

## HFS Report to Legislative Task Force Hepatitis C

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## Hepatitis C Virus (HCV)

- Slowly progressive disease
- 40 years- Median time from initial infection → cirrhosis
- Majority (76%) of Americans infected with HCV were born between 1945 and 1965
- Risk factors for progression to cirrhosis
  - Male
  - Alcohol intake
  - Higher fibrosis score
  - Elevated Bilirubin
  - Low albumin, platelets

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## Hepatitis C Risk Factors

Contact with blood of an infected person

- **At highest risk**
  - Intravenous Drug Use-60% of all new infections 
  - Blood transfusion/transplant prior to 1992
- **At risk**
  - Sex (Multiple sex partners, men who have sex w/men)
  - Baby boomers born between 1945-1965
  - Procedures (acupuncture, hemodialysis) 
  - Body Piercing and Tattoos, especially w unsterile tools 
  - Birth to an infected mother (Breastfeeding not a risk!)
  - Health care workers (accidental needle stick)

<http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section1>

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### HCV Incidence in HFS Covered Population

Diagnosis*	Beneficiaries
Hepatitis C	13,300
Chronic HCV (Some may be counted above)	7,200

\*Based on Diagnosis Information in FY13 Medical Claims Data

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### HFS Annual Non-Drug Costs to Treat HCV

\*Dollars in Thousands

Service type and site	Beneficiaries	Services	Payments*
Inpatient	226	1,858	\$4,000
Emergency Room	163	201	\$54
Hospital Outpatient	2,003	2,876	\$453
Other Medical Services	6,823	50,330	\$1,300

Based on FY13 Claims Data

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### HFS Historical HCV Drug Costs

FY	Beneficiaries	Scripts	Payments	Comments
2010	547	4,925	\$6.0M	
2011	454	4,438	\$5.7M	
2012	506	5,510	\$13.1M	First Generation of Direct Acting Antivirals (DAAs), Protease Inhibitors, introduced: Victrelis (boceprevir) and Incivek (telaprevir)
2013	357	3,093	\$6.7M	SMART Act Prior Approval (PA) Required (July 2012); PA ensures appropriate patient selection, patient compliance, and appropriate treatment duration
2014*	309	2,051	\$16.2M	Second generation of DAA, Nucleotide Analog, introduced: Sovaldi (Sofosbuvir); Additional Protease Inhibitor introduced: Olysio (Simeprevir)

\*Not a full FY. Based on Claims received through April 30, 2014.

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### Beneficiaries Utilizing Sovaldi

Indicator	Number/Percentage of Beneficiaries
Total Sovaldi Users (YTD)*	186
ACA Eligible	43 (23% of utilizing beneficiaries)
Total adult beneficiaries (19-65yrs)	1,130,000
Total ACA eligible adult beneficiaries	280,000 (25% of total)

\*Fee-for-service population only

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### Co-morbidities/Conditions in Sovaldi Users

Co-morbidity	Beneficiaries
Total Sovaldi Utilizing Beneficiaries today (YTD)*	186
Beneficiaries with Dx of Alcoholism or Substance Abuse in FY14	59
Add'l Beneficiaries with Dx of Alcoholism or Substance Abuse in FY13	17
Beneficiaries with a history of Dx of Serious Mental Illness	44
Beneficiaries with a dx of "lack of housing" on an FY14 Claim**	2

\*Fee-for-service population only

\*\*Likely under-reflects homelessness. Not all homeless beneficiaries will have a medical claim with a diagnosis of lack of housing.

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### Clinical Data Limitations of Sovaldi

- Only 1 trial with genotype 1, most common form of HCV
- Minority populations not well represented
- Did not include a large number of patients with cirrhosis
- Only treatment naïve patients were included
- No data for patients previously failed on protease inhibitors
- Did not compare to standard treatment

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### Illinois Medicaid Budget Impact

Coverage Scenarios	Budget Impact
If 50% of beneficiaries with chronic HCV treated with sofosbuvir	\$ 300 M

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### National Controversy Over High Price of Sovaldi

- AIDS Healthcare Foundation sent letter to State Medicaid Directors urging non-coverage of Sovaldi and other new Hepatitis C treatments until the drugs are made affordable
  - "The unjustifiably high price manufacturers are seeking to charge for these medications will unnecessarily drive up health care costs and limit access to potentially lifesaving care."
- Congressional Committee on Energy and Commerce sent strong letter to Gilead questioning pricing of Sovaldi and requesting Congressional Briefing
  - "Our concern is that a treatment will not cure patients if they can't afford it."
  - Requested information including methodology used to establish pricing and public health impact of insurers decisions not to cover the drug.
- Medicaid and Other Government and Non-Government Payers Carefully considering coverage criteria
- Sovaldi being offered to other countries at a small fraction of the cost of the drug in the United States
  - In Egypt, Sovaldi offered at a 99% discount

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### Treatment: Weighing Cost Vs Benefit

Payors Carefully Considering Appropriate Coverage Decisions

- Department of Veterans Affairs recommends: defer treatment for patients without advanced liver disease.
- California Technology Assessment Forum, which provides guidance to California Medicaid and other payors: Sovaldi could be deferred for patients without advanced liver disease
- Express Scripts recommends: defer treatment except for advanced liver disease until there is competition in the market

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### State Medicaid Agencies “Struggling” to define Appropriate Sovaldi Coverage

- State A: Deferring approval of Sovaldi
- State B: Allowing Sovaldi only for pts w Metavir Score of 4
- 3 States: Limit Sovaldi to pts w Metavir score  $\geq 3$  with cirrhosis/ bridging fibrosis with only 1 lifetime tt course
- 2 States: Limit Sovaldi to pts with Metavir score  $\geq 3$  x12 weeks; restricted to Rx by GI and Infectious Disease specialists
- 2 States: Require confirmed abstinence from alcohol and illicit drugs

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### Current HFS Sovaldi Coverage Policy

Sovaldi will be considered on case-by-case basis for:

- Pts with decompensated liver disease awaiting transplant
- Pts with cirrhosis rapidly progressing to decompensation
- Patients must be drug and alcohol free for minimum 6 months

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### Status of Newer Therapies

- Clinicians are waiting for
  - Interferon free regimens
  - Higher SVR rates ( 100%)
  - Shorter duration
- Newer agents are expected in late 2014 and early 2015
- Some pipeline products appear to be single pill regimen for 4 weeks with almost 100% cure rate.



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