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Data presented are for illustration purposes only
How to Assess Values in Drug Development?

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Value of Innovation

- Unmet Need
- Burden of Disease
- Comparative Effectiveness

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Burden of Disease

Payor Burden
• Resource Use
• Cost of care

Patient Burden
• Impact on work life
• Impact on Quality of Life
• Economic burden (Co-pay etc)
• Caregiver burden

System Burden
• Public health implications
• Lost productivity

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<table>
<thead>
<tr>
<th><strong>Direct and Indirect Cost Burden of Chronic Hepatitis C</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Objective</strong></td>
</tr>
<tr>
<td>• To estimate the direct healthcare and indirect work-loss cost burden of chronic HCV</td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td>• Data Source: Health insurance claims from 60 self-insured Fortune 500 US companies covering 13 million individuals</td>
</tr>
<tr>
<td>• Cohorts were matched and were compared for direct (pharmacy and medical services) and indirect (disability and medically related absenteeism) costs using per patient per year (PPPY) incremental costs (IC).</td>
</tr>
<tr>
<td><strong>Key Findings</strong></td>
</tr>
<tr>
<td>• Overall, HCV patients incurred significantly greater direct and indirect costs versus non-HCV patients (PPPY direct costs: $16,721 vs $6063; IC, $10,503 [95% CI, $9683-$11,361]. PPPY indirect costs: $3310 vs $1723; IC, $1523 [95% CI, $1248-$1794]).</td>
</tr>
<tr>
<td>• The direct IC associated with HCV increased with disease</td>
</tr>
<tr>
<td>• The indirect IC associated with HCV also increased with disease severity (non-cirrhosis</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
</tr>
</tbody>
</table>

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HCV Direct/Indirect Cost Burden: Incremental PPPY Costs Associated with HCV Stratified by Liver Disease Severity

- Annual all-cause direct healthcare costs were $10,503 higher (95% CI: 9,683-11,361, $P<0.001) in HCV vs. non-HCV cohort (PPPY direct costs: $16,721 vs. $6,063).
- Incremental costs increased with disease severity (cost difference [95% CI]: non-cirrhosis=$5,536 [4,844-6,333]; compensated cirrhosis=$6,833 [5,326-8,474]; ESLD=$22,466 [20,182-24,729]).

*Denotes statistically significant comparison ($P<0.001) of HCV vs. non-HCV patients; PPPY: per person per year; ESLD: end stage liver disease.

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Unmet Need

- Current treatment patterns
- Effectiveness of current treatments
- Drivers of cost
- Impact on co-morbidities

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<table>
<thead>
<tr>
<th>Impact of Chronic Hepatitis C (CHC) Treatment on Post-Therapy Healthcare Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Objective</strong></td>
</tr>
</tbody>
</table>
| **Methodology** | • Data Source: Health insurance claims from 60 self-insured US companies were analyzed (01/2001–03/2012).  
• During the post–48-week treatment period, cohorts were compared for healthcare resource utilization using rate ratios (RRs), as well as healthcare costs using per-patient per-year (PPPY) cost differences. |
| **Key Findings** | • A total of 1017 patients who completed and 953 patients who discontinued interferon therapy were identified.  
• Relative to the discontinued therapy cohort, the completed therapy cohort had significantly fewer hospitalizations, outpatient visits and ER which translated into significantly lower total healthcare costs PPPY and hospitalization  
• Non–CHC-related costs accounted for 55% and CHC-related costs accounted for 45% of the all-cause cost difference between cohorts. |

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Impact of Chronic Hepatitis C (CHC) Treatment on Post-Therapy Healthcare Costs

Table 4. Comparison of PPPY healthcare cost between all beneficiaries in the complete vs discontinued HCV therapy cohorts.

<table>
<thead>
<tr>
<th>PPPY healthcare costs (US $2012)</th>
<th>Complete therapy cohort</th>
<th>Discontinued therapy cohort</th>
<th>Complete vs discontinued therapy cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of patients, n</td>
<td>1017</td>
<td>953</td>
</tr>
<tr>
<td></td>
<td>Observation periodb, days, mean (SD)</td>
<td>1395 (999)</td>
<td>1257 (962)</td>
</tr>
<tr>
<td>All-cause healthcare costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>$13,294 (28,106)</td>
<td>$17,834 (38,328)</td>
<td>$-4540</td>
</tr>
<tr>
<td>ER visits</td>
<td>$3,347 (14,965)</td>
<td>$6,386 (28,754)</td>
<td>$-3039</td>
</tr>
<tr>
<td>Outpatient visits</td>
<td>$223 (607)</td>
<td>$286 (913)</td>
<td>$-63</td>
</tr>
<tr>
<td>Pharmacy dispensing</td>
<td>$5,062 (14,602)</td>
<td>$5,847 (10,477)</td>
<td>$-785</td>
</tr>
<tr>
<td>CHC-related healthcare costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>$3535 (10,285)</td>
<td>$5,286 (21,240)</td>
<td>$-1,750</td>
</tr>
<tr>
<td>ER visits</td>
<td>$953 (7852)</td>
<td>$2,661 (19,825)</td>
<td>$-1,708</td>
</tr>
<tr>
<td>Outpatient visits</td>
<td>$1 (15)</td>
<td>$3 (35)</td>
<td>$-1</td>
</tr>
<tr>
<td>Pharmacy dispensing</td>
<td>$450 (868)</td>
<td>$544 (1039)</td>
<td>$-94</td>
</tr>
<tr>
<td></td>
<td>$2,131 (5782)</td>
<td>$2,077 (6341)</td>
<td>$54</td>
</tr>
</tbody>
</table>

PPPY, per-patient per-year; HCV, hepatitis C virus; SD, standard deviation; CHC, chronic hepatitis C; CI, confidence interval; ER, emergency room; RBV, ribavirin.

*Adjusted cost differences are obtained using ordinary least-squares regressions, adjusting for baseline characteristics including age, gender, type of beneficiary, geographic region, payer type, year of index date, Quan-Charlson comorbidity index, and healthcare costs. Confidence intervals (95% CI) and p-values were calculated using a non-parametric bootstrap with 999 replications.

*bThe observation period spanned from 48 weeks past the index date until the earliest date between the end of insurance coverage or the end of data availability.

*cCHC-related pharmacy dispensing costs were identified with NDC codes for any of these medicated treatments: peginterferon alfa-2a or alfa-2b, interferon alfa-2a or alfa-2b, or interferon alfacon-1, RBV, telaprevir, and boceprevir.

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# Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C

## Key Objective
- To identify demographics and clinical characteristics associated with high healthcare resource utilization (HRU) and liver disease progression among CHC patients.

## Methodology
- **Data Source:** Health insurance claims from January 2001-March 2013.
- **Generalized estimating equations** were used to identify the demographic and clinical characteristics of being in the 20% of patients with the highest HRU. Factors predicting liver disease progression were also identified.

## Key Findings
- In the study population (n = 4898), liver disease severity and both CHC- and non-CHC-related comorbidities and conditions were strong predictors of high healthcare costs.
- CHC- and non-CHC-related comorbidities and conditions were also strong predictors of liver disease progression.

## Reference
J. LaMori et al, Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C. *Journal of Medical Economics*. Vol. 19, No. 4, 2016, 364–373.

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Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C

Predictorsa (Ref=Non-Cirrhotic)

- Rheumatologist visit: 0.92 (0.64-1.32)
- Gastroenterologist visit: 2.01 (1.80-2.25)\textsuperscript{T}
- 1 CHC comorbidity: 1.53 (1.34-1.74)\textsuperscript{T}
- ≥2 CHC comorbidities: 2.18 (1.83-2.60)\textsuperscript{T}
- 1 non-CHC comorbidity or condition: 1.46 (1.25-1.70)\textsuperscript{T}
- ≥2 non-CHC comorbidities or conditions: 1.50 (1.14-1.97)\textsuperscript{T}
- Interferon therapy: 0.73 (0.60-0.88)\textsuperscript{T}

Figure 3. Predictors of patients with CHC being diagnosed with compensated cirrhosis or ESLD (n = 4676). CHC, chronic hepatitis C; ESLD, end-stage liver disease; CI, confidence interval. \textsuperscript{T}Denotes statistical significance. Additional predictors not reported include the following: age group (i.e., <45, 45-65, >65 years), female, type of beneficiary, type of insurance (i.e., health maintenance organization, point of service, preferred provider organization, indemnity), region (i.e., Northeast, Midwest, South, and West), and the index year (i.e., 2001–2013).

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Comparative Effectiveness & Budget Impact Models

- Cost per response
- Cost per QALY
- Budget Impact

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Models for Health Technology Assessments

Cost per Response
- Ratio of incremental cost of treatment and incremental primary efficacy or effectiveness rates (ex: PASI in Psoriasis, SVR in HCV, CDAI in Crohn’s)

Cost per QALY
- The incremental cost of new treatment is divided by the QALY (Quality Adjusted Life Years: Quantity and Quality of Life) gained by the new treatment to give the cost per QALY ($ per QALY).

Budget Impact Models
- Estimates the expected change in the expenditure of a health plan or a system as a result of a new intervention.

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