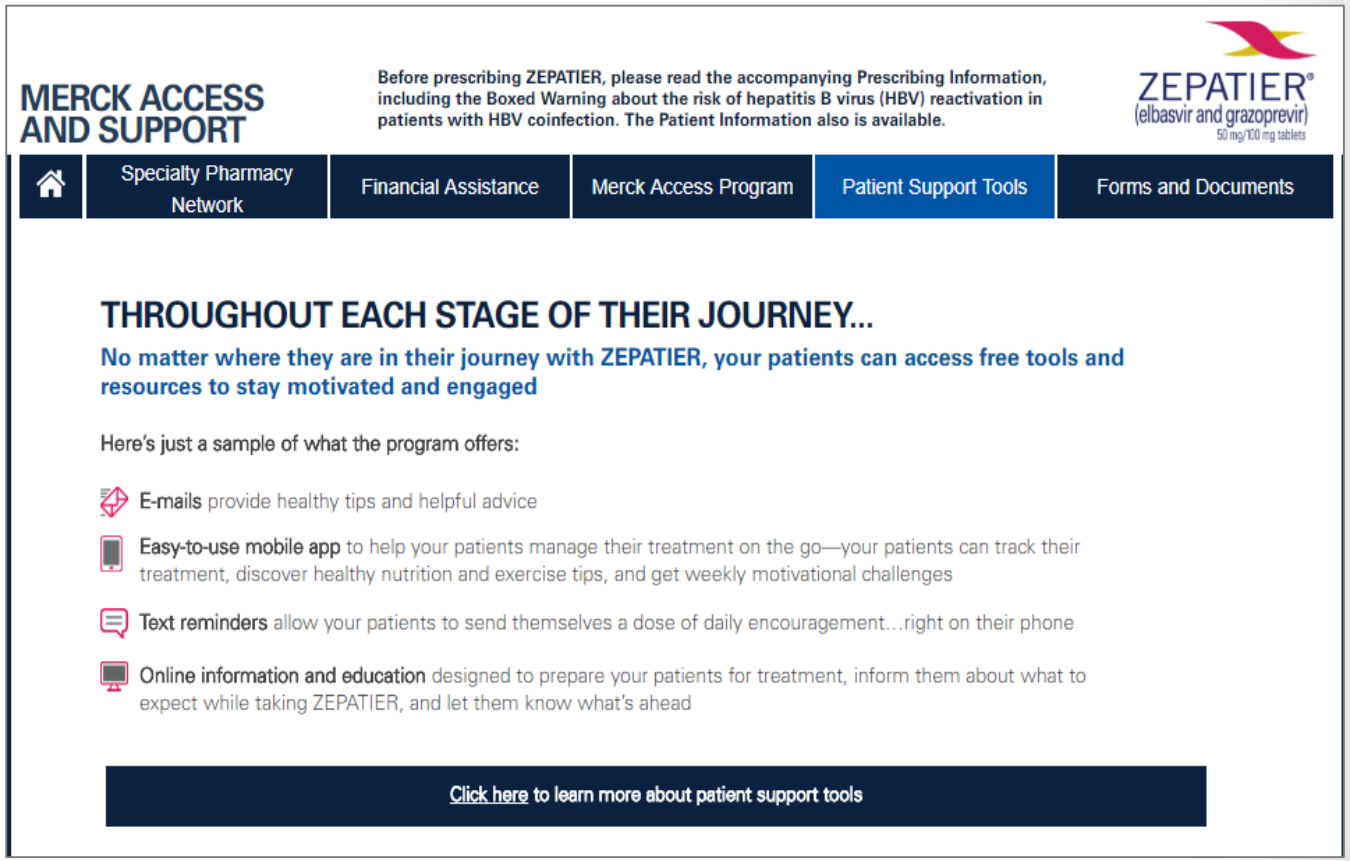
For Merck Patient Assistance Program only

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):

https://www.merckaccessprogram-zepatier.com/static/pdf/merck-access-program-zepatier-enrollment-form.pdf

Provider Support: Merck Access Program

- Support after approval
  - Emails
  - App
  - Text reminder
  - Education materials



https://www.merckaccessprogram-zepatier.com/hcp/patient-support-tools/

Outline

- HCV Review
- HCV and Healthcare Finances
- Navigating the System
  - Patients With Prescription Insurance
  - Patients Without Prescription Insurance
- Tools
  - Manufacturer Patient Support
  - HCV Treatment Access Resources
- **Access On the Horizon**

Medicaid Access: 2014 to 2017

- Liver damage restrictions:

	Known criteria	No minimum requirement	At least F3 fibrosis
2014	34 states (68%)	0 states	31/34 states (91%) surveyed
2017	50 states (PR and DC, 100%)	18 states (36%)	12 states (24%)

- Sobriety requirements:

	Known criteria	No requirement	6 months	1 year
2014	37 states (73% surveyed)	0 states	18 states (49% surveyed)	2 states (5% surveyed
2017	50 states (PR,DC, 100%)	10 states (19%)	18 states (35%)	2 states (4%)

- Prescriber Restrictions:

	Known criteria	Specialist Prescribe or Consult	Specialist Prescribe Only
2014	23 states (42%)	23 states (10 surveyed	14 states (4 surveyed
2017	49 states (98%)	14 states (27	9 states (18

Access On the Horizon

- Current state of treatment access
  - Overall improved with few Pharmacy Benefit Managers denying treatment
  - Barriers remain
- Hopeful in the near future
  - Decreased cost
  - Increased competition
  - Increased access

Other Access Resources

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

Treatment Access Pearls

- Develop a relationship with a specialty pharmacy
- Complete prior authorization forms completely
- Identify staff to become familiar with requirements
- Try to obtain necessary work-up and signatures at first visit
- Incorporate a discussion of the access process in first visit counseling
- Document approval dates
- Ensure 4 week lab completion

Summary

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

Thank you!

Questions?

Autumn.Zuckerman@VUMC.org

Cody.A.Chastain@VUMC.org