Price and Affordability of Hepatitis C Drugs: How Did We Get Into This Mess?

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Disclosures

• Dr. Graham has joined Trek Therapeutics, a public benefits corporation
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”
• 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

• 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
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
Drug Pricing: What Physicians Want to Know

• Actual price paid (?)
  – Paid by whom?
  – How will this information be used?

• At what price point will everyone be allowed to be treated?
  – At what point would onerous prior authorization requirements be relaxed?
### "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>Cost per SVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegasys + Ribavirin x 48 weeks¹</td>
<td>41%</td>
<td>$41,758</td>
<td>$101,849</td>
</tr>
<tr>
<td>Telaprevir + PegIFN + Ribavirin x 24 weeks²</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>

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 New Hepatitis C Regimen XYZ 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

Retail, Mail and Specialty Pharmacies

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

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

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

340B Programs (safety net providers)

Medicare (prohibited from negotiating prices)

Private insurers (>600)

State and local prisons and jails

Relationships can represent negotiated payments, rebates or discounts, or drug distribution; lines are a fraction of the actual relationships.

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

• 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
  – Presume that ultimate goal is elimination of HCV
  – 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