

Medication Access Coinfected HIV/HCV



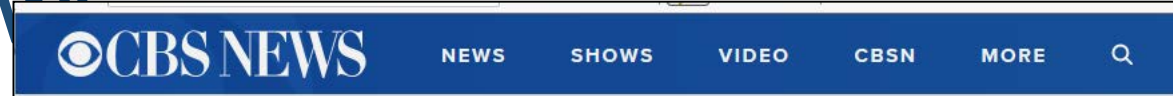
Disclosure

Gilead - HCV Pharmacist Advisory Group

Objectives

- Explain the state of Hepatitis C medication access in the United States
- Analyze the medication access process for the HIV/HCV co-infected patients in the state of New York

What's in the news



THE WALL STREET JOURNAL. PHARMALOT



RESEARCH & DEVELOPMENT FDA LITIGATION PRICING & PATIENT ACCESS CLINICAL TRIALS MARKETING

10:17 am ET
May 26, 2015 HEPATITIS C

Consumers Sue Anthem for Denying Coverage for a Gilead Hepatitis C Drug

PREVIOUS
Pharmalot.
Pharmalittle.. Good
Morning: We're Catching
up on AstraZeneca,
Glaxo and Lots More!!

NEXT
Pharmaceutical Industry
Must Pay for Drug Take-
Back Programs

es new \$1,125- tis C drug



ARTICLE COMMENTS (35)

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FDA Sued by Health Advocates Over High Cost of Harvoni

July 7, 2015, 12:15:00PM. By Gordon Gibb

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Hartford, CT: It is difficult to know what is really motivating two public health groups bent on finding out why Harvoni, the blockbuster Hep C drug, is so darned expensive. But one can assume, given a rise in denied claims and corresponding **Harvoni Denied Insurance Claim Lawsuits**, that Treatment Action Group (TAG) and the Global Health Justice Partnership (GHJP) can envision on the horizon a pattern of denied claims as insurance providers balk at the expense inherent to Harvoni.



Physician Partners

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.”

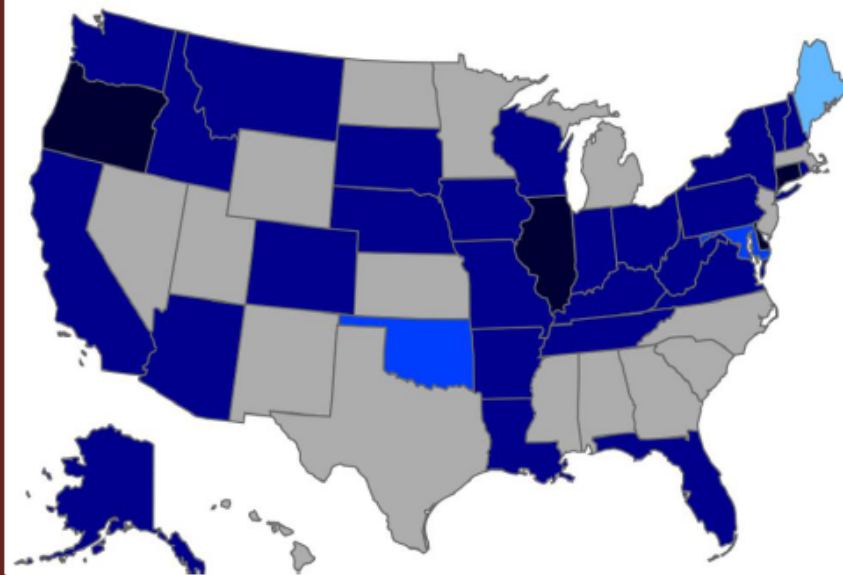
Chronic Hepatitis C infection can cause liver failure, liver cancer, brain damage, and kidney failure – and, if left untreated, can result in cirrhosis and be fatal. Chronic liver



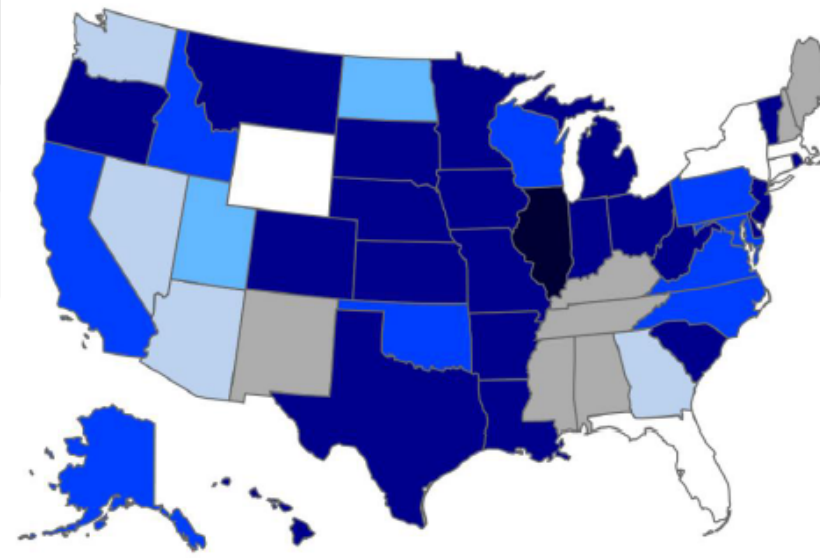
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Comparing 2014 & 2016 Medicaid FFS Liver Disease Requirements

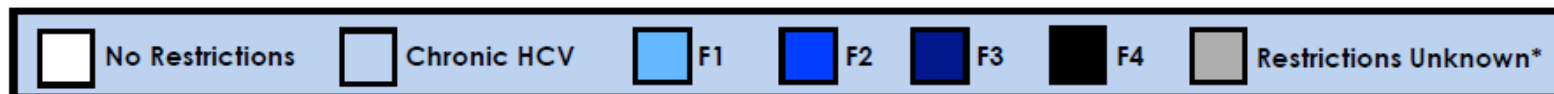
2014 FFS Medicaid Liver Disease Requirements



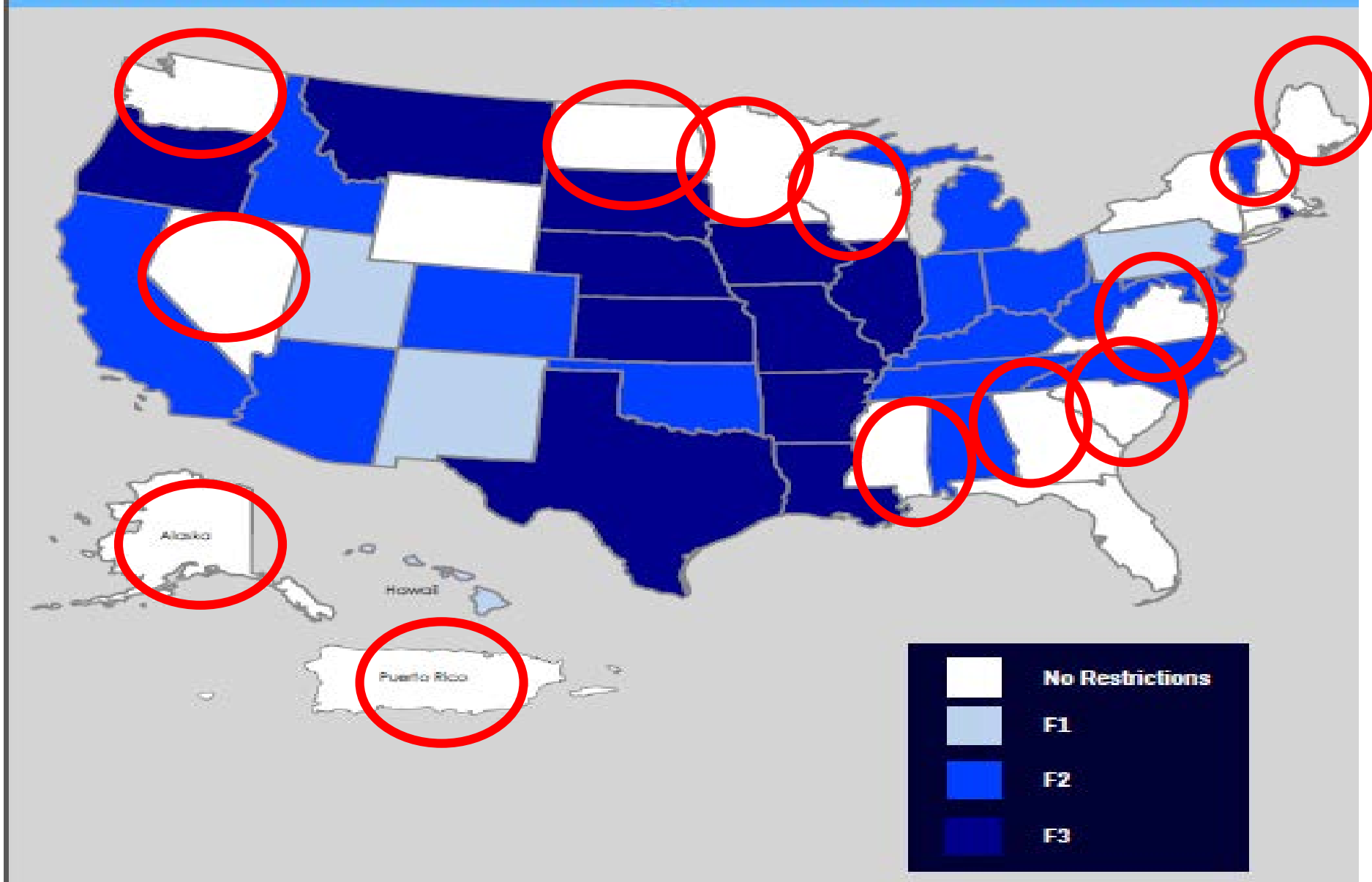
2016 FFS Medicaid Liver Disease Requirements



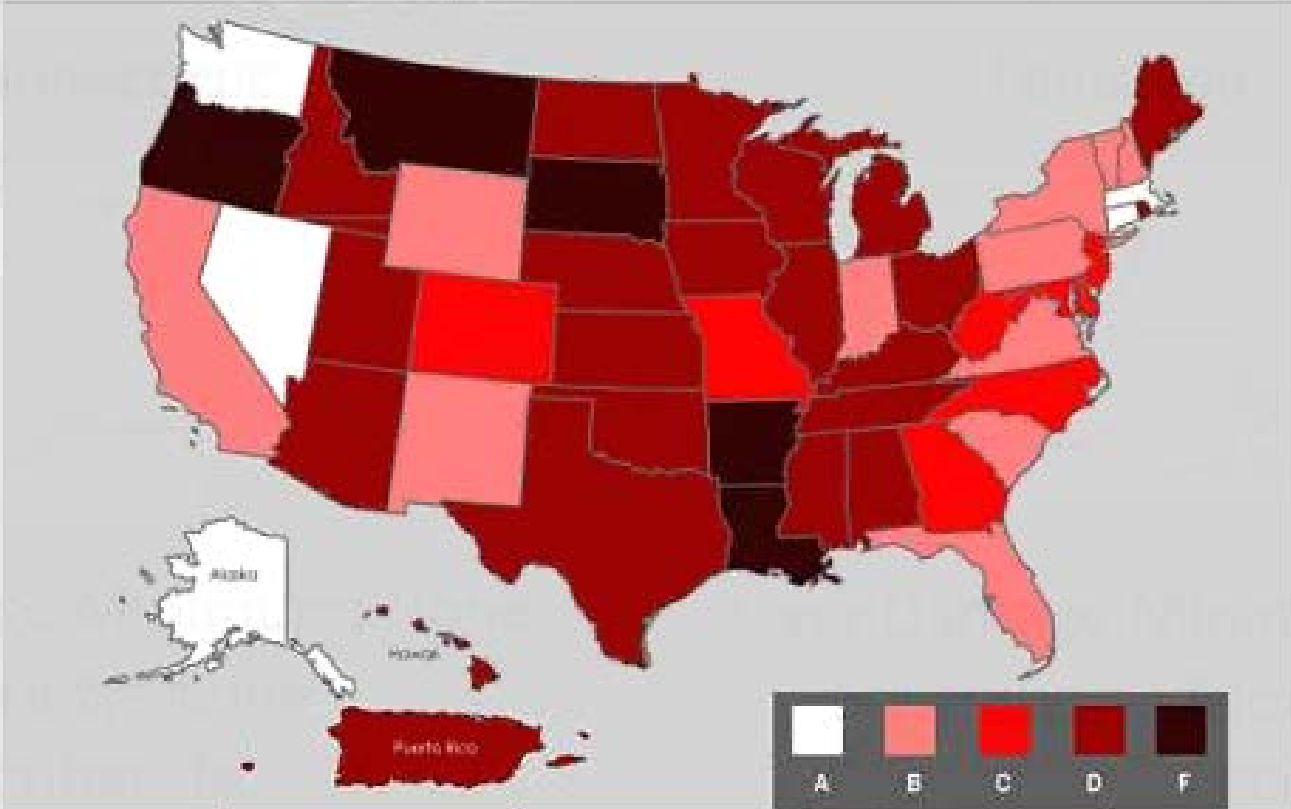
* Includes states that were characterized as “none indicated” and “unknown” in the Annals of Internal Medicine 2014 analysis. In the 2016 analysis, only includes states whose stage of liver disease restrictions are unknown. 2014 data from Barua S., Greenwald, R., Grebely, J., Dore, G., Swan, T., and Taylor, L. “Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infections in the United States,” *Ann Intern Med.* 2015; 163:215-223.



2017 Medicaid FFS Liver Damage Restrictions for HCV Treatment



FINDINGS: OVERALL STATE OF ACCESS



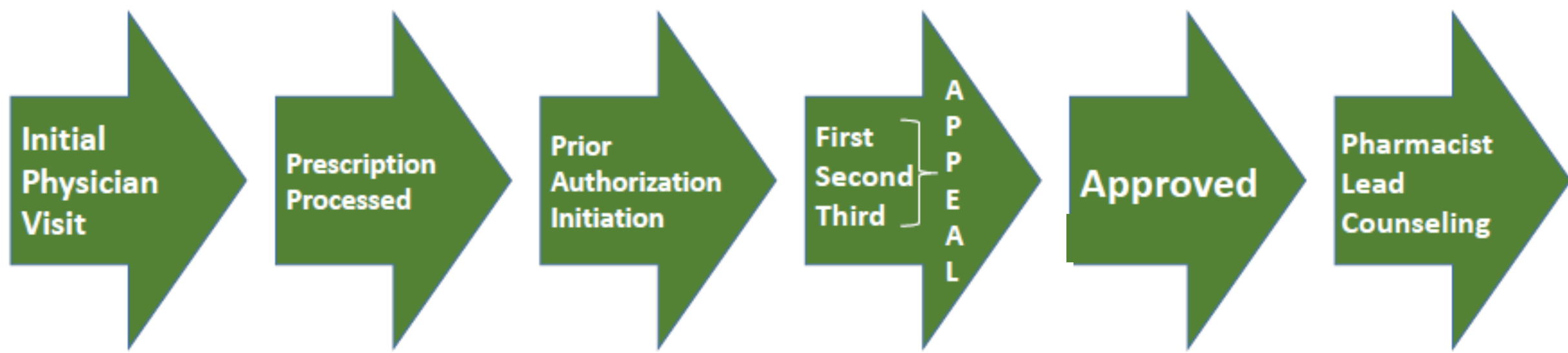
A	B	C	D	F
10%	21%	17%	42%	10%



3.5 MILLION AMERICANS ARE LIVING WITH THE HEPATITIS C VIRUS

Hepatitis C is our nation's deadliest infectious disease, yet many state Medicaid programs have discriminatory restrictions that keep Americans from being cured and stop us from ending the epidemic.

PROCESS FLOW CHART



Prior Authorization

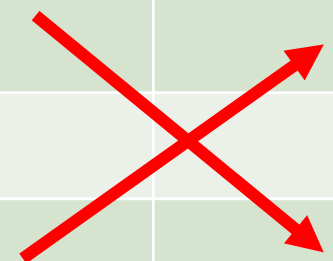


- ✓ Chart note
- ✓ CBC / CMP
- ✓ Viral Load
- ✓ Genotype
- ✓ Fibrosis score
- ✓ Resistance Testing



Approval Process

Process	General Population	HIV/HCV Patients
Prescription	22 (5%)	4 (17%)
Prior Authorization	299 (73%)	17 (73%)
Appeal	79 (19%)	2 (8%)
Patient Assistance Program	5 (1%)	0
Not approved	5 (1%)	0
TOTAL Approved	405 (99%)	23 (100%)
Total Not Approved	5 (1%)	0



How long does it take to get the medication approved?

Year	General Population Average PA sent to Approval date (days)	HIV/HCV Average PA sent to Approval date (days)
2014	94.4	11
2015	40.4	17
2016	17.8	18.4
2017		0.5 = 12 hours!!!

How much does the HCV drug cost patients?

Type of Insurance	General Population Average 1st Copayment	HIV/HCV Average 1st Copayment
Medicaid	\$2.33	\$1.00 n=8
Medicare	\$317.01	\$1.66 n=7
Commercial	\$890.44	\$22.66 n=8

Characteristics of the HIV/HCV infected Patients

Genotype	N (%)
1A	16 (70)
1b	5 (22)
3a	1 (4)
4	1 (4)
Grand Total	23 (100)

Medication	N (%)
Harvoni	19 (83)
Viekira + Ribavirin	2 (9)
Harvoni + Ribavirin	1 (4)
Vosevi	1 (4)
Grand Total	23 (100)

Liver fibrosis	N (%)
F0 / NC	5 (22)
F1	6 (26)
F2	4 (17)
F3	1 (4)
F4 / C	7 (31)
Grand Total	23 (100)

Treatment History	N (%)
TN	15 (65)
TE	8 (35)
Grand Total	23 (100)

Row Labels	Count of Regimen of Tx Hx
None	15 (65)
INF	1 (4)
INF + RBV	2 (8)
PEG INF + RBV	1 (4)
PEG INF + RBV + Sovaldi	1 (4)
Sovaldi+ Daklinza / INF + RBV	1 (4)
Unknown	2 (8)
Grand Total	23 (100)



REAL WORLD CURE RATE

97%

Cure Rate(%)	Medication Approved	Number of Patients
98.1	HARVONI [®]	540
97.8	VIEKIRA [®] + RIBAVIRIN [®]	46
93.5	SOVALDI [®] + RIBAVIRIN [®]	31
96.6	VIEKIRA [®]	29
84.2	DAKLINZA [®] + SOVALDI [®]	19
100	HARVONI [®] + RIBAVIRIN [®]	8
100	ZEPATIER [®]	3
100	DAKLINZA [®] + SOVALDI [®] + RIBAVIRIN [®]	2
100	TECHNIVIE [®] + RIBAVIRIN [®]	1
100	EPCLUSA [®] + RIBAVIRIN [®]	1
	Grand Total	680

CHARACTERISTICS OF TREATMENT FAILURES (17/680 = 97% SVR)																	
Patient #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Age	60	71	64	53	46	54	67	66	53	55	59	66	62	62	77	63	67
Gender	Female	Male	Female	Male	Male	Female	Female	Male	Female	Female	Female	Female	Female	Male	Female	Female	Male
Race	White	White	Black	White	White	White	White	White	Hispanic	Black	Black	White	Hispanic	Black	Black	White	White
Treatment History	TN	TN	TN	TE	TN	TE	TN	TN	TE	TE	TE	TE	TE	TN	TN	TN	TE
Medication	Harvoni	Sovaldi + RBV	Harvoni	Harvoni	Harvoni	Harvoni	Sovaldi + RBV	Harvoni	Daklinza + Sovaldi	Viekira	Viekira + RBV	Daklinza + Sovaldi	Harvoni	Harvoni	Harvoni	Daklinza + Sovaldi	Harvoni
Duration (In weeks)	12	24	8	12	12	12	12	12	16	12	24	12	24	12	12	12	12
Fibrosis Score	F2	F4	F4	F4	F1	F3	F4	F1	F4	F3	F4	F4	F4	F4	F4	F4	F4
HCV Genotype	1b	3a	1a	1a	1a	1a	2b	1a	3a	1b	1a	3	1b	1b	1a	3	1a
Baseline Viral Load	1,319,612	1,657,285	6,507,552	27,340,448	1,204,389	1,570,923	55,726	25,470	2,695,749	7,910,090	600,600	42,408	884,310	1,188,825	2,295,481	1,115,155	3,925,181
Resistance Associated Variant	None	n/a	Q30R	n/a	M28V	Q30H Y93H	n/a	n/a	n/a	Q54H Y93H	M28L Y93H	n/a	n/a	L31I/M Y93H	n/a	Not Detected	Q80K Q30E/G/Q
PPI	No	Yes	No	No	No	No	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No
End of Treatment Response	Yes	Yes	Yes	Yes	Yes	Unknown	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No
SVR 12	Unknown	Yes	Unknown	No	No	No	Unknown	No	No	No	No	No	No	No	Unknown	No	No
# of weeks post Treatment – Relapse	17	22	19	12	10	3	17	3	13	14	5 wk into tx	3	15	3	20	9	9

Foundations

Foundation	Phone number	Possible Requirements
Patient Access Network (PAN)	866-316-7263	1. Social Security Number 2. # of people under the household 3. Household annual income < 70K? 4. Proof of address
Healthwell	800-675-8416	
Goodeys	877-968-7233	
Patient Advocate Foundation	800-532-5274	

Drug Interactions Check

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	Daclatasvir	Elbasvir/Grazoprevir	Ledipasvir/Sofosbuvir	OBV/PTV/r + DSV	Simeprevir	Sofosbuvir
Amiodarone	Do Not Coadminister	Potential Interaction	Do Not Coadminister	Do Not Coadminister	Potential Interaction	Do Not Coadminister
Antacids	No Interaction Expected	No Interaction Expected	Potential Interaction	No Interaction Expected	No Interaction Expected	Potential Interaction
Aspirin	No Interaction Expected	No Interaction Expected	No Interaction Expected	No Interaction Expected	No Interaction Expected	No Interaction Expected
Cannabis	No Interaction Expected	No Interaction Expected	No Interaction Expected	Potential Interaction	Potential Interaction	No Interaction Expected

Appeal Letters

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HCV DAA Treatment Appeal Letters (Updated 3/9/17)

03.09.2017



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[Denial Appeal - GT1 Naive 12 Wk Treatment With ViekiraPak and Riba for Cirrhotic INF Contraindicated Patient](#)

[Denial Appeal - GT1 8-Week Sovaldi for INF Contraindicated Patient](#)

[Denial Appeal - GT1 Harvoni Re-Treat Post Sofosbuvir and Ribavirin Relapse](#)

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November 20, 2017

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October 10, 2017

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October 6, 2017

HCV Treatment Quick Guide Updated Oct 2017
October 6, 2017

Current Management of Alcoholic Hepatitis - August 2017
August 31, 2017

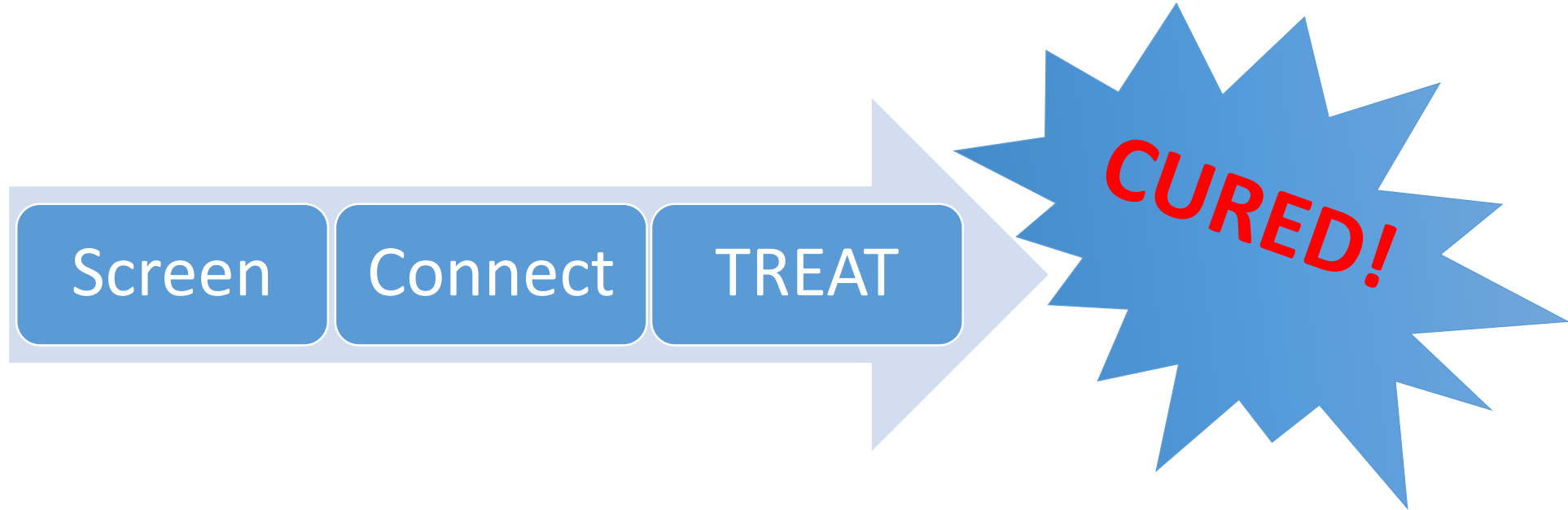
HCV-HBV-HCC Perspectives - U.S. approach using global data
August 15, 2017

Drugs in Development for Hepatitis B (June 2017)
August 2, 2017

Sliddeck: HBV Treatment Endpoints and Research Directions for (Functional) Cure

<http://www.robertgish.com/single-post/2017/03/09/HCV-DAA-Treatment-Appeal-Letters-Updated-3917>

Summary



Let's Eliminate Hepatitis C!!!