Understanding the Reimbursement Environment in Hepatitis C

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Current Negative Environment Created By Discussions about High Price of HCV Drugs

- Confusion and doubt among HCV providers about whom to treat
- Hesitation to perform or encourage hepatitis C testing from PCPs, DPH, community health centers, drug rehabilitation centers, prisons
- Concern among payers (public and private) about budget impact
- Rationing of treatment (ie F3-F4; substance use) and conflict between provider, patient and payer over rationing
  - Justification for overt discriminatory practices like mandating clean urine samples
- No discussion of cure-as-prevention
- Confirmation by patients that they are not "worth" treatment
- Loss of vision about transformative, curative developments

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Unique Aspects of Hepatitis C

- Relatively common disease
- Majority of people infected 20 – 40 years ago (75% in 1945-1965 birth cohort)
- Peak of severe liver complications expected to occur over this next decade, so urgency to identify and treat people soon
- Everyone who has >1 year life expectancy is theoretically a treatment candidate
- Pricing more similar to treatments for rare diseases

"Standard of Care" Regimens for Hepatitis C Have Been Expensive for Years: Examples for Treatment of Genotype 1, Naïve, Non-Cirrhotic Patients

Regimen	SVR rates	WAC Price	Cost per SVR
Pegasys + Ribavirin x 48 weeks[1]	41%	$41,758	$101,849
Telaprevir + PegIFN + Ribavirin x 24 weeks[2]	75%	$86,843	$115,791
Sofosbuvir + PegIFN + Ribavirin x 12 weeks	90%	$94,421	$104,912
Sofosbuvir+Ledipasvir x 8 weeks	94%	$63,000	$67,021 ($36,191?)*
Sofosbuvir + Ledipasvir x 12 weeks	99%	$94,500	$95,454 ($51,545?)*

Package inserts for products; *http://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/

Cost-Effectiveness of HCV Treatment

Study	Key Findings
Leidner, Hepatology 2015	For 55 y/o treated with $100,000 regimen and SVR = 90%, treating at F2 compared to waiting until F3 had CE = $37,300/QALY Threshold cost for treating at F0 versus waiting until F1 to yield $50,000/QALY = $22,200
Rein, CID 2015	Harvoni and Viekira Pak compared to no treatment yields $32,000 to $35,000/QALY Compared to no treatment, threshold cost for treating F0 with all-oral regimen = $47,000
Najafzadeh, Annals Int Med 2015	Compared to no treatment in genotype 1, costs per additional QALY gained for Harvoni = $25,291 and Peg-IRN/RBV = $24,833 If Harvoni <$66,000/treatment course, would be cost saving
Chhatwal, Annals Int Med 2015	Average ICER for sofosbuvir-based treatment compared to prior SOC = $55,378/QALY Range = $9,703/QALY for naïve, cirrhotic geno 1 to $410,548 for treatment experienced, geno 3 without cirrhosis

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Why are People Still Hysterical About HCV Drug Prices?

- Up until the approvals of sofosbuvir and simeprevir, payers relied on the inability/refusal of most patients to take interferon-alfa as the mechanism to keep HCV drug expenditure down
- With the combinations of sofosbuvir+ribavirin and sofosbuvir +simeprevir, nearly all patients with HCV infection theoretically could be treated
- How appropriate is this concern about pricing with recently announced reductions in cost?

Payer Dilemmas

- Most payers had no idea how much they were actually spending per treated patient (or per cure) in the interferon era
  - PI/P/R in cirrhotic patients ~ $266,000 per cure[1]
- Pharmacy budgets often separate from medical budgets
  - Pharmacy budgets don't get "credit" for avoidance of medical costs
  - Annual budgets
    - "Is it cost effective?" (off-sets over the long term)
    - "Is it affordable?" (costs over one year)

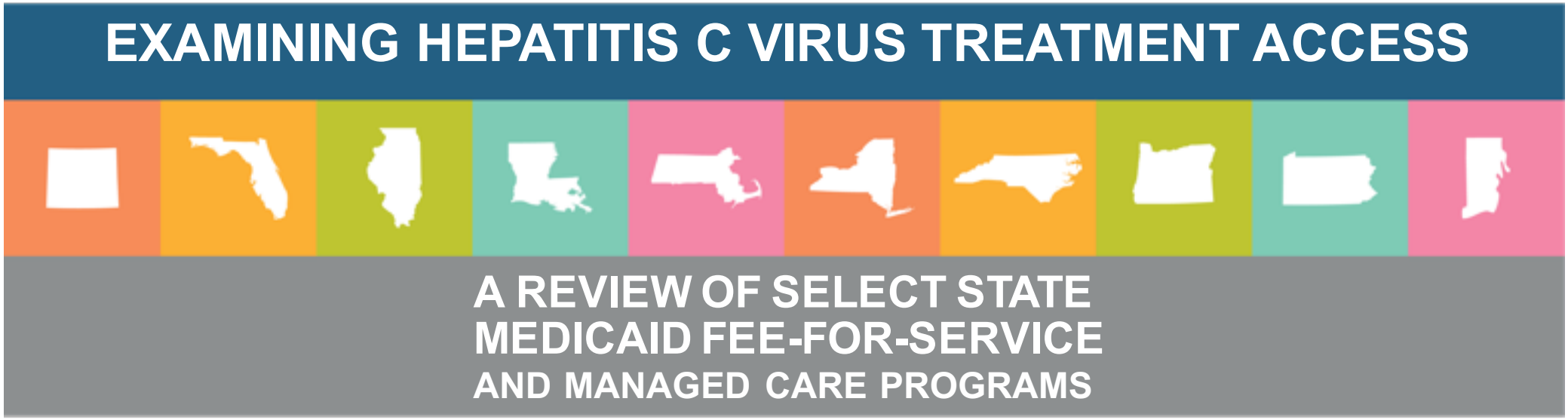
[1]Sethi, AASLD 2013

What Do Recently Announced Discounts Mean for HCV Regimens?

Regimen	WAC Price	46% Discount
SOF + LDV x 8 wks	$63,333	$34,200
3D + RBV x 12 wks	$85,820	$46,343
SOF + LDV x 12 wks	$95,000	$51,300
SOF + LDV + RBV x 12 wks	$97,500	$52,650
SOF + SMV x 12 wks	$150,000	$81,000
3D + RBV x 24 wks	$171,640	$92,686
SOF + LDV x 24 wks	$190,000	$102,600
SOF + SMV x 24 wks	$300,000	$162,000

Gilead reveals a 46% gross-to-net discount compared to 22% in 2014: http://www.firstreportnow.com/articles/gilead%E2%80%99s-sofosbuvir-close-becoming-best-selling-drug-world-report

Comments based on findings of recently released report:



- Examines accessibility of Sovaldi through Medicaid fee-for-service in 10 states
  - CO, FL, IL, LA, MA, NY, NC, OR, PA, RI
- Also examines Sovaldi access in 5 select states Medicaid managed care plans
  - MA, NY, LA, PA, OR
- Report and corresponding webinar available at www.chlpi.org

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

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Limitations on Access to HCV Treatments

- **Limits Based on Stage of Fibrosis**
- **Restrictions Based on Substance Use**
- **Prescriber Limitations**
- **Other restrictions**
  - HIV Co-Infection limitations
  - “Once per lifetime” limitations
  - Genotype limitations
  - Previous history of treatment adherence requirements
  - Specialty pharmacy restrictions
  - Exclusivity agreements with insurers

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Illinois Sovaldi Prior Authorization Criteria: More Restrictive Then Most States

Coverage

+ Non-preferred drug

Fibrosis

+ Metavir score of ≥F4

Substance Use

+ No evidence of substance abuse in past 12 months

Prescriber Limitations

+ If prescriber is not a specialist, required one-time written consultation within past 3 months

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MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive Then Most States

Coverage

+ Preferred drug

Fibrosis

+ No restrictions (form inquires)

Substance Use

+ No restrictions (form inquires about current use)

Prescriber Limitations

+ No restrictions

Additional Restrictions

+ No additional restrictions based on HIV Co-infection or previous adherence

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MassHealth MCOs Sovaldi Prior Authorization Criteria

	Boston Med. Ctr. Health Net Plan	Neighborhood Health Plan	Tufts Health Plan Network Health	Health New England
Fibrosis	F3-4	F3-4	F3-4	F4
Requirements Related to Substance Use	Not abused substances for 6 months	(For members with past/current issues) abstain from use for 6 months and participation in supportive care	No substance abuse within past 6 months OR receiving counseling services	(Known substance abusers) must have been referred to specialist; abstinence from substance abuse for 6 months; ongoing participation in treatment program; adequate psychosocial supports
Prescriber Limitations	Prescribed by or in consultation with specialist	Prescribed by or in consultation with specialist	Prescribed by specialist	Prescribed by specialist
HIV Co-Infection	Yes, with non-suppressable viral load or elevated MELD scores	Not without meeting additional requirements above	Not without meeting additional requirements above	Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load
Additional Adherence Requirements	No history of nonadherence; enrollment in compliance monitoring program	Individual must demonstrate understanding of the proposed treatment, and display the ability to adhere to clinical appointments	"[M]ember has been assessed for potential nonadherence."	No ongoing non-adherence to previously scheduled appointments, meds or treatment; adherence counseling; willing to commit to monitoring

Massachusetts Affordable Care Act Qualified Health Plans – Prior Authorization Criteria

	Fallon Health	Tufts	Harvard Pilgrim
Fibrosis	**F3-4**	**F3-4**	**F3-4**
Requirements Related to Substance Use	"[N]ot engaged in any habits that would negate the efficacy of the medications."	No illicit substance abuse within past 6 months OR receiving substance or alcohol abuse counselling services/seeing addiction specialist	None
Prescriber Limitations	Prescribed by specialist	Prescribed by specialist	Prescribed or supervised by specialist
HIV Co-Infection	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.
Additional Adherence Requirements	Must have been adherent to past therapies; must be prepared/motivated to start treatment. Application "require[s] a member's psychological and behavioral habits assessment to determine if therapy is right for him/her."	"[M]ember has been assessed for potential nonadherence."	None

NEXT STEPS

Reframe the Response

Shift the focus from cost to cure

- U.S. government sets pharma laws with varying perspectives if effective – if not, change laws, rather than deny access to HCV cure
- Recognize payer concerns, but accurately assess the value of cure – with supplemental rebates the cure is now ~$40,000
- Comparative effectiveness matters
  - We paid over ~$250,000 per HCV cure in interferon age
  - In HIV, no cure and we pay ~$10,000 per year for life for HAART
- Pharmacy budgets may increase but others will decrease
- Medicaid is an entitlement program in part to grow to meet the demands created by innovation

Respond to HCV Treatment Advances From a Public Health Perspective

HCV must be addressed as a serious public health issue

+ Screening and treatment have significant individual and public health benefits

+ Baby boomer generation is not the end of the epidemic, with increasing evidence of growing incidence in young people

+ Other serious diseases are not similarly treated (i.e., requiring disease progression or sobriety) and this undermines the public health response

+ Insurers should adopt, not ignore, lessons learned from HIV treatment guidelines, where early and unrestricted access is the rule

Follow Medicaid and ACA Law

Both public and private health insurance laws preclude restrictive, unfair and discriminatory HCV treatment access practices

- Under the Medicaid Act all prescription drugs of a manufacturer who enters into rebate agreements must be covered, with only exceptions allowed for safety and clinical effectiveness
- While states have more discretion under prior authorization, even here courts have supported challenges when access is severely curtailed or final authority to provide drugs does not rest with the prescribing health care providers
- Under Massachusetts law, as well as in other states, state medical necessity laws require even fewer restrictions on access to effective, life-saving medications
- Under the ACA differential treatment of HCV rises to the level of a discriminatory insurance practice

Payer Decisions to Limit Access to HCV Treatment

- Medical need restrictions
- Insurance restrictions
- Prescriber restrictions
- Specialty pharmacy restrictions
- Insurance termination / switch during treatment

Response to Restricting Treatment to F3/F4

- Cannot require liver biopsy (may be highest risk of death in HCV care with all-oral regimens)
- Since no test can perfectly distinguish F2 from F3 or F3 from F4, limiting access to F3/F4 really means directing treatment to cirrhotic patients
- If we wait until advanced fibrosis, need to do life-long screening for HCC every six months even if cured (expense, logistics, patient anxiety)
- Prioritization of F2-F4 unless other compelling urgency may align with provider capacity

Restrictions Based on Current or History of Substance Use

- Prescriber assessment and documentation
  - 3 to 12 months sobriety/abstinence from EtOH/drug use
  - Completion or enrollment in a treatment center
  - May require drug testing results
- Participate in counseling services
- Engage in care with an addiction specialist

Compare: Department of Veterans Affairs (VA) Guidelines for PWID

"There are no published data supporting a minimum length of abstinence as an inclusion criterion for HCV antiviral treatment. Patients with active substance- or alcohol-use disorders should be considered for therapy on a case-by-case basis and care should be coordinated with substance-use treatment specialists."

- http://www.hepatitis.va.gov/provider/guidelines/2014hcv/special-groups.asp

Discussing Substance Use Restrictions with Payers

- Address potential impact on adherence
  - Many people with substance use issues able to remain adherent
  - Data from peg-IFN/RBV treatment shows good adherence with adequate support
- Concern about reinfection
- Legal medical marijuana use
  - May improve adherence via management of side effects
- Most DAA clinical trials allow methadone +/- buprenorphine – not a concern with adherence
  - Need programs that integrate HCV treatment into opiate replacement centers
- Inability to study cure-as-prevention
- Ask: Would we limit treatment in someone with XX disease?

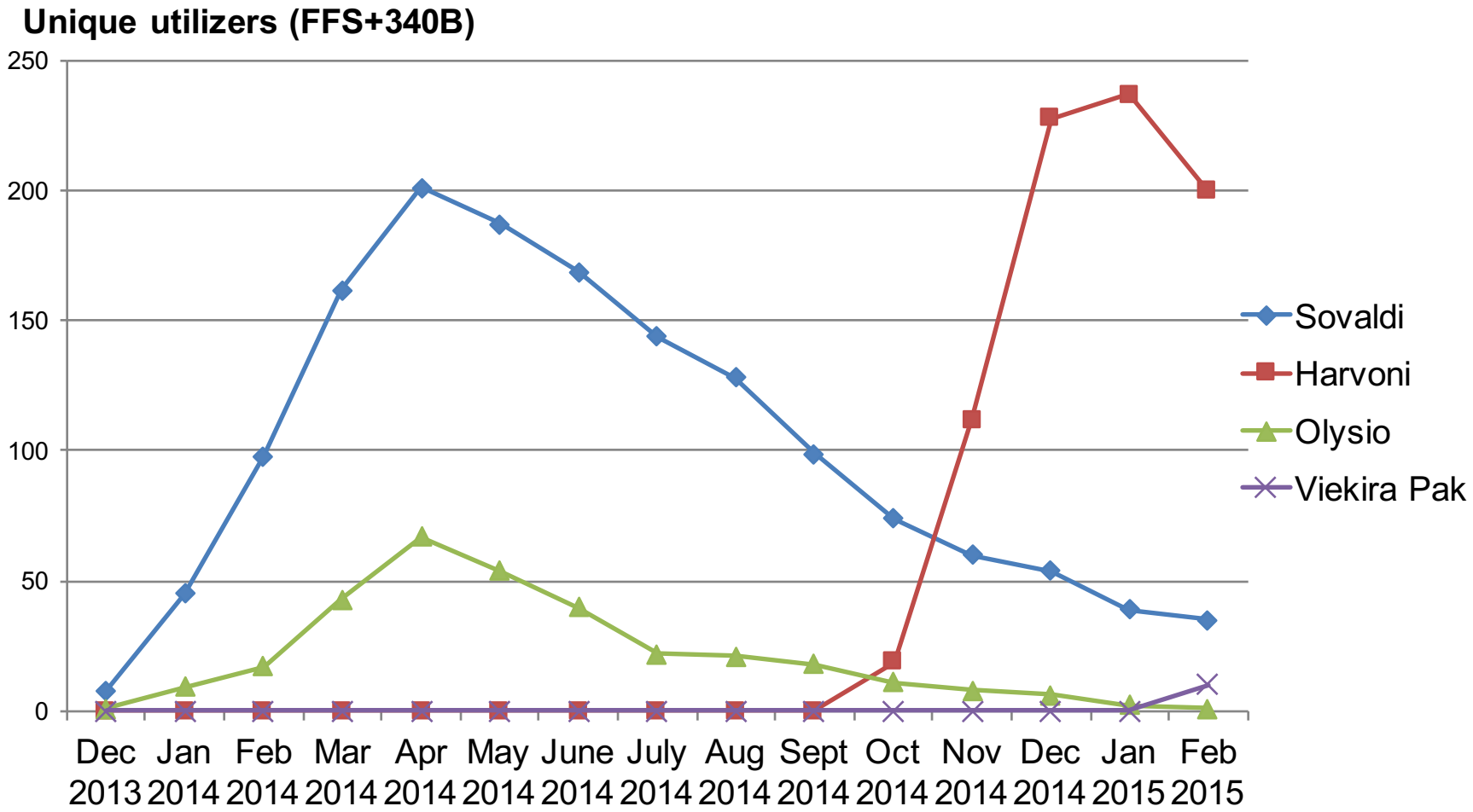
HCV Providers Collaborating with Payers

- Share your understanding and concern about the budget impact of HCV treatments
- Efficacy and safety will not be compromised (non-negotiable)
- Express responsibility for our shared resources:
  - For reasonably equivalent treatment options, include cost as a factor
  - Optimize adherence and AE management
  - Prioritize reducing re-infection rates
  - Minimize other causes of liver damage like alcohol

Monthly Trends in Hepatitis C Utilization

December 18, 2013 – February 28, 2015

Month-by-month changes in total paid claims for Harvoni, Viekira Pak , Olysio and Sovaldi



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Hepatitis C Adherence Program Overview & Monitoring Program

- Discuss appropriate regimens offering greatest cure and lowest cost
- Refer members with prior or current substance use disorder to care management services
- Claims monitoring for approved members
- Contact prescriber when non-adherence suspected
  - Within 2 days of anticipated fill
- Obtain end viral load to determine cure rates

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Interventions Resulting in Regimen Change

Requested Regimen	Recommended Regimen	# of Members	Additional Cost or Cost-Avoidance
HCV Genotype 1 Infection PA Approvals			
LDV/SOF x 12 weeks	LDV/SOF x 24 weeks	6	Additional cost
LDV/SOF x 8 weeks	LDV/SOF x 12 weeks	7	Additional cost
LDV/SOF x 12 weeks	LDV/SOF x 8 weeks	48	Cost-avoidance
LDV/SOF x 24 weeks	LDV/SOF x 12 weeks	8	Cost-avoidance
LDV/SOF x 24 weeks	LDV/SOF + RBV x 12 weeks	7	Cost-avoidance
LDV/SOF x 24 weeks	LDV/SOF x 8 weeks	1	Cost-avoidance
SOF+SMV x 12 weeks	LDV/SOF x 12 weeks	5	Cost-avoidance
SOF+SMV x 12 weeks	LDV/SOF x 8 weeks	3	Cost-avoidance
SOF+SMV x 24 weeks	LDV/SOF + RBV x 12 weeks	1	Cost-avoidance
SOF+PEG/RBV x 12 weeks	LDV/SOF x 12 weeks	1	Cost-avoidance
HCV Genotype 3 Infection PA Approvals			
SOF+RBV x 24 weeks	LDV/SOF + RBV x 12 weeks	4	Cost-avoidance
HCV Genotype 4 Infection PA Approvals			
LDV/SOF x 24 weeks	LDV/SOF x 12 weeks	1	Cost-avoidance
Projected cost-avoidance		**84**	**$3,573,316**

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Overview of Approved Requests by Genotype

December 18, 2013 – March 27, 2015

Genotype	Regimen	Approved Requests
1 (752 Members) ~70%	**SOF + PEG/RBV x 12 wks**	**118**
	SOF/RBV x 24 wks	32
	SOF/SMV ± RBV x 12 wks	**141**
	SOF + DCV x 24 wks	2
	LDV/SOF ± RBV x 8 wks	159
	LDV/SOF x 12 wks	**263**
	LDV/SOF + RBV x12 weeks	43
	LDV/SOF x 24 wks	30
	LDV/SOF + RBV x 24 wks	4
	AOD ± RBV x12 wks	5
1 & 2 (6 Members) ~0.55%	SOF/SMV + RBV x 12 wks	1
	LDV/SOF ± RBV x 12 wks	6

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Overview of Approved Requests by Genotype (cont'd)

December 18, 2013 – March 27, 2015

Genotype	Regimen	Approved Requests
2 (150 Members) ~14%	**SOF/RBV x 12 wks**	**155**
	SOF/RBV x 16 wks	1
	LDV/SOF x 12 wks	2
3 (127 Members) ~11.8%	**SOF/RBV x 24 wks**	**111**
	SOF/RBV x 16 wks	1
	SOF + PEG/RBV x 12 wks	12
	SOF+DCV x 24 wks	1
	LDV/SOF + RBV x 12 wks	7
4 (33 Members) ~3%	**SOF + PEG/RBV x 12 wks**	**13**
	SOF + RBV x 24 wks	7
	LDV/SOF x 12 wks	**10**
	AOD + RBV x12 wks	6
6 (7 Members) ~0.65%	SOF + PEG/RBV x 12 wks	4
	SOF + RBV x 24 wks	7
Total		**1,141**

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Overview of Approved Requests by Liver Disease Staging

December 18, 2013 – March 27, 2015

Staging Category	Number of Requests Approved	Number of Members Approved
F0-F2	415	404 (37.6%)
F3	109	106 (9.8%)
F4 compensated	475	441 (41%)
F4 decompensated	51	44 (4%)
Unknown	33	33 (3.1%)
Unknown (non-cirrhotic)	58	57(5.3%)
Total	1,141	1,075

55%

A total of **1,141** requests were approved for **1,075** MassHealth members.

Based on the current data documented, **55%** of members have advanced fibrosis (F3-F4), **37.6%** of members are staged as F0-F2, **5.3%** of members are staged as unknown (non-cirrhotic) and **3.1%** of members are unknown

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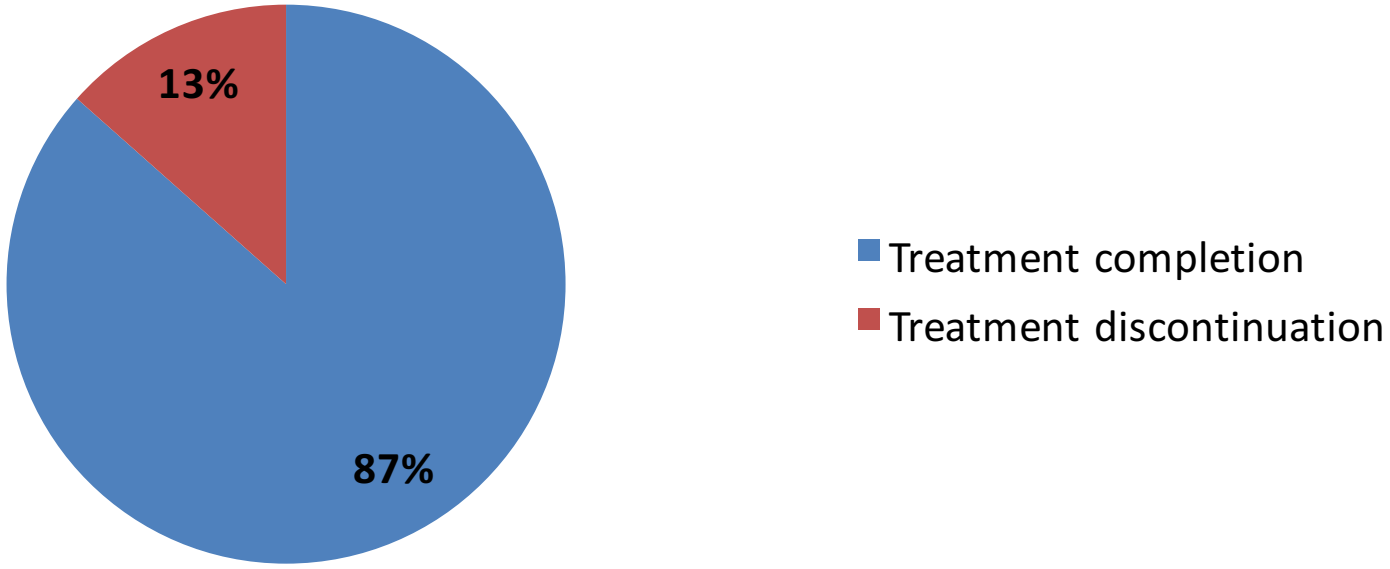
Adherence Rates

December 18, 2013 – March 27, 2015

There were a total of **695** completions in treatment and **108** discontinuations in treatment

Based on the current data documented, the adherence rate† is **86.6%**

† Note: the adherence rate calculation only includes members who have started treatment and discontinued (does not include members who did not start treatment, or members who have transitioned to another insurance carrier)



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Treatment Completion and Cure Rates

December 18, 2013 – March 27, 2015

Genotype	Completed therapy based on pharmacy claims data	Due for 12-week post-therapy completion viral load	SVR12	Detectable viral load after treatment
1	440	203	128	19
1 & 2	1	-	-	-
2	103	78	32	15
3	62	42	25	3
4	15	10	3	3
6	7	4	2	1
Total	**628**	**337**	**190†**	**41**

***There is at least a 12-week lag in data collection**
†9 additional members were undetectable within 7 days prior to viral load due date; therefore, included in cure rate calculation

A total of **199 members** had an SVR12 within 7 days of viral load due date and **41 members** had a detectable viral load after treatment

Based on the current data documented, the cure rate† is **82.3%** in members who have completed treatment

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Estimated Volume

- 7,658 members with HCV
  - PCC members continuously enrolled 12/6/13-7/30/14 with an ICD-9 code for HCV
- Currently 1,075 members approved for regimens
    - ~14% engaged in treatment

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Sampled Demographics

- 379 members with prior authorization requests submitted
  - 90% approved
  - Requests for Men > Women
  - Twice as many requests for ages 50 years or older
  - Less substance use disorder members
  - Residence: housed > homeless

DISCUSSION POINTS

- What is a reasonable health insurer response to HCV treatment access?
  - What, if any, restrictions make sense?
- What should the public health response to HCV treatment look like?
  - Can “Cure-as-Prevention” be a goal for Massachusetts?
  - What should medical management for high-risk or younger people in treatment look like?
- What regulations, policies and programs would need to be in place to support a sound HCV screening and treatment access initiative in MA?