

FIGHTING FOR YOUR PATIENTS: SUCCESSFUL PRIOR AUTHORIZATION TIPS FROM THE PROS

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Empire Liver Foundation

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Setting The Tone



SETTING THE TONE

- Most patients are unaware of the details of the Prior Authorization (PA) process
- Educate the patient:
 - Time, effort and paperwork involved in the process
 - Barriers to access insurance has in place, making approval process more difficult
 - Insurance Formulary Exclusion
 - History of IV Drug Use
 - Substance Use
 - Limited Prescribing Privileges
 - Hepatologist, Gastroenterologist, Infectious Disease
 - Initial visit for these providers can be up to 3 months
 - Incomplete data to determine clinical need ¹
 - **Number one reason for denial
 - Poor communication between insurer and providers office
 - Insurance often will state they did not receive forms, or appeals which were submitted
 - Adherence assessment required in most patients for PA criteria
 - Even when provider feels it is not necessary

SETTING THE TONE

- Deflate patient expectations:
 - Will not walk out of the door with a prescription to bring to local pharmacy
 - Detailed process in order to obtain prescription
 - Can be as short of a wait as 2 weeks until medication is approved, but present realistic time frames for patient such as 4-6 weeks, or longer if insurance has extensive criteria
- Patient involvement
 - Encourage your patient to follow up regularly with your specialty pharmacy (weekly/every other week)
 - Make the specialty pharmacy the primary contact for patients to obtain updates on the HCV prescription
 - Encourage your patient to follow up with the insurance company once an appeal is submitted for status updates.
 - Provide your patient with the correct phone number to obtain updates, not the customer service line

DELAYING TREATMENT CAN HARM PATIENTS: MEDICAL REASONS TO TREAT ALL PATIENTS WITH HCV

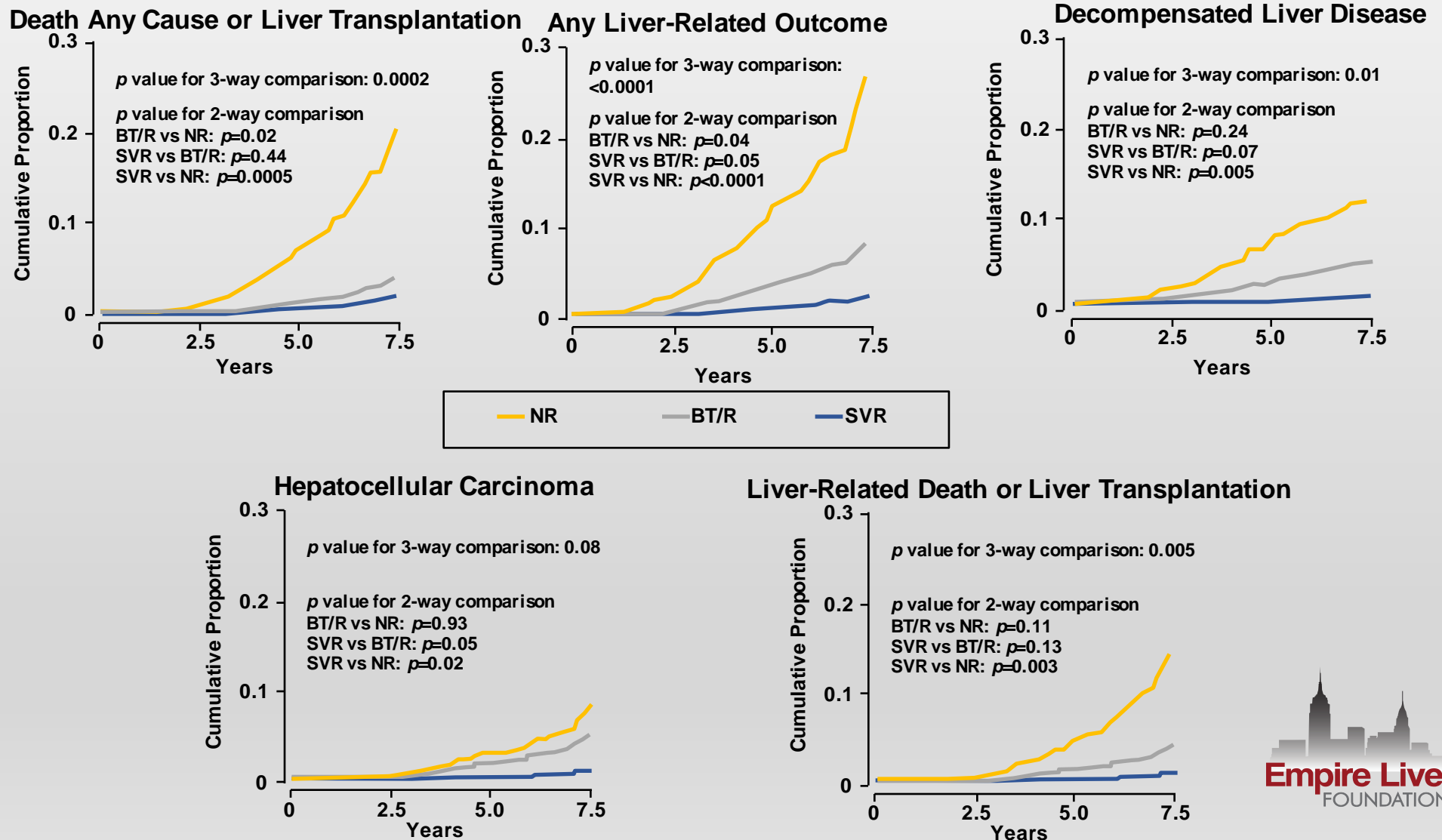
- Decreased morbidity and all-cause mortality, regardless of baseline fibrosis.¹
- Decrease in all-cause mortality in non-cirrhotics in 21,000 US Veterans.²
 - Survival advantage suggests an effect on non-liver–related comorbidities (cardiovascular disease, diabetes, and non-liver related cancers).
 - Similar results seen in a meta-analysis of >34,000 patients.³
- Delaying treatment until advanced fibrosis/cirrhosis has a detrimental impact on treatment effectiveness.⁴

DELAYING TREATMENT CAN HARM PATIENTS: MEDICAL REASONS TO TREAT ALL PATIENTS WITH HCV

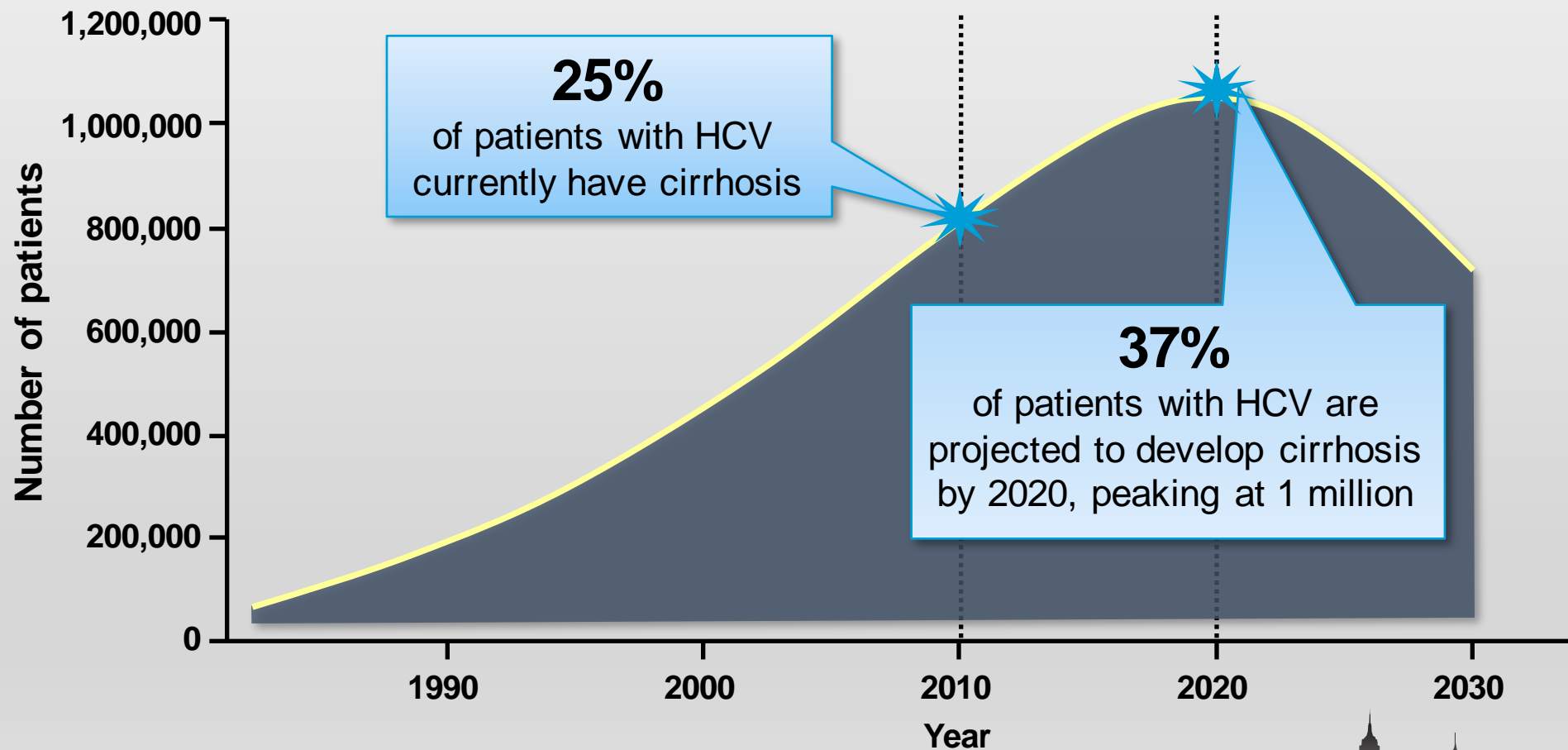
- Treatment may improve or prevent extra-hepatic complications not related to fibrosis stage.^{1,2,3}
- HCV affects well-being in all patients, regardless of fibrosis stage.⁴
- Achievement of SVR has been shown to substantially improve patient fatigue, improve health-related quality of life and work productivity.⁵



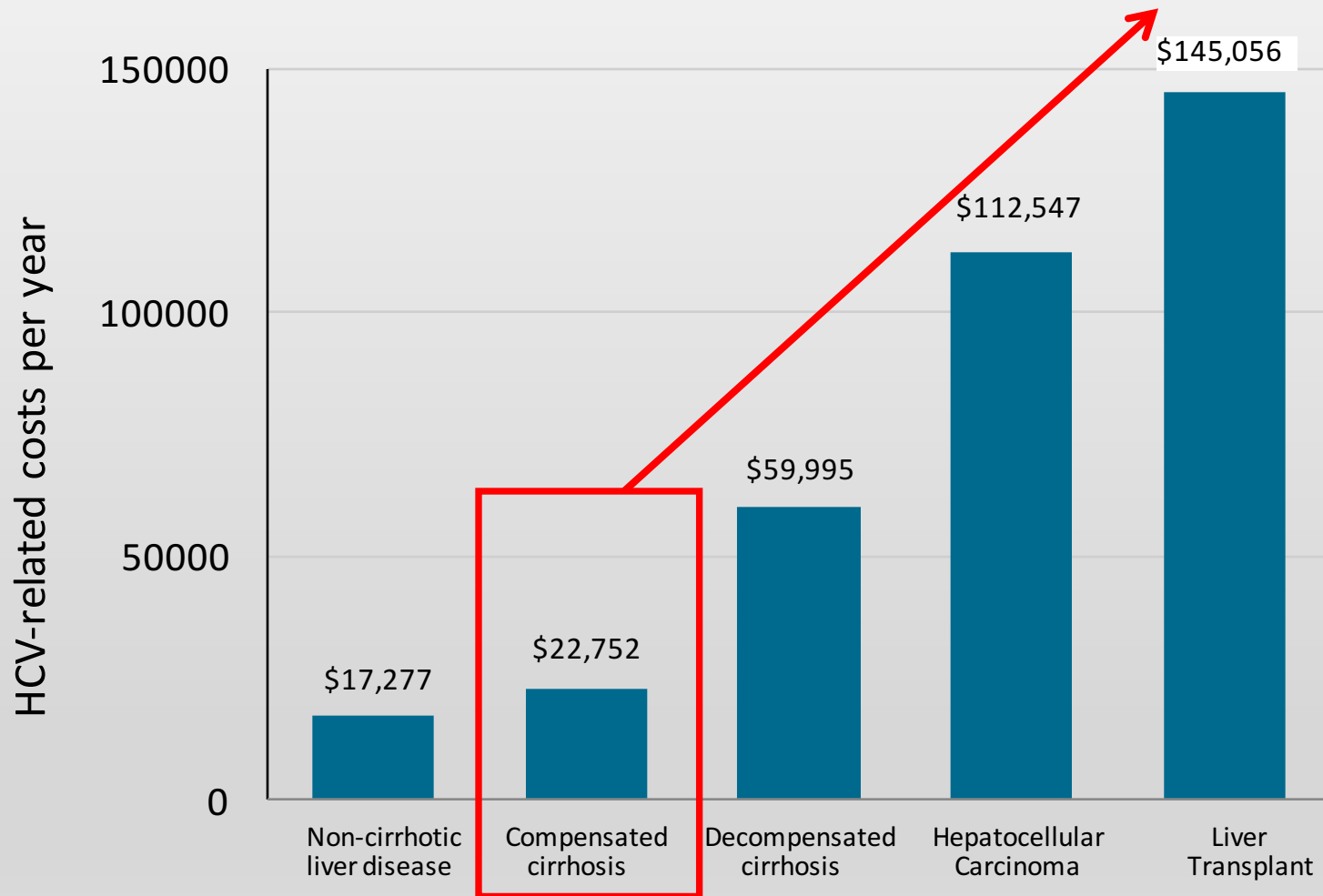
PATIENTS WITH ADVANCED FIBROSIS WHO ACHIEVE SVR HAVE A MARKED REDUCTION IN LIVER- RELATED MORBIDITY/MORTALITY



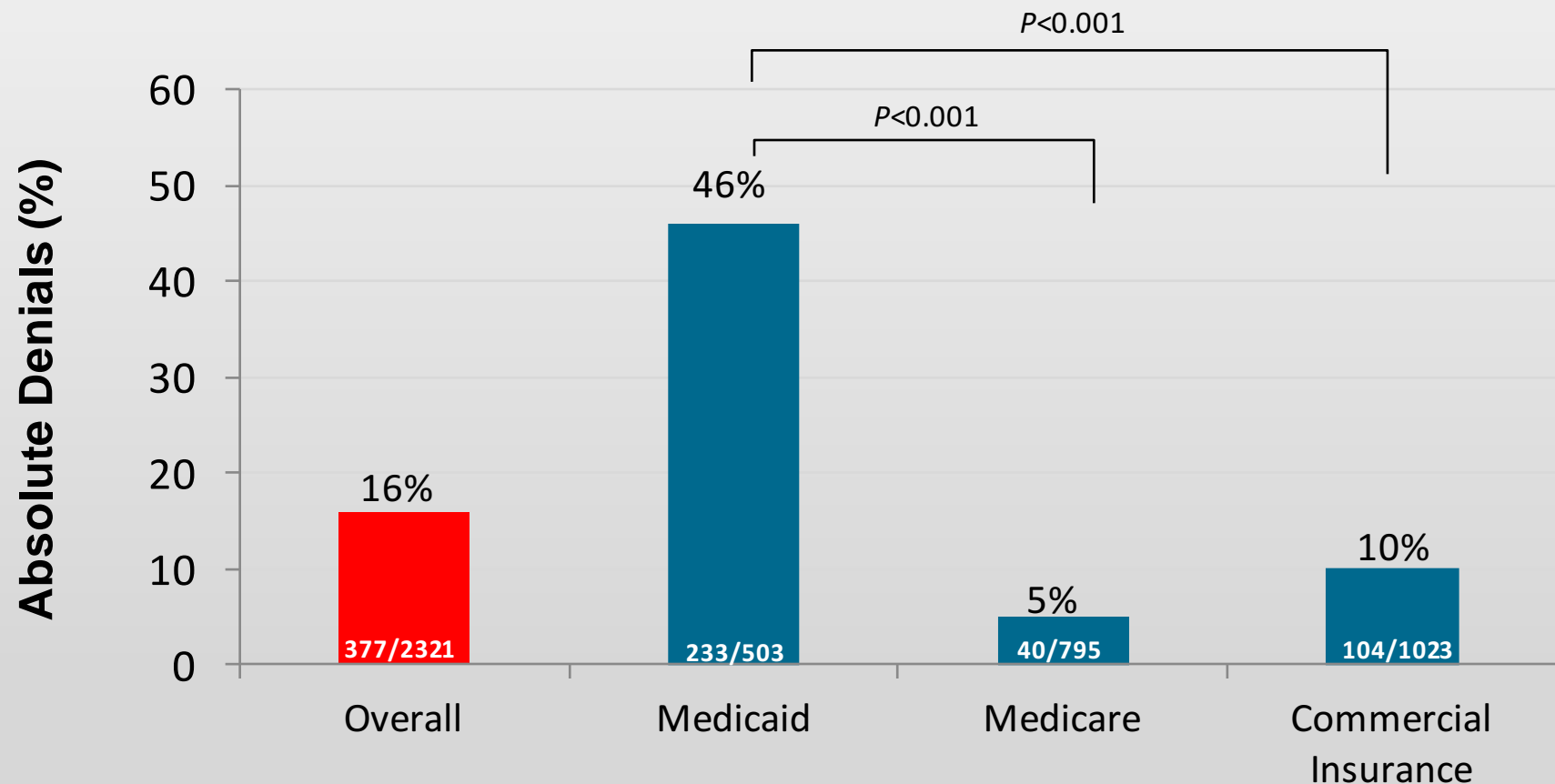
HEPATITIS C- RELATED CIRRHOSIS IS PROJECTED TO PEAK OVER THE NEXT 10 YEARS



TREATMENT HEALTH CARE COSTS IN CHRONIC HCV INCREASE AFTER DEVELOPMENT OF CIRRHOSIS



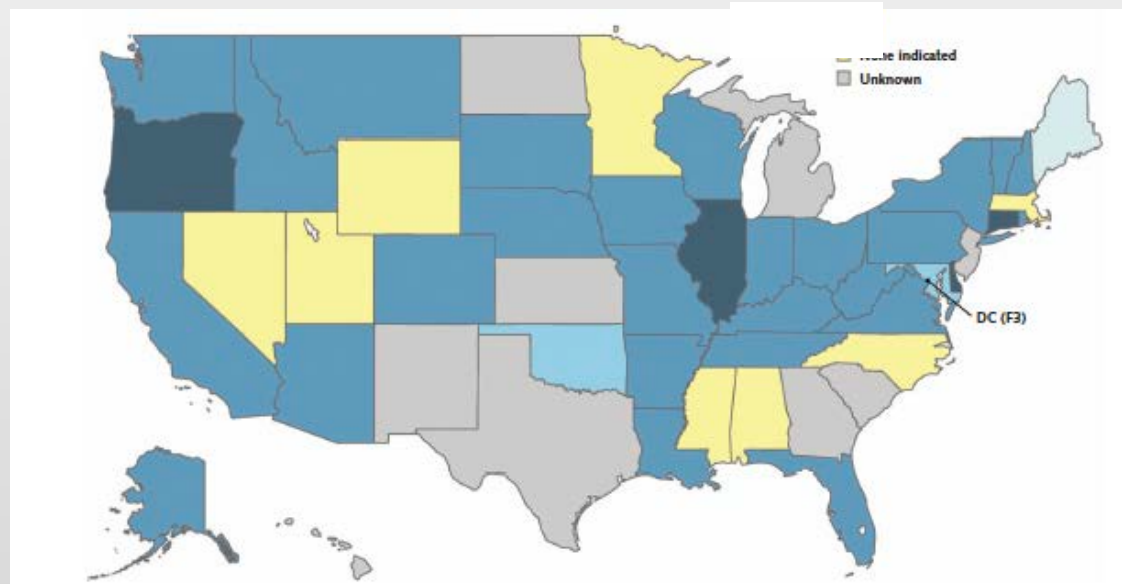
INCIDENCE OF ABSOLUTE DENIAL OF DAA THERAPY, BY INSURANCE (N=2,321*)



Extent to Which Payers Restricted Access to HCV Treatment Evaluated in 4 States Utilizing Data From a Specialty Pharmacy from 11/1/14 - 4/30/15.

MEDICAID RESTRICTIONS: BY FIBROSIS STAGE

74% of states limit treatment to advanced fibrosis or cirrhosis*.¹



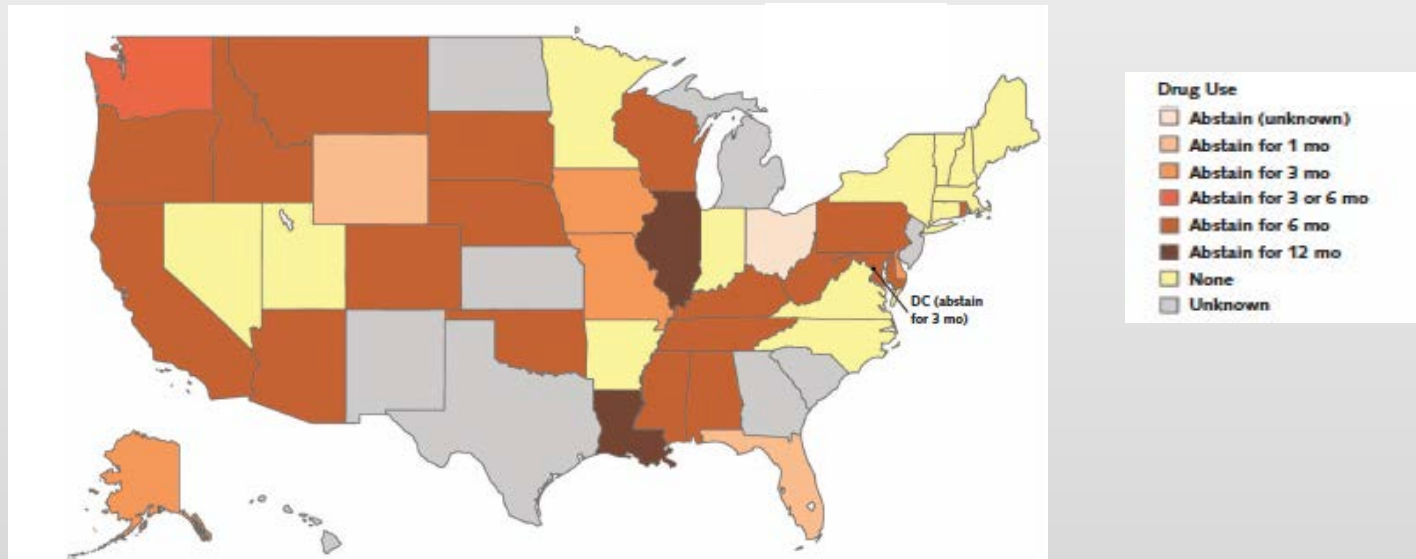
*Data collected up to 12/14 for states in which information was available. Some states have since changed restrictions.

- AASLD/IDSA Treatment guidelines recommend treatment for all HCV patients.
 - Restricting treatment to advanced disease is *“inadequate and shortsighted.”*²
- The Centers for Medicare and Medicaid (CMS) letter to State Medicaid Agencies:
 - Limiting treatment to advanced disease *“unreasonably restricts access.”*³



MEDICAID RESTRICTIONS: BASED ON DRUG AND/OR ALCOHOL USE

88% of states include drug or alcohol use in eligibility criteria. 50% require a period of abstinence of 3-12 months and 64% requiring negative urine drug screening*. ¹



*Data collected up to 12/14 for states in which information was available. Some states have since changed restrictions.

- AASLD/IDSA state that there is no evidence these type of restrictions identifies a population more likely to adhere to HCV treatment.²
- CMS has expressed concern that states are requiring a period of abstinence.³

SVR RESPONSE PREDICTS REGRESSION MEASURED BY FIBROTEST IN HCV INFECTED PATIENTS- 'EARLIEST TREATMENT PROVIDES MOST REGRESSION'

- Patients treated with OBV/PTV/r+DSV \pm RBV for 12 or 24 weeks
- FibroTest performed at baseline (BL) and SVR 12 visit (SVR12)
 - Improvement was defined as FibroTest score change of at least -0.10 from BL to SVR 12

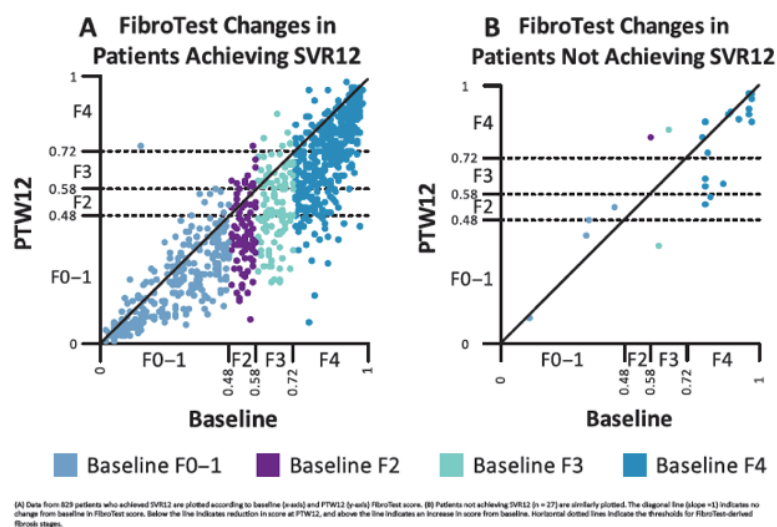
Among patients achieving SVR:

- 246/255 (96%) with BL F0-1 had unchanged fibrosis stage
- 59/85 (69%) with BL F2 had fibrosis regression
- 72/112 (64%) with BL F3 had fibrosis regression
- 192/377 (51%) with BL F4 had fibrosis regression
- **27/452 (6%) patients with BL F0-3 had fibrosis progression**

Among patients not achieving SVR:

- 6/22 (27%) patients with BL F2-F4 had fibrosis regression
- **3/8 (38%) patients with BL F0-F3 had fibrosis progression**

Figure 2. Plot of Individual Patient FibroTest Scores by Baseline and PTW12



Medicaid Pharmacy Prior Authorization Programs Update

On April 27, 2016, the New York State Medicaid Drug Utilization Review Board (DURB) recommended changes to the ~~Medicaid Fee-For-Service (FFS)~~ pharmacy prior authorization programs. The Commissioner of Health has reviewed the recommendations of the Board and has approved changes to the Preferred Drug Program (PDP):

Effective May 26, 2016, prior authorization (PA) requirements will change for some drugs in the Hepatitis C – Direct Acting Antivirals class:

- Preferred Agents: ribavirin, Daklinza, Harvoni, Sovaldi, Technivie, Viekira Pak, Zepatier
- Non-Preferred Agents: Copegus, Moderiba, Olysio, Rebetol, Ribapak, Ribasphere

~~In addition, the Hepatitis C – Direct Acting Antiviral clinical criteria has changed.~~
~~Disease prognosis and severity has been eliminated.~~ Remaining criteria includes:

- • **FDA labeling and compendia supported use**
 - Verification of diagnosis, genotype, dosing and duration, etc.
- • **Prescriber experience and training**
 - Prescribed by hepatologist, gastroenterologist, infectious disease specialist, transplant physician or health care practitioner experienced and trained in the treatment of HCV or a healthcare practitioner under the direct supervision of a listed specialist.
AND
 - Clinical experience is defined as the management and treatment of at least 10 patients with HCV infection in the last 12 months and at least 10 HCV- related CME credits in the last 12 months.
OR
 - Management and treatment of HCV infection in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria.
- • **Patient readiness and adherence**
 - Evaluation by using scales or assessment tools readily available to healthcare practitioners at: <http://www.integration.samhsa.gov/clinical-practice/screening-tools> or <https://prepc.org/> to determine a patient's readiness to initiate HCV treatment, specifically drug and alcohol abuse potential.

WHAT IS A SPECIALTY MEDICATION?

- Complex/life-threatening health conditions
- Complex to manufacture or require special handling and administration
- Injectable or oral, self-administered or administered by a health care provider
- Difficult for patients to take without ongoing clinical support; also challenging for providers to manage
- Costly treatment taken by a relatively small share of the population who have complex medical conditions

STATISTICS OF SPECIALTY MEDICATION

- Drug spending is only 10 percent of all health care spending, but that 10 percent equals around \$300 billion per year.¹
- Spending on specialty drugs in 2012 in the United States was about \$87 billion, comprising roughly 25 percent of total drug spending²
- The 3.6% of members who use specialty medications account for 25% of health care costs.³
- 40 percent of drugs under development (about 650 drugs) are considered specialty drugs⁴

ROLE OF SPECIALTY PHARMACY

- It is *not recommended* to utilize your local pharmacy when prescribing Hepatitis C treatment. Specialty Pharmacy's are recommended in these situations because this process is standard for most medications dispensed from their pharmacy.
- From the moment the prescription is written, until the completion of the therapy prescribed the specialty pharmacy should be involved the entire process.
 - *Drug Interaction Checks*
 - HUGE factor in HCV treatment in the world of DAA's
 - Specifically patients co-infected with HIV
 - Assist with Prior Authorization process in its entirety
 - Calling Insurance to have PA forms faxed to office
 - Once PA completed by Providers office Specialty pharmacy should assist in follow up
 - Denial
 - Specialty pharmacy should be able to guide Providers office through Appeal process, and assist in the follow up once submitted.
 - Often times have templates to assist providers with appeal letters.
 - Build relationships with the patients
 - Educate your patients to rely on your specialty pharmacy to be the primary contact for prescription update

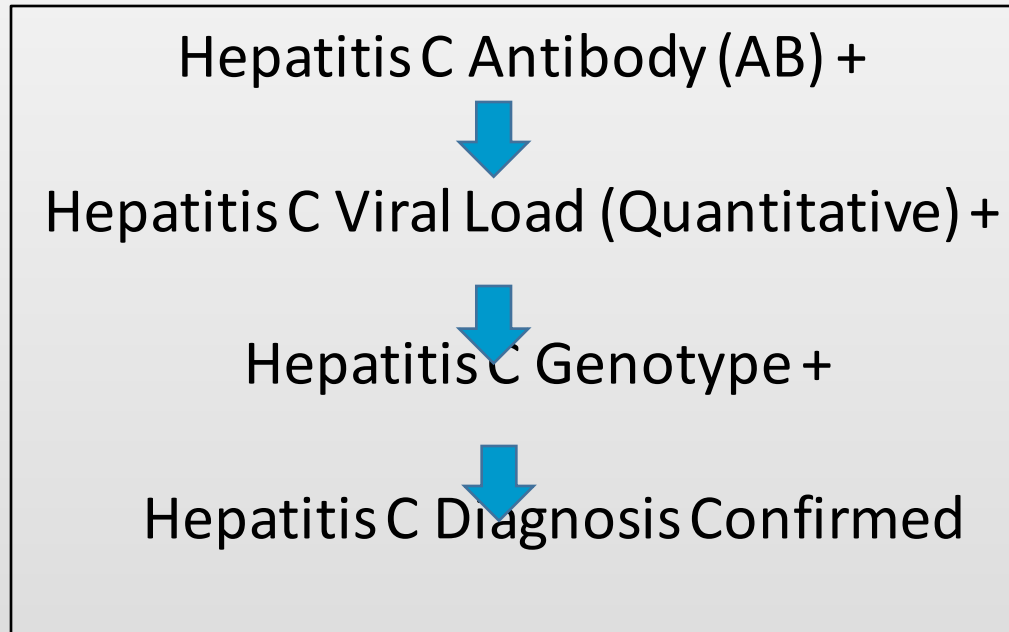
CLINICAL CRITERIA:

APPLYING FOR PRIOR AUTHORIZATION

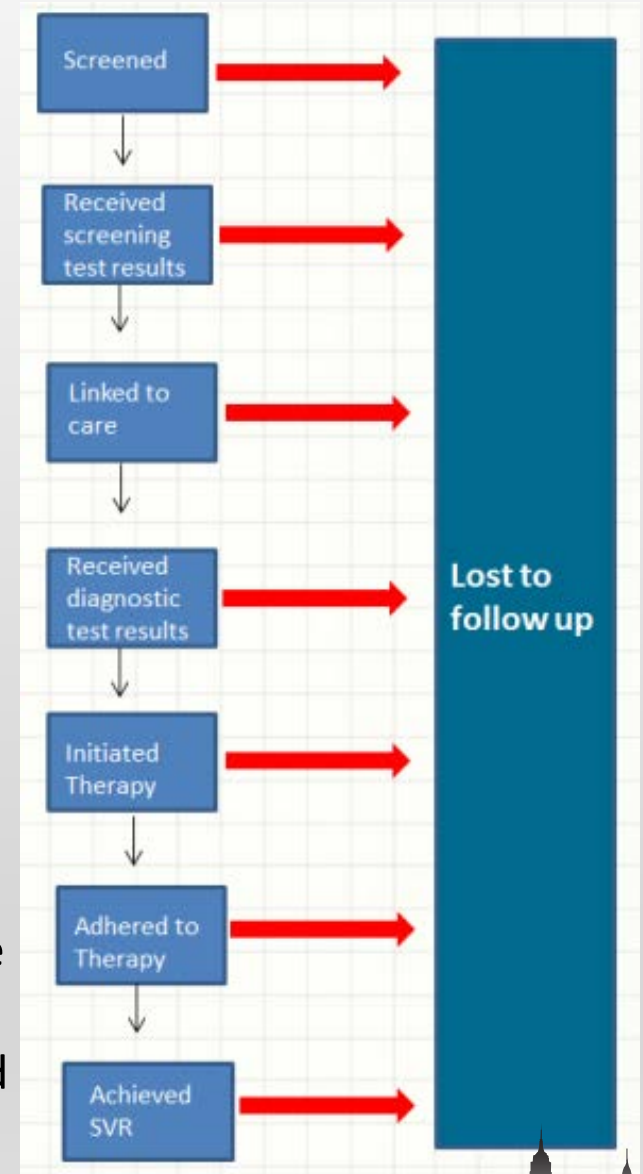
- Confirmation of Hepatitis C Diagnosis (ICD-10 B18.2)
- Evaluation of Liver Fibrosis, and/or Cirrhosis
- Treatment History
- Treatment Readiness (adherence assessment)
- Negative Drug Toxicology report, urine *
- Baseline Ns5a Resistance Testing *
- Evidence of extra-hepatic manifestations
- Evidence of concomitant conditions/comorbidities

* See PA Criteria, not needed for all insurances

CONFIRM HEPATITIS C DIAGNOSIS



- Diagnosis is only the beginning of the hepatitis C treatment cascade
- There are many points within the PA process where patients can be lost to follow up
- It is important to ensure that your patient, staff and specialty pharmacy is engaged throughout the process



EVALUATION OF LIVER FIBROSIS

- Liver Fibrosis can be evaluated in many ways:

- Liver Biopsy

- Fibroscan



Metavir	Range
F0-F1	0-7.0 kpa
F2	7.1-9.4 kpa
F3	9.5 – 12.5 kpa
F4	>12.5 kpa

- APRI (AST to Platelet Ratio Index)

$$\text{APRI} = \frac{\frac{\text{Patient AST (IU/L)}}{\text{AST (upper limit of Normal)}} \times 100}{\text{Patient Platelet Count (10}^9\text{/L)} \times 100}$$

- Fibrosure (FibroTest- ActiTest)¹

Fibrosis Stage	Range
F0- No Fibrosis	0.00-0.21
F0- F1	0.21-0.27
F1- Portal Fibrosis	0.27-0.31
F1-F2	0.31-0.48

Fibrosis Stage	Range
F2- Bridging fibrosis w/ few septa	0.48-0.58
F3-Bridging fibrosis w/ many septa	0.58-0.72
F3-F4	0.72-0.74
F4 Cirrhosis	0.74-1.00

CONFIRM DIAGNOSIS OF CIRRHOSIS

- FibroSure has excellent utility for identification of cirrhosis, but lesser accuracy for earlier stages.¹
- Cirrhosis proven by lab testing often leads to a request from the insurance for additional diagnostic information
 - Biopsy/Fibroscan
 - Imaging consistent with cirrhosis, ie: portal hypertension, nodular contour

2

3. Does this patient have cirrhosis?
☐ Yes ☐ No
If yes, prescriber must submit evidence of cirrhosis with at least one of the following.
Any other forms of evidence or indirect markers are not acceptable.

<input type="checkbox"/> Liver Biopsy
<input type="checkbox"/> FibroScan
<input type="checkbox"/> CT Scan of the Liver
<input type="checkbox"/> Hepatic Ultrasound
<input type="checkbox"/> Transient Ultrasound Elastography
<input type="checkbox"/> Magnetic Resonance Elastography

1 Shaheen et al Am J Gastroenterol 2007;102:2589–2600

2 Emblem Health Hepatitis C Prior Authorization Form

CIRRHOTIC PATIENTS

1

- **Child's Pugh Score: Calculator to evaluate severity of Cirrhosis in a patient (A, B or C)**
 - Patients identified as having cirrhosis require additional information when prescribing HCV therapy, for safety reasons
 - **Protease Inhibitors and regimens which contain protease inhibitors are contraindicated in patients who have decompensated cirrhosis, and Child's Pugh Scores of B and C.**

A	B	C
5-6	7-9	10-15

Encephalopathy

☐ None +1

☐ Mild to moderate (grade 1 or 2) +2

☐ Severe (grade 3 or 4) +3

Ascites

☐ None +1

☐ Mild to moderate (diuretic responsive) +2

☐ Severe (diuretic refractory) +3

Bilirubin (mg/dL)

☐ < 2 +1

☐ 2-3 +2

☐ > 3 +3

Albumin (g/dL)

☐ > 3.5 +1

☐ 2.8-3.5 +2

☐ < 2.8 +3

International normalized ratio

☐ < 1.7 +1

☐ 1.7-2.3 +2

☐ > 2.3 +3

Child-Turcotte-Pugh Class obtained by adding score for each parameter (total points)

TREATMENT HISTORY

- Treatment history influences how patients are treated in the world of Direct Acting Antivirals (DAA's)
 - Treatment Naïve
 - Never been treated for Hepatitis C
 - *May* have the option for shorter treatment durations
 - Previously Treated
 - Historically: Non-responder/Relapser/Partial
 - 2016: Treated with or without a DAA?
 - If treated with a DAA, the options for re-treatment may be limited.
 - If the patient has cirrhosis, and they were previously treated review the Package insert and AASLD treatment guidelines as duration of therapy may be extended, and/or ribavirin may be recommended to increase success

TREATMENT READINESS

- Many, if not all, insurance plans will require patients to take part in treatment readiness (adherence) assessment.
 - These assessments are important as they may bring to light barriers to initiating or completing hepatitis C therapy.
 - NYS Medicaid FFS requires the completion of one of the following assessments (most managed care plans will follow this criteria)
 - DAST-10 (10 Items) ; AUDIT (10 Items), AUDIT- C (3 Items), CAGE-AID (4 Items)
Above questionnaires can be found:
 - SAMHSA HRSA Center for Integrated Health Solutions- Drug and Alcohol Screening Tools: <http://www.integration.samhsa.gov/clinical-practice/screening-tools#drugs>
- OR**
- PREP-C Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment <https://prepc.org/>
 - Prep-C has an abbreviated evaluation and an extended evaluation dependent on you and your patient's needs.

CAGE-AID - Overview

The CAGE-AID is a conjoint questionnaire where the focus of each item of the CAGE questionnaire was expanded from alcohol alone to include alcohol and other drugs.

Clinical Utility

Potential advantage is to screen for alcohol and drug problems conjointly rather than separately.

Scoring

Regard one or more positive responses to the CAGE-AID as a positive screen.

Psychometric Properties

The CAGE-AID exhibited ¹ :	Sensitivity	Specificity
One or more Yes responses	0.79	0.77
Two or more Yes responses	0.70	0.85

CAGE-AID Questionnaire

When thinking about drug use, include illegal drug use and the use of prescription drug use other than prescribed.

Questions:	YES	NO
1. Have you ever felt that you ought to cut down on your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have people annoyed you by criticizing your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever felt bad or guilty about your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	<input type="checkbox"/>	<input type="checkbox"/>

The Alcohol Use Disorders Identification Test (AUDIT), developed in 1982 by the World Health Organization, is a simple way to screen and identify people at risk of alcohol problems.

1. How often do you have a drink containing alcohol?

- (0) Never (Skip to Questions 9-10)
- (1) Monthly or less
- (2) 2 to 4 times a month
- (3) 2 to 3 times a week
- (4) 4 or more times a week

2. How many drinks containing alcohol do you have on a typical day when you are drinking?

- (0) 1 or 2
- (1) 3 or 4
- (2) 5 or 6
- (3) 7, 8, or 9
- (4) 10 or more

3. How often do you have six or more drinks on one occasion?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

4. How often during the last year have you found that you were not able to stop drinking once you had started?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

5. How often during the last year have you failed to do what was normally expected from you because of drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

6. How often during the last year have you been unable to remember what happened the night before because you had been drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

7. How often during the last year have you needed an alcoholic drink first thing in the morning to get yourself going after a night of heavy drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

8. How often during the last year have you had a feeling of guilt or remorse after drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?

- (0) No
- (2) Yes, but not in the last year
- (4) Yes, during the last year

10. Has a relative, friend, doctor, or another health professional expressed concern about your drinking or suggested you cut down?

- (0) No
- (2) Yes, but not in the last year
- (4) Yes, during the last year

Add up the points associated with answers. A total score of 8 or more indicates harmful drinking behavior.

Practice/Test	Is this for an actual patient or for practice/test?
Abbreviated	Administer full or abbreviated version of Prep-C?
Male	Gender
48	Age
non-Hispanic	Ethnicity
White	Race
United States	Region of Residence
New York	State
Yes	Prior Treatment for Hepatitis C Infection
<input type="checkbox"/> discontinued treatment early <input checked="" type="checkbox"/> non-response <input type="checkbox"/> partial response <input type="checkbox"/> relapse <input type="checkbox"/> unsure <input type="checkbox"/> other	What was the patient's response to prior treatment? (Check all that apply)
1	HCV Genotype
HIV-negative	HIV Status
Check regimen to be used: <input checked="" type="radio"/> All-oral regimen <input type="radio"/> Interferon-based regimen <input type="radio"/> Unsure	Proposed Treatment

Before beginning the interview say to the patient:

"I will be asking you about several areas of your life and about Hepatitis C treatment to make sure that you well-prepared when you begin the treatment. After we finish all of the questions, I will review your responses and give you feedback. If anything comes up that is of concern and I cannot address, I will have you talk to other staff members before you leave today. Do you have any questions?"

It is recommended that the 9 sections of the PREP-C be administered in the order they appear below. Click on the first section ("Motivation") below to begin the PREP-C interview. You are however free to administer the sections in any order you choose and to skip sections entirely if you choose.

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

M1
M2
M3

Q

How important is it to you to begin Hepatitis C treatment?

A

1

2

3

4

5

6

7

« Not important at all
Extremely Important »

Notes

« Start Page
Scoring » Skip »
NEXT »

VIEW PRINTABLE REPORT

S Satisfactory
 CBI Could Be Improved
 NFE Needs Further Evaluation

1. Motivation	S	CBI	NFE	Click here to print this report
2. Information	S	CBI	NFE	
3. Medication Adherence	S	CBI	NFE	
4. Self-Efficacy	S	CBI	NFE	
5. Social Support and Stability	S	CBI	NFE	
6. Alcohol and Substance Use	S	CBI	NFE	
7. Psychiatric Stability	S	CBI	NFE	
8. Energy Level	S	CBI	NFE	
9. Cognitive Functioning	S	CBI	NFE	

Under evaluation to begin HCV treatment

Decision made not to proceed with HCV treatment at this time

HCV treatment started

- If patient answers question appropriately may reduce number of questions per section
- On average can take anywhere from 15-30 minutes per patient

ADDITIONAL DOCUMENTATION

- Negative drug toxicology report, urine
 - Not required by all insurances, review criteria
 - Ensure the test performed lists all toxins which were tested
 - In the phase 3 Ion-1 study of sofosbuvir/ledipasvir with or without ribavirin, on treatment illicit drug use did not impact treatment outcome
- Baseline Ns5a resistance testing
 - Check PA criteria, not needed for all HCV treatment regimens
 - Consult with package insert and AASLD treatment guidelines

ADDITIONAL DOCUMENTATION:

EXTRAHEPATIC MANIFESTATIONS/CONCOMITANT COMORBIDITIES

- Curing Hepatitis C reduces symptoms and mortality from severe extrahepatic manifestations
 - cryoglobulinemic vasculitis (affecting 10% to 15% of HCV-infected patients)

Only Use this information in initial PA if asked, or if you feel that the reviewer can actually overturn a decision if the patient does not meet the criteria set forth by the insurance plan

Type 2 Diabetes

- Relationship between HCV and DM II incompletely understood
- Prevalence and incidence of diabetes is increased in the context of hepatitis C
- Patients over 40 have more than a three fold greater risk
- Insulin resistance and type 2 diabetes are independent predictors of a more rapid progression of liver fibrosis

AASLD/IDSA HCV Guidance 2016

When and in Whom to Initiate HCV Therapy

Host	Viral
Nonmodifiable	HCV genotype 3
Fibrosis stage	Coinfection with hepatitis B virus or HIV
Inflammation grade	
Older age at time of infection	
Male sex	
Organ transplant	
Modifiable	
Alcohol consumption	
Nonalcoholic fatty liver disease	
Obesity	
Insulin resistance	

Updated February 24, 2016.

Table 1. Factors Associated With Accelerated Fibrosis Progression

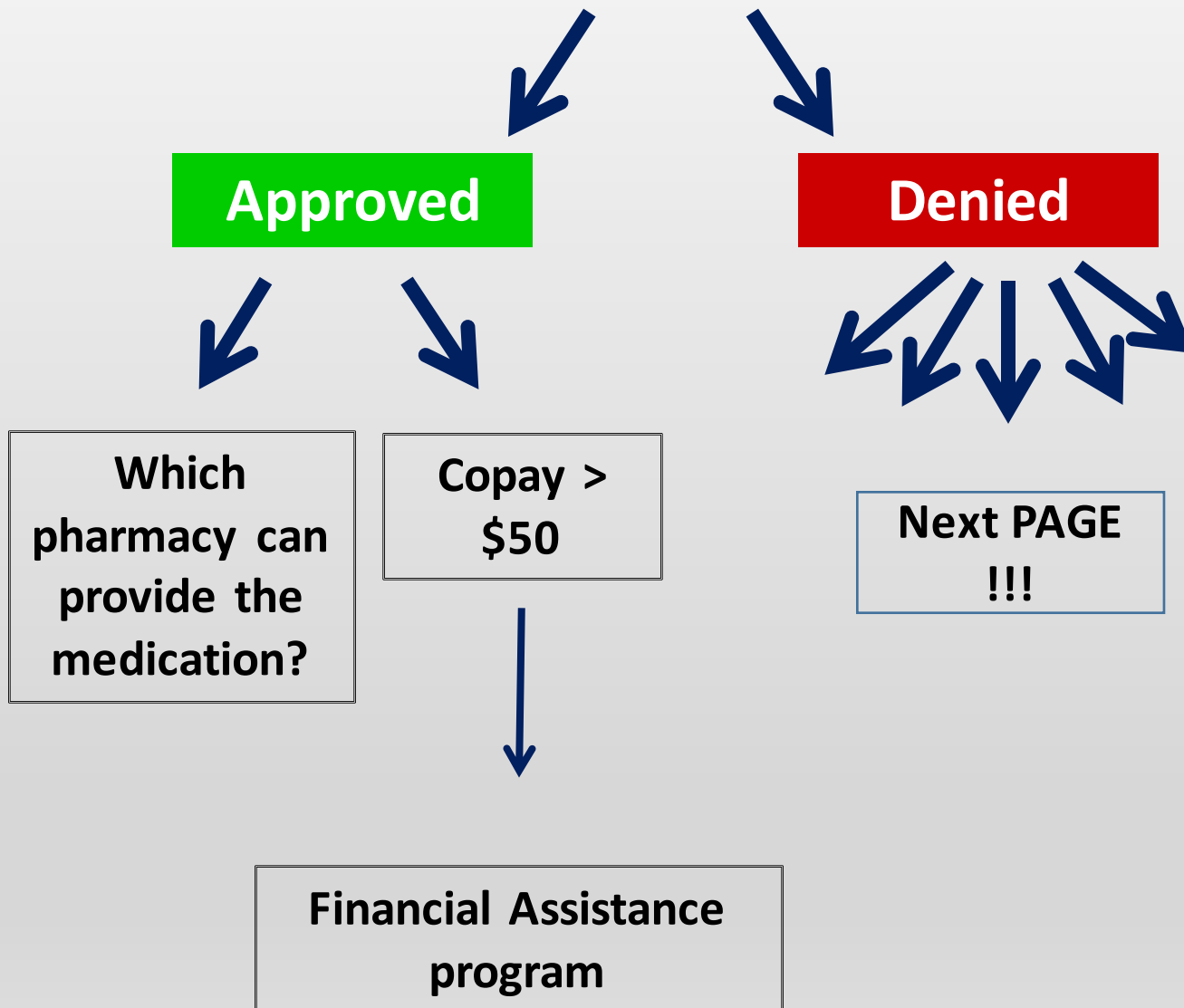


Prior Authorization Process

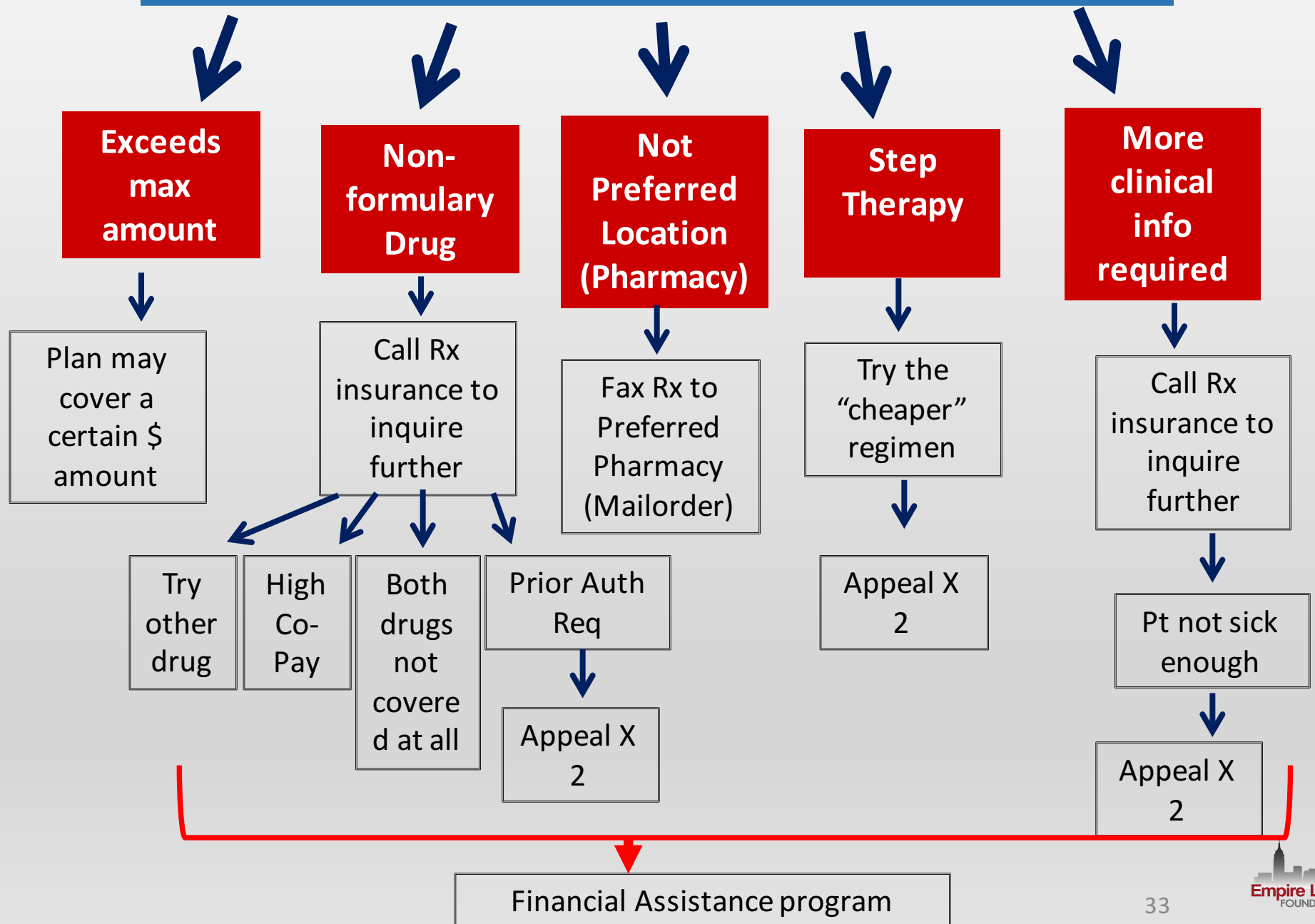
Prior Authorization

- ✓ Chart note
- ✓ CBC / CMP
- ✓ Viral Load
- ✓ Genotype
- ✓ Fibrosis score
- ✓ Resistance Testing

Prescription sent to a Pharmacy



Prescription Denied



Controversies

- Prescription vs medical insurance
- Illicit drug use / Alcohol abuse

Appeal process

Increased cost leads to payers limiting access to therapy by:

- Approved providers only
- F3-4 disease (advanced fibrosis)
- Extra-hepatic manifestations
- Failures of previous therapies
- Approval for 14 or 30 days only
- Apply for reauthorization at end of first month
- Futility rules for initiating therapy
- Strict non-replacement policy
- Strict ETOH and drug policy
- Strict vacation policy
- Adherence monitoring programs
- Limit coverage to once in a lifetime



03/03/2015

RE: Coverage Review Denial

Patient: [REDACTED]

File ID: [REDACTED]

DAVID BERNSTEIN
300 COMMUNITY DR
MANHASSET, NY 11030

COVERAGE DETERMINATION

Dear DAVID BERNSTEIN :

We have reviewed the medication coverage request to approve the prescription for **HARVONI** with directions of **take 1 tablet by mouth once daily** submitted by **DAVID BERNSTEIN** on behalf of the above UnitedHealthcare Community Plan. On the basis of the available information, this request is denied.

The information provided does not allow for an exception to the preferred drug list (PDL), also sometimes known as the formulary.

Our decision is based on the following reason(s):

The request does not meet the established medical necessity criteria or guidelines at this time.

The requested medication is used for a virus when you have advanced liver fibrosis. The facts given to us do not show that you have advanced liver fibrosis. This decision was made per the UnitedHealthcare Community Plan Harvoni medication guideline.

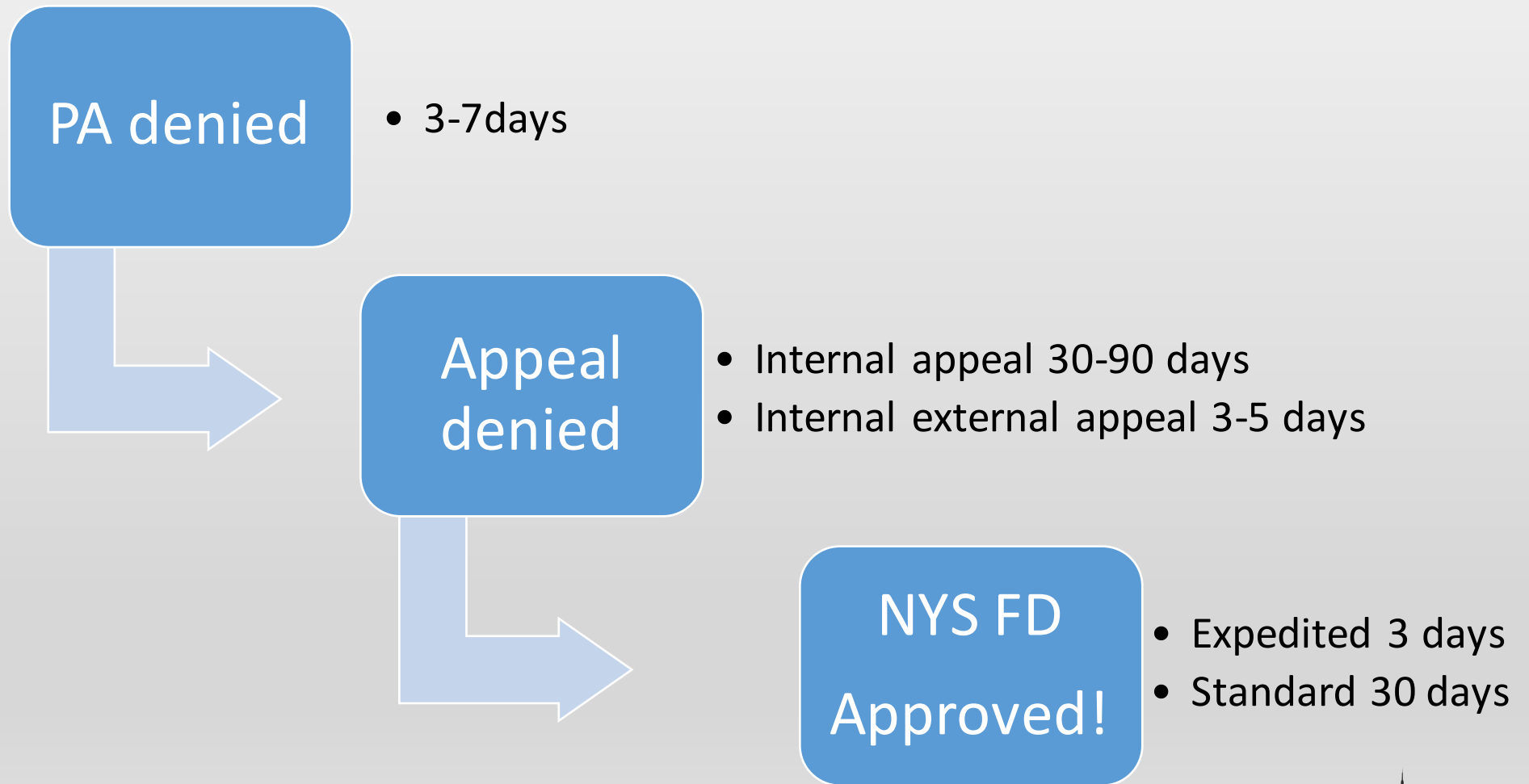
Harvoni is provided for patients who are chronic hepatitis C infection genotype 1, treatment experienced, and without cirrhosis when there are medical records documenting advanced fibrosis (eg, liver biopsy confirming a METAVIR score of F3, or alternative scoring equivalent), patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia), HCV reinfection following liver transplantation, or the patient is co-infected with HIV. Additional requirements include the patient has no history of illicit drug abuse or alcohol abuse or the patient has a known history of abuse and the patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months and a negative drug screen result collected within 30 days prior to onset of treatment has been submitted. Harvoni is required to be prescribed by a state-approved prescriber. The information reviewed does not show that the patient has evidence of advanced fibrosis, serious extrahepatic manifestations of HCV, HCV reinfection following liver transplantation, or the patient is co-infected with HIV. This decision was made per the UnitedHealthcare Community Plan Harvoni medication guideline.

This decision will take effect on: 03/03/2015

Appeals

- Prior Authorization
- Internal Appeal
- Internal External Appeal
- State Finance Department
- “Self insured” or “Self funded” plans
 - employer, rather than an insurance plan, assumes the risk for paying for covered services
 - self-insured employers pay for each out of pocket claim as they are incurred instead of paying a fixed premium to an insurance carrier

Appeal Process



Special Circumstances

- Self funded patients:
 - No jurisdiction from NYS Finance Department
 - Human Resource Department
- Union plans
 - Learn the union's process
 - Union office is the independent reviewer of the medication approval
 - Denial letter from union → Manufacturer Financial Assistance Program
- Patients with no prescription coverage
 - Required to utilize manufacturer assistance program

Attorney General Eric T. Schneiderman

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A.G. Schneiderman Announces Major Agreement With Seven Insurers To Expand Coverage Of Chronic Hepatitis C Treatment For Nearly All Commercial Health Insurance Plans Across New York State

Insurers In New York Will No Longer Restrict Treatment For Hepatitis C Based On Disease Severity

NEW YORK- Attorney General Eric T. Schneiderman today announced a major agreement with seven health insurance companies to revise their coverage policies for chronic Hepatitis C treatment: Affinity Health Plan, Empire BlueCross BlueShield, Excellus Health Plan, HealthNow, Independent Health, United Healthcare/Oxford, and MVP Health Plan. As a result of these agreements, nearly all commercial health insurance plans in New York State will cover treatment for chronic Hepatitis C without requiring members to develop advanced disease, such as liver scarring, and will not deny coverage because the member uses alcohol or drugs, or because the authorizing physician is not a specialist.

"New Yorkers diagnosed with Hepatitis C deserve to be treated, and these agreements will vastly improve access to the medications needed to cure their disease," said **Attorney General Schneiderman**. "Hepatitis C is a potentially life-threatening disease and thousands of New Yorkers are diagnosed each year. My office will do everything possible to ensure treatment for Hepatitis C is available, so that patients can be cured and we can minimize the spread of the disease to others."

Chronic Hepatitis C infection can cause liver failure, liver cancer, brain damage, and kidney failure – and, if left untreated, can result in cirrhosis and be fatal. Chronic liver



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

Health Care Helpline (800) 428-9071

The Health Care Bureau's toll-free Helpline provides information and assistance to thousands of New Yorkers annually, including resolution of individual consumer health-related complaints, and ensuring consumers get access to the health care, including health care coverage, to which they are entitled. The Health Care Bureau safeguards the rights of health care consumers statewide through investigation of and enforcement actions against insurers, providers, drug companies and other individuals and entities that engage in fraudulent, misleading, deceptive, or illegal practices in the health care market. In addition, the Bureau advocates for legislation and policy initiatives to enhance the rights of consumers.

“Self insured” or “Self funded” plans

- employer, rather than an insurance plan, assumes the risk for paying for covered services
- self-insured employers pay for each out of pocket claim as they are incurred instead of paying a fixed premium to an insurance carrier

Appeal letters to insurance companies

- Be specific
- Address the insurance company
- Patient Name, date of birth, ID or reference #
- States objective and subjective information
- Back it up with supportive data

Letter of Medical Necessity

To Whom It May Concern:

I am writing this appeal letter in response to a letter to me from _____ services dated ____ denying _____ therapy for the above mentioned patient. This letter is being written after a **SECOND APPEAL** letter that I wrote in support of this patient was not effective in overturning the decision of ____ to deny _____ treatment due to it being **"not medically necessary"**.

____ is followed by me in _____. This patient has hepatitis C, genotype 1A and relapsed following treatment with pegylated interferon and ribavirin. The patient's last Fibrosure test is consistent with mild-moderate fibrosis

I believe that it is medically necessary that this patient be treated with _____ for her chronic hepatitis C. The FDA approved _____ for the treatment of patient with chronic hepatitis C and the latest AASLD/IAS Guidance Document dated December 2014 recommends treatment of all patients infected with chronic hepatitis C.

The letter from ____ states that ____ was denied therapy because this **patient does not have advanced fibrosis. These are not the criteria for which these medications were approved.** There are no published papers which recommend the denial of care that this organization has adopted. **I was unaware that in New York State an insurance company is able to practice medicine and make complex medical decisions which disagree with both the treating physician and the recommendations of the FDA.**

The recent study by Hill et al. (abstract 44) presented at the annual meeting of the American Association for the Study of Liver Diseases held in Boston in November 2014 clearly showed the dramatic survival benefit of treating all patients with chronic hepatitis C, especially those without cirrhosis.

Kaiser Permanente presented data at the European Association for the Study of Liver Diseases in Vienna, Austria in April 2015 which showed cancer rates in hepatitis C patients are significantly higher than non-hepatitis C infected patients for the following cancers: liver, esophagus, stomach, colon, pancreas, myeloma, non-Hodgkin's lymphoma, lung, renal, and prostate. (Nyberg et al. EASL 2015)

As hepatitis C is associated with the development of the above mentioned cancers and as treatment has been shown to be both medically and cost-effective, not treating _____ **is akin to committing malpractice.**

I would hope and expect that you would overturn the egregious denial of _____ by _____ services and not deny her the treatment which this patient needs and wants.

Please do not hesitate to contact me with any further questions. My cell phone number is _____.



Financial Assistance/Resource

Approved may not mean approval...

- Deductible
- Insurance pays \$5,000 for the lifetime
- Coverage pays 75%
- Approved but patient has to burden the 100% of cost
- Preferred mail order pharmacy

Cost of Medication Regimen

Generic Name	Brand Name	Cost of 12 week Treatment (Wholesale Acquisition Cost WAC)
Simeprevir	Olysio®	12 week (\$66,360)
Sofosbuvir	Sovaldi®	12 week (\$84,000)
Ledipasvir/sofosbuvir	Harvoni®	12 week (\$94,500)
Daclatasvir	Daklinza®	12 week (\$63,000)
Paritaprevir/ritonavir/ ombitasvir/dasubuvir	Viekira Pak®	12 week (\$83,319)
Paritaprevir/ ombitasvir/ritonavir	Technivie ®	12 week (\$76,653)
Elbasvir and Grazoprevir	Zepatier®	12 week (\$54,600)

Financial Assistance via Manufactures coupons

- Not applicable to patients with Medicaid and Medicare prescription insurance

Harvoni® (Ledipasvir/ Sofosbuvir)  **HARVONI®**
Manufactured By: Gilead Sciences ledipasvir/sofosbuvir
90 mg/400 mg tablets

***Pay as little as 5 dollars per prescription.**

[SIGN UP HERE](#)

PAY \$5
AS LITTLE AS

PER PRESCRIPTION

MAXIMUM SAVINGS ARE LIMITED

 **Bristol-Myers Squibb**
patient support CONNECT™
Co-pay Program Card**

RxBIN: **610524** ISSUER: **(80840)**
RxPCN: **Loyalty** ID: **XXXXXXXXXX**
RxGRP: **50776971**

*Eligibility requirements and terms of use apply.
**Patient is responsible for applicable taxes, if any.
This offer is not insurance.

Pay as little as \$0 Per Month

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

To activate this coupon, go to
<https://www.activatecard.com/7208>.

MULTIUSE SAVINGS COUPON

Eligible privately insured patients may pay as little as \$5 per qualifying prescription of ZEPATIER. The maximum benefit is 25% of the catalog price of ZEPATIER (as set by the manufacturer at the time of purchase) per prescription.

RxBIN: **610524** RxGRP: **50777208**
RxPCN: **Loyalty** ISSUER: **(80840)**
ID: **947053721**

This coupon is not insurance. Terms and Conditions apply.
Expiration Date: 06/30/2017

 **MERCK**  **McKESSEN**

Financial Assistance via Patient Assistance

Medication	Financial Assistance Resources
Harvoni® & Sovaldi®	SupportPath www.mysupportpath.com (P) 855-769-7284
Daklinza®	BMS Patient Assistance Foundation www.bmspaf.org (P) 800-736-0003
Olysio®	Janssen Patient Assistance http://www.olsio.com/support/financial-assistance (P) 800-652-6227
Ribasphere RibaPak®	Patient Assistance Program www.ribapak.com/hcp/resources.html (P) 888-668-3393
Viekira®, Technivie®	Proceed https://www.viekira.com/proceed-program (P) 855-765-0504
Zepatier®	http://www.merckhelps.com/ZEPATIER (P) 866-251-6013

Financial Assistance Foundations

- **Patient Assistance Network**

www.panfoundation.org

866-316-7263

- **Patient Advocate Foundation**

www.copays.org

866-512-3861

- **Healthwell**

www.healthwellfoundation.org

800-675-8416

- **Gooddays**

www.gooddaysfromcdf.org

877- 968-7233

Financial Assistance

- Diagnosis
- Product
- Product insurance coverage
- Financial qualifications
 - household size and income, demographics, etc.
- U.S. citizenship (via SSN)

No other options...

- Clinical trials
- Change of prescription insurance plan
- Bench time
- NYS Attorney General's office

Summary

- Setting the tone
 - No, you won't have the medication tomorrow
- PA Clinical Criteria
 - Complete PA packet will save you time in the long run
- PA process
 - Initial denial vs "Final Adverse" Denial
- Appeal process
 - The ultimate jurisdiction for non-self funded insurance plans is from the New York State Finance Department.
- Financial Assistance/Resource
 - Utilize multiple resources

Post Questions

Question 1

What are the patient's barriers of medications approval?

- A. Insurance medication formulary
- B. Early stages of liver fibrosis
- C. History of intravenous drug use
- D. None of the above
- E. All of the above

Answer: (E)

Rationale: Choices A-C maybe reasons why patient's PA request may be denied.

Question 2

Most appeals must be submitted within 90 days of the denial, or else a new Prior Authorization must be initiated

- A. True
- B. False

Answer: (A)

Rationale: Insurance companies may have limitation on when an appeal can be initiated

Question 3

How many times can a denial be appealed?

- A. 1-2 times
- B. 2-3 times
- C. 3-4 times
- D. 4-5 times
- E. 5-6 times

Answer: (B)

Rationale: 1st appeal to the insurance companies internal appeal, second and third may happen simultaneously one to the insurance companies external appeal and another to the New York States Finance Department.

Question 4

The ultimate jurisdiction for non self funded insurance plans in New York States comes from New York State Finance Department.

- A. True
- B. False

Answer: (A)

Rationale: Self funded plans must appeal back to the company's Human Resources department but all other funds can appeal to the NYS Finance Department

Thank You!