
Karen M. Clements, ScD1 Parag Kunte, MPH2, Bonnie Greenwood, PharmD BCPS3, Carter Pratt, MPH2, Laura Sefton, MPP1, Melissa Clark, PhD2, Sharina Person, PhD3 and Deborah Gurewich, PhD1, 1University of Massachusetts Medical School/Commonwealth Medicine, Shrewsbury, MA, 2University of Massachusetts Medical School, Worcester, MA, 3VA Boston Healthcare System, Boston, MA

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 DAAAs demonstrated that low numbers of individuals were treated

Study Objectives

- Examine the uptake of DAAAs 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>
<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 for chronic HCV</td>
<td>Yes/No</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>Male/Female</td>
<td></td>
</tr>
<tr>
<td>PA Restrictions</td>
<td>Restriction in place in plan, by type:  - Prescribing provider specialist  - SUD  - Advanced HCV</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

Results

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

<table>
<thead>
<tr>
<th>Plans</th>
<th>2014</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Percentage of sample from each state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State A</td>
<td>7</td>
<td>92%</td>
</tr>
<tr>
<td>State B</td>
<td>4</td>
<td>3%</td>
</tr>
<tr>
<td>State C</td>
<td>2</td>
<td>5%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Age</th>
<th>2014 (%)</th>
<th>2017 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-34</td>
<td>11,163 (33%)</td>
<td>17,476 (33%)</td>
</tr>
<tr>
<td>35-49</td>
<td>9,637 (33%)</td>
<td>14,907 (33%)</td>
</tr>
<tr>
<td>50-64</td>
<td>12,103 (37%)</td>
<td>17,146 (37%)</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 DAAAs 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

Acknowledgements: Elena Nicolella, New England States Consortium Systems Organization; Lise Farrand, RPh, Jonathan Ballard, MD, Andrew Chalsma, Margaret Clifford, RPh, Jerry Fingerut, MD, Karen Mariano, RPh, Kim Lenz, PharmD, Paul Jeffrey, PharmD, from New England Medicaid Agencies. Supported by AHRQ grant S01HS025717-02

Discussion

- Uptake of DAAAs among Medicaid members with HCV, three New England states, by month, Dec, 2013 – June, 2018

Figure 1. Number of plans with PA restrictions on DAA, by type of restriction, by month, Dec, 2013 – Dec, 2017

Figure 2. Uptake of DAAAs among Medicaid members with HCV, three New England states, by month, Dec, 2013 – June, 2018

Figure 3. Uptake of DAAAs among Medicaid members with HCV, three New England States, by gender and year, 2014-2017

Figure 4. Uptake of DAAAs among Medicaid members with HCV, three New England States, by age and year, 2014-2017

References

- Fingerut, MD, Karen Mariano, RPh, Kim Lenz, PharmD, Paul Jeffrey, PharmD, from New England Medicaid Agencies. Supported by AHRQ grant S01HS025717-02