



Assessing the Burden of Illness of Chronic Hepatitis C and Impact of Direct-Acting Antiviral Use on Healthcare Costs in Medicaid

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November 18, 2019

Hepatitis C Medicaid Affinity Group Meeting

Acknowledgements

Citations

- Roebuck, M.C. and J.N. Liberman. 2019. “Assessing the Burden of Illness of Chronic Hepatitis C and Impact of Direct-Acting Antiviral Use on Healthcare Costs in Medicaid.” *American Journal of Managed Care* 25(8 Suppl):S131-S139.
- Roebuck, M.C. and J.N. Liberman. “Burden of Illness of Chronic Hepatitis C in Medicaid.” Presented at the 23rd Annual Meeting of the International Society for Pharmacoeconomics and Outcomes Research, Baltimore, MD, May 22, 2018.
- Funding received from Pharmaceutical Research and Manufacturers of America



Background

- Hepatitis C virus (HCV) infects about 3.5 million Americans and imposes substantial costs on society.
- Until 2011, treatment was pegylated interferon plus ribavirin—a poorly tolerated regimen that achieved sustained virologic responses (SVR) in <60% of patients.
- Direct-acting antiviral (DAA) medications were introduced in 2011—interferon-free in December 2013—with fewer side effects and SVR >92%.
- DAAs were launched at much higher list prices, but they have since declined from nearly \$100,000 to under \$24,000 per treatment course.
- Given their budget constraints and higher rates of HCV infection, Medicaid programs require a better understanding of both the economic costs and benefits of the cure to inform coverage and reimbursement decisions.



Objectives

- To quantify the burden of illness of chronic hepatitis C virus (HCV) infection, and
- To estimate the impact of interferon-free direct-acting antiviral (DAA) treatment on healthcare costs in Medicaid



Burden of Illness of HCV in Medicaid



Data

- Medicaid Analytic eXtract (MAX) data obtained via CMS Data Use Agreement
- MAX data include pharmacy & medical claims and encounter records, as well as eligibility information on all individuals enrolled in Medicaid.
- MAX files for the year 2012, from 16 states—AL; CA; CT, FL; IL; IN; LA; MI; NH; NM; NY; OH; OR; PA; VA; WA
- Analysis included individuals ages 18 to 64, with unrestricted benefits, and without a gap in coverage of more than 30 days
- After these criteria were imposed, 5,210,249 adult Medicaid recipients remained.
- Individuals then segmented according to their Medicaid basis of eligibility: either blind/disabled adults or non-blind/disabled adults
- Further stratified by plan type: either fee-for-service (FFS) or managed care (MC)



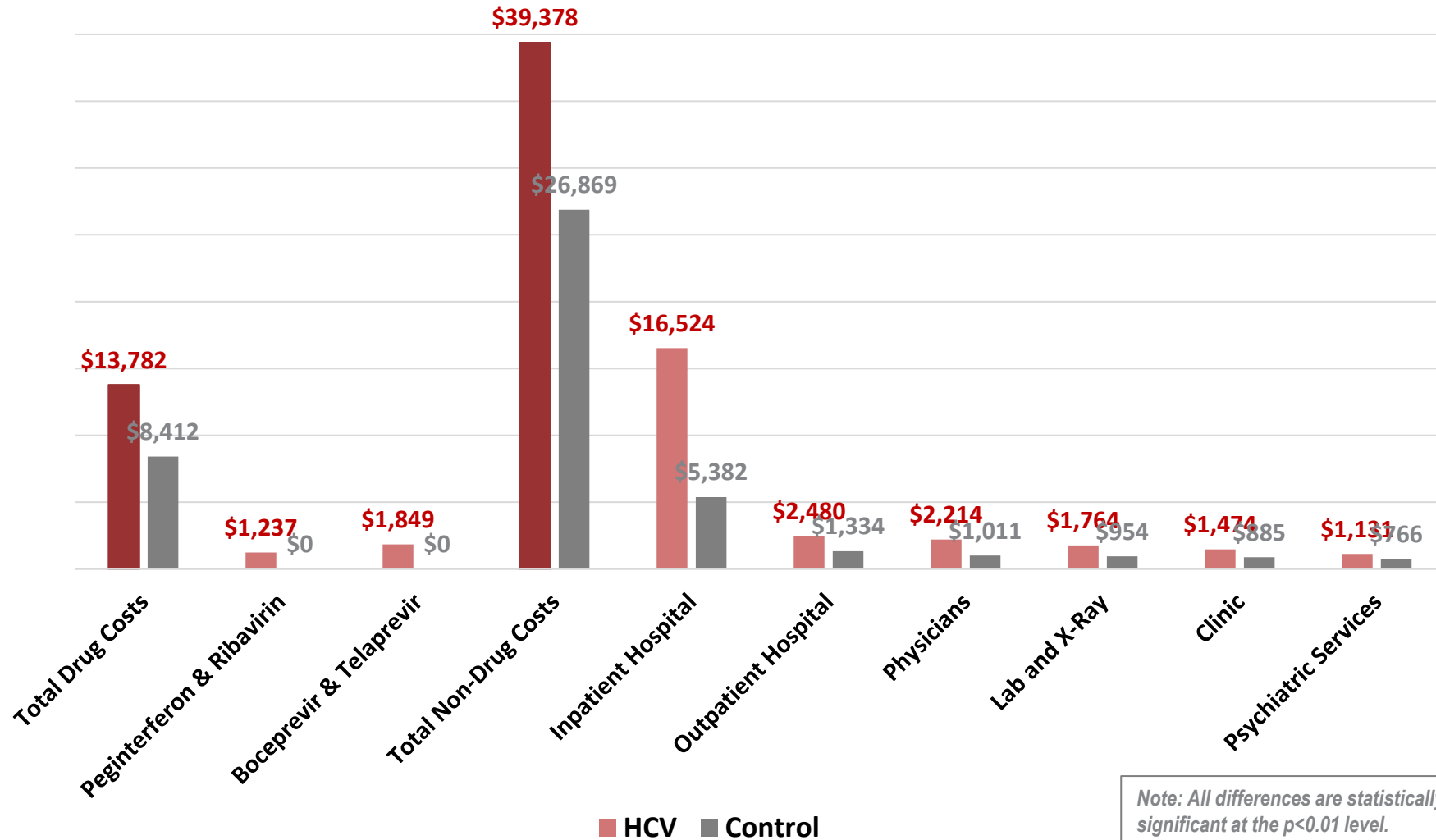
Methods

- Individuals with chronic HCV were identified via ICD-9 diagnosis codes on MAX claims and encounters (excluding HCV testing).
- A total of 72,109 were classified as having chronic HCV during the study period.
- Patients were then assigned to 1 of 3 liver disease severity cohorts: noncirrhotic, cirrhosis, or end-stage liver disease (ESLD)—also based on ICD-9 diagnosis codes (*results not presented herein*).
- Individuals with chronic HCV were then exact-matched 1:1 to controls (i.e., Medicaid recipients without HCV) on a robust set of patient and plan characteristics.
- Burden of HCV illness measured in terms of incremental health services use (*results not presented herein*) and incremental costs (using FFS cohorts; inflated to 2017\$) via differences in mean values between HCV and control groups.



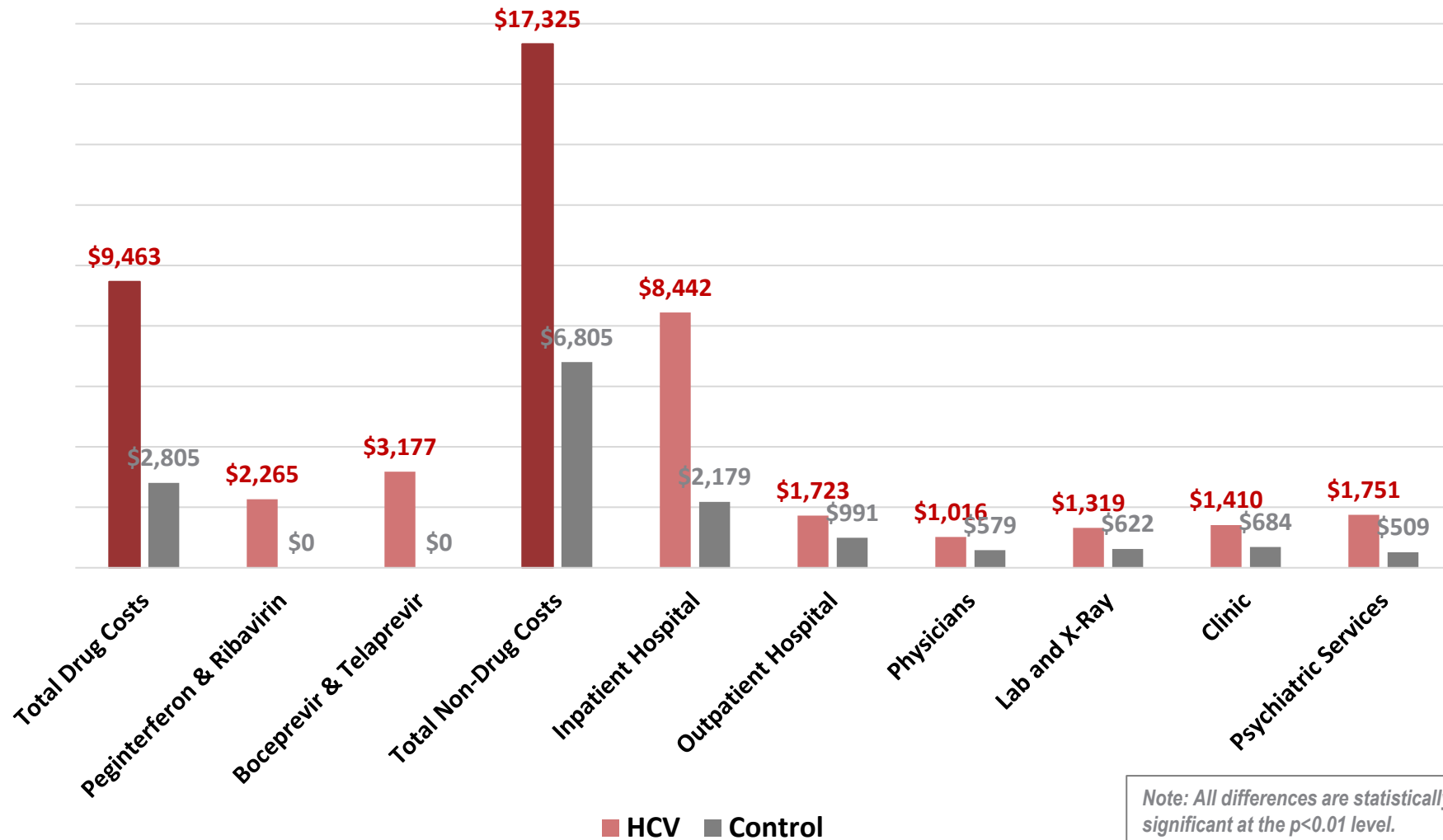
Results

Mean Annual Healthcare Costs, Disabled Adults (2017\$)



Results

Mean Annual Healthcare Costs, Non-Disabled Adults (2017\$)



Main Findings

- Mean annual total healthcare costs were \$53,159 per disabled patient with chronic HCV versus \$35,280 for controls without HCV, a difference of **\$17,879**.
- 62% of these incremental costs was attributed to inpatient hospitalizations.
- 30% linked to prescription drugs—most of which was for older HCV medications
- Among disabled adults, annual healthcare costs were \$26,788 for patients with chronic HCV versus \$9610 for the control group, a difference of **\$17,178**.
- 75% of which was for inpatient hospitalizations and prescription drugs.



Impact of DAA Use on Medicaid Costs



Data & Methods

- The impact of DAA use on healthcare costs in Medicaid from 2013 through 2022 was projected by combining the results from the burden-of-illness analysis with actual DAA cost and utilization data.
- Medicaid State Drug Utilization Data (SDUD) files contain information on the counts and reimbursement amounts for all prescriptions dispensed in Medicaid.
- Obtained SDUD data on all IFN-free DAA fills from Q4/2013 through Q2/2018
- Estimated the average number of prescriptions filled per treated HCV patient based on package inserts for each DAA product
- Divided SDUD claim counts by this number to calculate the annual number of patients treated with DAAs
- Applied expected DAA-specific SVR rates to determine the estimated annual number of patients cured of the virus



Data & Methods

- Patients cured of HCV were expected to have health care costs similar to otherwise comparable individuals without the infection.
- Assumed 90% of estimated average burden of illness eliminated by the cure
- Remaining 10% of HCV costs would cover recommended post-treatment services (e.g., HCV testing, ultrasound examination, endoscopy)
- Total cost of DAA treatment equaled total annual reimbursements minus expected rebates, which considered both the statutory Medicaid Drug Rebate and any negotiated supplemental rebates due to competition from new products
- Total DAA expenditures were subtracted from total avoided healthcare costs to yield the net financial impact of DAA use on Medicaid costs, derived annually and cumulatively from 2013 through 2022.
- Projected costs for Q3-Q4/2018 through 2022 assumed DAA prices and utilization rates of Q1-Q2/2018 would persist unchanged (conservative).



Results

Appendix Table A3. DAA Drug Utilization and Cost in Medicaid, 2014					
NDC	Product Name	Plan Type	Quarter	Number of Prescriptions	Medicaid Amount Reimbursed
61958150101	Sofosbuvir	FFS	1	3,231	\$91,137,410
61958150101	Sofosbuvir	MC	1	4,928	\$135,515,246
61958150101	Sofosbuvir	FFS	2	7,554	\$210,574,435
61958150101	Sofosbuvir	MC	2	11,304	\$311,498,327
61958150101	Sofosbuvir	FFS	3	4,878	\$132,596,531
61958150101	Sofosbuvir	MC	3	10,248	\$279,616,569
61958150101	Sofosbuvir	FFS	4	2,877	\$76,365,177
61958150101	Sofosbuvir	MC	4	6,438	\$170,173,407
TOTAL >>>				51,458	\$1,407,477,103
Estimated Number of Patients Treated >>>				12,450	\$113,050 per patient treated
Estimated Number of Patients Cured >>>				11,454	\$122,881 per patient cured
61958180101	Ledipasvir/sofosbuvir	FFS	4	1,198	\$37,796,528
61958180101	Ledipasvir/sofosbuvir	MC	4	1,973	\$59,623,522
TOTAL >>>				3,171	\$97,420,049
Estimated Number of Patients Treated >>>				767	\$127,014 per patient treated
Estimated Number of Patients Cured >>>				721	\$135,118 per patient cured
<i>Notes: DAA=direct-acting antiviral; NDC=national drug code; FFS=fee-for-service; MC=managed care.</i>					



Results

Appendix Table A8. Impact of Direct-Acting Antiviral Use on Healthcare Costs in Medicaid, 2013-2022

Estimated Number of HCV Patients Cured		
Drug Name	2013	2014
Sofosbuvir	32	11,454
Ledipasvir/sofosbuvir	0	721
Total >>>	32	12,175
Cost of DAA Treatment (before rebates)		
Sofosbuvir	\$4,056,068	\$1,407,477,103
Ledipasvir/sofosbuvir	\$0	\$97,420,049
Total >>>	\$4,056,068	\$1,504,897,153
Estimated Average Rebate	23.1%	23.1%
Estimated Net Cost of DAA Treatment (after rebates)		
Total >>>	\$3,119,116	\$1,157,265,910
Estimated Healthcare Costs Savings		
HCV Burden (PPPY)	\$15,808	\$16,186
% of Burden Saved with Cure	90%	90%
HCV Burden Savings (PPPY)	\$14,227	\$14,567
Cumulative Number Cured	32	12,207
Total Healthcare Costs Saved	\$455,266	\$177,819,373
Net Total Healthcare Cost Savings	-\$2,663,850	-\$979,446,537
Net Total Savings (2017\$)	-\$2,978,324	-\$1,069,517,673
Cumulative Net Total Savings (2017\$)	-\$2,978,324	-\$1,072,495,997



Results

Appendix Table A8. Impact of Direct-Acting Antiviral Use on Healthcare Costs in Medicaid, 2013-2022

Estimated Number of HCV Patients Cured						
Drug Name	2015	2016	2017	2018 (proj)	2019 (proj)	2020 (proj)
Total >>>	26,199	35,157	40,344	43,612	43,612	43,612
Cost of DAA Treatment (before rebates)						
Total >>>	\$3,021,105,327	\$3,665,910,709	\$3,149,258,024	\$2,000,610,550	\$2,000,610,550	\$2,000,610,550
Estimated Average Rebate	31.0%	59.5%	54.1%	50.6%	53.3%	53.3%
Estimated Net Cost of DAA Treatment (after rebates)						
Total >>>	\$2,083,964,594	\$1,485,110,974	\$1,445,203,541	\$988,475,042	\$934,129,440	\$934,129,440
Estimated Healthcare Costs Savings						
HCV Burden (PPPY)	\$16,612	\$17,241	\$17,674	\$17,674	\$17,674	\$17,674
% of Burden Saved with Cure	90%	90%	90%	90%	90%	90%
HCV Burden Savings (PPPY)	\$14,951	\$15,517	\$15,907	\$15,907	\$15,907	\$15,907
Cumulative Number Cured	38,406	73,563	113,907	157,519	201,131	244,743
Total Healthcare Costs Saved	\$574,189,210	\$1,141,464,888	\$1,811,873,086	\$2,505,591,725	\$3,199,310,365	\$3,893,029,004
Net Total Healthcare Cost Savings	-\$1,509,775,384	-\$343,646,086	\$366,669,545	\$1,517,116,684	\$2,265,180,925	\$2,958,899,564
Net Total Savings (2017\$)	-\$1,606,326,228	-\$352,278,093	\$366,669,545	\$1,517,116,684	\$2,265,180,925	\$2,958,899,564
Cumulative Net Total Savings (2017\$)	-\$2,678,822,225	-\$3,031,100,318	-\$2,664,430,772	-\$1,147,314,089	\$1,117,866,836	\$4,076,766,400



Main Findings

- By the end of 2022, about 331,967 HCV cases will have been cured in Medicaid
- DAA costs have declined since 2015 with increased competition. For Medicaid, total annual DAA costs peaked in 2015 at \$2.1 billion and decreased to less than \$1 billion in 2018.
- Since 2017, total annual healthcare cost offsets (i.e., benefits) generated by curing HCV in Medicaid patients have exceeded total annual DAA costs.
- Although accrued spending on DAAs was higher than the accrued savings from reduced HCV burden between 2013 and 2018; beginning in mid-2019, Medicaid had fully recouped all its investment in these HCV cures.
- The cumulative impact of DAA use in Medicaid due to total healthcare expenditure reductions, net of cumulative DAA costs since 2013, is expected to grow from \$1.1 billion at the end of the 2019 to more than \$12 billion after 2022.



Conclusion

- Average annual healthcare costs due to chronic HCV are estimated at \$17,879 for blind/disabled adults and \$17,178 for nondisabled adults in Medicaid—blended about **\$18,325** in current (2019) dollars.
- Currently, a DAA treatment course costs Medicaid programs no more than **\$20,880** (i.e., generic list price of \$24,000 minus 13% Medicaid Drug Rebate).
- Thus, on average, DAA costs are fully offset by benefits after only **14 months**.
- Medicaid policies that restrict access to DAAs—such as requirements for liver biopsy, advanced disease stage, sobriety, and specialist prescribers—would seem to be shortsighted if cured patients are expected to remain in Medicaid for longer time periods.





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