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Background
- Prior to 2014, Hepatitis C Virus (HCV) treatment required injected interferon, with low efficacy and high side effects
- Direct acting antiviral (DAA) sofosbuvir (SOF) was introduced in December, 2013
- Shorter treatment duration, all-oral regimen for some
- Higher efficacy, fewer side effects, initially expensive
- All-oral regimen ledipasvir/sofosbuvir (LDV/SOF) was approved in October 2014; others followed
- Medicaid prior authorization (PA) requirements were initially common
- Prescribing provider specialist
- Abstinence or substance use disorder (SUD) treatment
- Advanced HCV
- Medicaid plans lifted restrictions over time, following Nov, 2015 CMS guidance
- Analysis of early uptake of DAA demonstrated that low numbers of individuals were treated

Study Objectives
- Examine the uptake of DAAs in Medicaid population of three New England states from Dec, 2013 – Dec, 2017
- Examine effect of introduction of LDV/SOF and lifting HCV PA restrictions on uptake
- Examine uptake by age and gender

Study Population
- Data Source: Enrollment, medical, and pharmacy claims from 13 Medicaid plans in three New England states, Dec, 2012 – Dec, 2017
- Study Population: Medicaid members ages 18-64 with a diagnosis of HCV between Dec, 2012 and Dec, 2017 and no evidence of previous HCV treatment

Measures
Table 1. Study measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV</td>
<td>2+ claims with ICD code for HCV diagnosis in one year or 1+ claim</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>for chronic HCV</td>
<td></td>
</tr>
<tr>
<td>DAA Uptake</td>
<td>1+ pharmacy claim for a DAA</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Age</td>
<td>Age as of Dec, 2012</td>
<td>18-34; 35-49; 50-64 years</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td>Male/Female</td>
</tr>
<tr>
<td>PA Restrictions</td>
<td>Restriction in place in plan, by type:</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>- Prescribing provider specialist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SUD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Advanced HCV</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Number of Medicaid plans and percentage of study population across states, 2014 and 2017

<table>
<thead>
<tr>
<th>Plans 2014</th>
<th>2014</th>
<th>Total N</th>
<th>32,302</th>
<th>45,909</th>
</tr>
</thead>
<tbody>
<tr>
<td>State A</td>
<td>7</td>
<td>2%</td>
<td>92%</td>
<td>90%</td>
</tr>
<tr>
<td>State B</td>
<td>4</td>
<td>3%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>State C</td>
<td>2</td>
<td>5%</td>
<td>6%</td>
<td></td>
</tr>
</tbody>
</table>

Results

Table 3. Demographic characteristics of Medicaid members with HCV, 2014 and 2017

<table>
<thead>
<tr>
<th>Measure</th>
<th>2014</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 18-34</td>
<td>9,562 (30%)</td>
<td>13,856 (30%)</td>
</tr>
<tr>
<td>Age 35-49</td>
<td>10,637 (33%)</td>
<td>14,907 (32%)</td>
</tr>
<tr>
<td>Age 50-64</td>
<td>12,103 (37%)</td>
<td>17,146 (37%)</td>
</tr>
<tr>
<td>Gender Male</td>
<td>19,163 (59%)</td>
<td>27,063 (59%)</td>
</tr>
<tr>
<td>Gender Female</td>
<td>13,139 (41%)</td>
<td>18,846 (41%)</td>
</tr>
</tbody>
</table>

Methods
- Members were included in the study population in each month from first HCV diagnosis until treated or left Medicaid
- Interrupted time series (ITS) with segmented autocorrelation-adjusted regression modeled trends in treatment uptake prior to and after two time points:
  - Oct, 2014 (LDV/SOF approval date)
  - July, 2016 (date PA restrictions in 10 plans were lifted)
- Chi-square testing evaluated demographic differences in DAA uptake in 2014 and 2017

Principal Findings
- DAA uptake rose from 3.3% in 2014 to 7.7% in 2017 (p = <0.01 for trend). Cumulatively, 18% were treated by 2017
- While uptake increased in the month following SOF introduction, uptake overall was flat until LDV/SOF was introduced, doubled in the month after approval and remained flat during the subsequent 20 months
- Uptake doubled again in the month following the lifting of PA restrictions then remained steady through 2017
- Uptake rose earliest among those ages 50-64 years; by 2017 uptake was slightly higher in younger adults
- Throughout the period the percentage of men treated was higher than females

Conclusion/Implications
- While initial uptake of DAAs was low in this multi-state Medicaid population, treatment increased through 2017
- Introduction of new medications and lifting of PA restrictions was followed by an immediate increase in uptake followed by relatively flat monthly utilization

Policy Implications
- Sharp increase in uptake after LDV/SOF introduction may indicate warehousing of members in anticipation of LDV/SOF approval
- Treatment rate increase after PA restrictions were lifted indicates demand among those affected by restrictions
- A large percentage of the Medicaid population with HCV remains untreated; planned provider interviews will identify barriers and facilitators to treatment for HCV
- Multi-state population provides wider range of member and plan characteristics than a single state analysis

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