Price and Affordability of Hepatitis C Drugs

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Disclosures

• Dr. Graham has joined Trek Therapeutics, a public benefits corporation
• Author, UpToDate
• Associate Editor, Clinical Infectious Disease
• Former member, P&T Committee, Tufts Health Plan
• Former member, Drug Utilization Review Board, MassHealth (MA Medicaid)
HCV Treatment: A Time for Celebration

- SVR rates >90% for nearly all patient groups
  - Gaps in cure rates for African Americans and HIV-coinfected patients finally closed
- Almost everyone can become a “treatment candidate” with appropriate support
- Potential to
  - Lower overall mortality
  - Improve quality of life
  - Reduce long-term costs of complications
  - Implement cure as prevention
Challenges Posed by High Price of HCV Drugs (and stigma)

- Media focus on $1,000 a pill gave cover to (and driven by) payers to impose rationing
- Payers disregard science/guidelines
- Loss of perspective by patients and providers about the value of HCV treatment and cure
- Difficulty advocating for treatment access due to lack of price transparency
- Hesitation to implement broader HCV screening and awareness programs
- Reinforcement that people with HCV infection are not “worth” expensive treatments
Why Focus on Price and Affordability?

Patients do not benefit from a drug they cannot afford.

John Ward, MD
New England Journal of Medicine Editorial
November 17, 2015
No Reimbursementment

No Treatment

No Elimination
Role of IOM in Defining a Vision for HCV

• Create reality: HCV can be eliminated in the US
  – Address population as well as individual needs
• The government has to be the key force behind this vision
  – Viral Hepatitis Action Plan plus legislation
• Detail barriers encountered by, and/or erected by, each key stakeholder
• Propose solutions, including for pharma and payers
  – Help align specific actions needed by all stakeholders
Cost is not Price

• Cost includes manufacturing and distribution costs, costs to meet regulatory requirements
  – Development costs are “sunk costs”
  – Marketing (?)

• Price is the $$ amount actually paid to acquire a drug/regimen
  – Complicated supply chain
  – Rebates/discounts
  – Confidential negotiations
Hepatitis C Drug Spend is High

<table>
<thead>
<tr>
<th>RANK</th>
<th>DRUG NAME</th>
<th>PMPY SPEND</th>
<th>% OF TOTAL SPECIALTY SPEND</th>
<th>UTILIZATION TREND</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sovaldi® (sofosbuvir)</td>
<td>$43.13</td>
<td>17.6%</td>
<td>32627.8%</td>
</tr>
<tr>
<td>2</td>
<td>Humira® (adalimumab)</td>
<td>$12.78</td>
<td>5.2%</td>
<td>31.3%</td>
</tr>
<tr>
<td>3</td>
<td>Enbrel® (etanercept)</td>
<td>$9.35</td>
<td>3.8%</td>
<td>29.2%</td>
</tr>
<tr>
<td>4</td>
<td>Atripla®</td>
<td>$8.82</td>
<td>3.6%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>5</td>
<td>Truvada®</td>
<td>$8.77</td>
<td>3.6%</td>
<td>3.8%</td>
</tr>
<tr>
<td>6</td>
<td>Copaxone® (glatiramer)</td>
<td>$6.51</td>
<td>2.7%</td>
<td>-2.7%</td>
</tr>
<tr>
<td>7</td>
<td>Viread® (tenofovir)</td>
<td>$5.58</td>
<td>2.3%</td>
<td>1.8%</td>
</tr>
<tr>
<td>8</td>
<td>Tecfidera®</td>
<td>$5.19</td>
<td>2.1%</td>
<td>247.7%</td>
</tr>
<tr>
<td>9</td>
<td>Avonex®</td>
<td>$4.61</td>
<td>1.9%</td>
<td>-20.1%</td>
</tr>
<tr>
<td>10</td>
<td>Enoxaparin</td>
<td>$4.32</td>
<td>1.8%</td>
<td>-11.7%</td>
</tr>
</tbody>
</table>

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Using Capitalism to Set Prices

What I want

What I have
Pricing of Drugs

• Patents promote innovation and can create monopolies
• Value-based pricing does not take budget impact into account
• Competition has resulted in lower drug prices in HCV

Can consumer preference drive resource allocation in medicine? Danzon, Health Affairs 2011
“Standard of Care” Regimens for Hepatitis C Have Been Expensive for Years: Examples for Treatment of Genotype 1, Naïve, Non-Cirrhotic Patients

<table>
<thead>
<tr>
<th>Regimen</th>
<th>SVR rates</th>
<th>WAC Price</th>
<th>Price per SVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegasys + Ribavirin x 48 weeks(^1)</td>
<td>41%</td>
<td>$41,758</td>
<td>$101,849</td>
</tr>
<tr>
<td>Telaprevir + PegIFN + Ribavirin x 24 weeks(^2)</td>
<td>75%</td>
<td>$86,843</td>
<td>$115,791</td>
</tr>
<tr>
<td>Sofosbuvir + PegIFN + Ribavirin x 12 weeks</td>
<td>90%</td>
<td>$94,421</td>
<td>$104,912</td>
</tr>
<tr>
<td>Sofosbuvir + Ledipasvir x 8 weeks</td>
<td>94%</td>
<td>$63,000</td>
<td>$67,021(^*)</td>
</tr>
<tr>
<td>Sofosbuvir + Ledipasvir x 12 weeks</td>
<td>99%</td>
<td>$94,500</td>
<td>$95,454(^*)</td>
</tr>
</tbody>
</table>

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

- Cost-effectiveness models
- Budget impact models
- Benchmarking against similar regimens
- Surveys and focus groups with payers (commercial and public insurance, PBMs) to understand what market will bear
- Expectations of shareholders
- Cost of investment in drug development
- Cost of manufacturing and marketing

Ultimately, price is what the market will bear
# Let’s Pretend We Are the Team Helping Set Harvoni Price

<table>
<thead>
<tr>
<th>Factor</th>
<th>Price Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifetime cost of not treating anyone(^1)</td>
<td>$100.3 billion</td>
</tr>
<tr>
<td>Cost-effectiveness vs no treatment at $50,000/QALY(^1)</td>
<td>$139,000</td>
</tr>
<tr>
<td>Benchmark (WAC 2013): Telaprevir+Peg-IFN+RBV x 24 weeks</td>
<td>$97,680</td>
</tr>
<tr>
<td>Real-world all cost-per-cure PI/P/R(^2)</td>
<td>$125,915 – $302,070</td>
</tr>
<tr>
<td>Benchmark (WAC 2014): Sofosbuvir+Peg-IFN+RBV</td>
<td>$94,421</td>
</tr>
<tr>
<td>Cost-per-cure of drugs: SOF/P/R (90% SVR)</td>
<td>$104,912</td>
</tr>
<tr>
<td>Maximum market will bear (WAC; 2014): Sofosbuvir+Simeprevir x 12 weeks</td>
<td>$150,000</td>
</tr>
<tr>
<td>Premium for all-oral regimen (difference in cost-per-cure for P/R versus SOF/R in genotype 2)</td>
<td>$42,000</td>
</tr>
<tr>
<td>Premium for one-pill-once-a-day</td>
<td>$1,000</td>
</tr>
<tr>
<td>Cost-per-cure XYZ x 12 weeks (if 95% SVR)</td>
<td>X + 5%</td>
</tr>
<tr>
<td>Price for XYZ for 12 weeks</td>
<td>???</td>
</tr>
</tbody>
</table>

\(^1\)Rein, CID 2015; \(^2\)Sethi, AASLD 2013; 1847; Washington Post, Dec 1, 2015 (Senate Finance Committee investigation)
Who Pays What Price?

Pharmaceutical company (sets Wholesale Acquisition Cost = WAC)

Average Manufacturer Price (AMP)

Wholesale distributors (e.g. AmerisourceBergen, McKesson, Cardinal Health) buy drugs

50 State Medicaid programs (Fee-for-Service and MCO)

23.1% discount off difference between AMP and "best price"

340B Programs (safety net providers)

Federal Supply Schedule participants (e.g. VA, DoD, IHS, Federal prisons)

Private insurers (>600)

State and local prisons and jails

Medicare (prohibited from negotiating prices)

Avalere.com/research/docs/Follow_the_pill.pdf; Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens. www.HCVguidelines.org

Relationships can represent negotiated payments, rebates or discounts, or drug distribution; lines are a fraction of the actual relationships.
Uncertainties in Estimating HCV Treatment Investment: What Payers Want to Know

• How many people will be treated?
• Over how many years will treatment be spread?
• What will happen to drug regimen costs over time?
Budget Impact Model

- **Current Environment**
  - Total Population
    - Sick Population
      - Target Population
        - Resource Utilization (Hospital, prescriptions)
          - Cost of Illness

- **Key Factor**
  - Incidence Prevalence
  - %Diagnosed %Treated
  - Current Treatment
  - Unit costs

- **Impact On**
  - Incidence
  - Diagnosis Treatment
  - Hospital and clinic visits, tests

- **New Environment**
  - New Total Population
    - New Sick Population
      - New Target Population
        - New Resource Utilization (Hospital, prescriptions)
          - New Cost of Illness

**Difference**

Institute for Clinical and Economic Review: “The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection” for the California Technology Assessment Forum

<table>
<thead>
<tr>
<th>Factor</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollee plan</td>
<td>1 million enrollees</td>
</tr>
<tr>
<td>1.7% prevalence HCV infection</td>
<td>17,000 enrollees</td>
</tr>
<tr>
<td>50% undergo treatment in one year</td>
<td>8,500 enrollees</td>
</tr>
<tr>
<td>Estimated HCV treatment cost (per 1 enrollee)</td>
<td>$70,588</td>
</tr>
<tr>
<td>Total treatment (8,500 x $70,588)</td>
<td>$600 million</td>
</tr>
<tr>
<td>Cost of HCV treatment per enrollee ($600 million/1 million enrollees)</td>
<td>$600/year</td>
</tr>
<tr>
<td>Cost per member per month</td>
<td>$50</td>
</tr>
</tbody>
</table>

Conclusion: Simeprevir and sofosbuvir are superior in terms of clinical effectiveness compared to 1st generation PIs and Peg-IFN/RBV, but of “low value” due to high cost (as prices of DAAs have decreased, this value is now “high”)
Payer Dilemmas

• Most payers had no idea how much they were actually spending 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 don’t account for long term benefits
• Competition fears led to avoidance of premium increases to address future increased volume of HCV treatment
• Desire to avoid being the only “favorable” payer choice
• Anti-trust laws prevent payers from fully understanding community needs
• Stigma fuels justification of rationing treatment
Payer Actions

• May create own cost-effectiveness and budget impact models
• Treatment guidelines
  – Usually derived from existing guidelines
• Formulary placement
• Reimbursement/contracting
• Prior authorization criteria
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

# MassHealth MCOs Sovaldi Prior Authorization Criteria

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fibrosis</strong></td>
<td>F3-4</td>
<td>F3-4</td>
<td>F3-4</td>
<td>F4</td>
</tr>
<tr>
<td><strong>Requirements Related to Substance Use</strong></td>
<td>Not abused substances for 6 months</td>
<td>(For members with past/current issues) abstain from use for 6 months and participation in supportive care</td>
<td>No substance abuse within past 6 months OR receiving counseling services</td>
<td>(Known substance abusers) must have been referred to specialist; abstinence from substance abuse for 6 months; ongoing participation in treatment program; adequate psychosocial supports</td>
</tr>
<tr>
<td><strong>Prescriber Limitations</strong></td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
</tr>
<tr>
<td><strong>HIV Co-Infection</strong></td>
<td>Yes, with non-suppressable viral load or elevated MELD scores</td>
<td>Not without meeting additional requirements above</td>
<td>Not without meeting additional requirements above</td>
<td>Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load</td>
</tr>
<tr>
<td><strong>Additional Adherence Requirements</strong></td>
<td>No history of nonadherence; enrollment in compliance monitoring program</td>
<td>Individual must demonstrate understanding of the proposed treatment, and display the ability to adhere to clinical appointments</td>
<td>“[M]ember has been assessed for potential nonadherence.”</td>
<td>No ongoing non-adherence to previously scheduled appointments, meds or treatment; adherence counseling; willing to commit to monitoring</td>
</tr>
</tbody>
</table>
MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive Than 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
Recommended regimens for patients with HCV genotype 1a or 1b infection who have compensated cirrhosis, in whom prior PEG-IFN and RBV treatment has failed

- Daily fixed-dose combination of ledipasvir/sofosbuvir for 24 weeks
  
  **Rating:** Class I, Level A

- Daily fixed-dose combination of ledipasvir/sofosbuvir plus weight-based RBV for 12 weeks...
  
  **Rating:** Class I, Level B

- Daily fixed-dose combination of paritaprevir/ritonavir/ombitasvir plus twice-daily dosed dasabuvir and weight-based RBV for 24 weeks is recommended for patients with HCV genotype 1a...
  
  **Rating:** Class I, Level A

- Daily sofosbuvir plus simeprevir with or without weight-based RBV for 24 weeks...
  
  **Rating:** Class IIa, Level B

Adapted from www.hcvguidelines.org
MassHealth: 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
  • Over 90% of PAs approved
  • ~14% of diagnosed patients engaged in treatment
Examples of Approaches to Improve Access to HCV Treatment (for Providers)

• Share successful appeal letters
  – National Viral Hepatitis Roundtable is collecting examples to share (NVHR.org)

• Share stories with media (obtain institutional and patient permission)

• Join local P&T committees

• Educate local payers (public and private) about hepatitis C and the value of treatment on a state level
  – Presume that ultimate goal is elimination of HCV
  – Describe care models and patient support
  – Individual or small group with one payer
  – State DPH, local advocates, coalition of HCV treaters and ALL payers

• Consider joining in lawsuits to force access
  – Harvard Law School is developing model suits
Bottom Line

• HCV cannot be used as a “test case” for payers attempting to limit high prices of future specialty drugs

• Pharmaceutical companies have to be encouraged to engage in volume pricing
  – Working within current capitalist system

• Innovative payment strategies for FFS and MCO Medicaid, state prisons, and persons dependent on public health care

• Government needs to invest more in HCV
  – New laws for financing treatment of communicable diseases that require a public health approach