ADAP Coverage of HCV Treatment Medications

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AGENDA

- Background
- National ADAP Formulary Database: HCV Coverage
- NASTAD Consultation: Strategies to Increase Hepatitis C Treatment Within ADAPs
- Key Considerations for ADAPs
- Related NASTAD Technical Assistance
- Questions & Answers
Background
The Ryan White HIV/AIDS Program Section 2616(c)(6) of the Public Health Service Act and HRSA policy places the following requirements on ADAP formularies:

- Must include at least one drug from each class of HIV antiretroviral medications.
- ADAP funds may only be used to purchase medications approved by the Food and Drug Administration (FDA) or devices needed to administer them.
- They must be consistent with the HHS Adolescent and Adult HIV/AIDS Treatment Guidelines.
- All treatments and ancillary devices covered by the ADAP formulary, as well as all ADAP-funded services must be equitably available to all eligible/enrolled individuals within a given jurisdiction.

In a letter sent to ADAPs in February 2015, the HRSA HIV/AIDS Bureau (HAB) encouraged ADAPs to add HCV treatment to their formularies.
BACKGROUND: ADAPs

- In providing access to life-saving treatments, ADAPs operate via two prongs:
  - Full-pay prescription program
  - ADAP-funded insurance program (i.e., program in which individuals who had an insurance (i.e., Medicare Part D, Medicaid, private insurance) payment (premium, co-payment/co-insurance and/or deductible) paid on their behalf using ADAP funds, either fully or in part)
National ADAP Formulary Database: HCV Coverage
The National Ryan White HIV/AIDS Program Part B and ADAP Monitoring Project is a long-standing effort of NASTAD to document new developments and challenges facing RWHAP Part B and AIDS Drug Assistance Programs (ADAPs), assess key trends over time, and provide the latest available data on the status of RWHAP Part B programs and ADAPs. It is comprised of:

- National ADAP Formulary Database
Among 15 ADAPs able to report HCV co-infection among their clients, 2% of clients served in calendar year 2016 were reported as HCV co-infected at some point during the reporting period.
The online AIDS Drug Assistance Program (ADAP) Formulary Database (the Database) provides an online, searchable, publicly available resource detailing state-by-state ADAP coverage of medications both individually and by drug class including HIV antiretroviral (ARV) treatments, “A1” Opportunistic Infections (A1 OI) medications, treatments for hepatitis B and C, mental health and substance use treatment medications, and various vaccines and laboratory tests and includes ADAP formulary coverage for all 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands as of August 31, 2017.

- Twice-annual comprehensive National ADAP Formulary Survey
- Monthly update surveys
As of August 31, 2017:

- 40 ADAPs cover one or more HCV treatment medication.
- 34 cover one or more directly-acting antiviral (DAA) HCV treatment medications:
  - 25 ADAPs cover daclatasvir (Daklinza)
  - 30 ADAPs cover dasabuvir, ombitasvir, paritaprevir, ritonavir (Viekira Pak XR)
  - 28 ADAPs cover elbasvir and grazoprevir (Zepatier)
  - 11 ADAPs cover glecaprevir and pibrentasvir (Mavyret)
  - 30 ADAPs cover ledipasvir and sofosbuvir (Harvoni)
  - 25 ADAPs cover ombitasvir, paritaprevir and ritonavir (Technivie)
  - 22 ADAPs cover simeprevir (Olysio)
  - 28 ADAPs cover sofosbuvir (Sovaldi)
  - 26 ADAPs cover sofosbuvir, velpatasvir (Epclusa)
  - 11 ADAPs cover sofosbuvir, velpatasvir, and voxilaprevir (Vosevi)
NASTAD Consultation: Strategies to Increase Hepatitis C Treatment Within ADAPs
On June 9, 2016, NASTAD led a consultation regarding strategies to increase hepatitis C (HCV) treatment within ADAPs. This consultation was funded under NASTAD’s cooperative agreement, U69HA26846, with the Health Resources and Services Administration (HRSA). Topics covered as part of the consultation included:

- Reasons ADAPs are seeing low utilization among their co-infected clients
- Methods to encourage other ADAPs to add these medications to their formularies, while still maintaining fiscal solvency
PARTICIPATION

- ADAP and viral hepatitis program staff from jurisdictions in which one or more curative directly-acting antiviral (DAA) HCV medication had been added to the ADAP formulary
- Federal partners (Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services (HHS), HRSA, and the U.S. Department of Veterans Affairs (VA))
- Providers specializing in treatment for HIV/HCV co-infection
- Community partners
- NASTAD staff
MEETING HIGHLIGHTS

- Federal Panel (CMS, HHS, HRSA, VA)
- Best Practice in ADAP HCV Treatment Utilization
- Participant discussion of:
  - Impediments and Opportunities within the Broader Health System
  - Clinical Management of HIV/HCV Co-Infection
  - Policies and Procedures for HCV Treatment Among PLWH
Respondents included 17 of the 20 eligible ADAPs

As of May 1, 2016:

- 324 ADAP clients received a DAA HCV prescription via the full-pay prescription program
  - Among the six ADAPs able to report clients’ cure rate, 105 clients had been reported as cured.

- 283 ADAP clients received a DAA HCV prescription via the ADAP-funded insurance program
  - Among the four ADAPs able to report clients’ cure rate, 40 clients had been reported as cured.
## ADAP FORMULARY COVERAGE

<table>
<thead>
<tr>
<th>DAA HCV Medication</th>
<th>Full-Pay Prescription</th>
<th>ADAP-Funded Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>daclatasvir (Daklinza)</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>dasabuvir, ombitasvir / paritaprevir / ritonavir (Viekira Pak)</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>elbasvir and grazoprevir (Zepatier)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>ledipasvir and sofosbuvir (Harvoni)</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>ombitasvir, paritaprevir and ritonavir (Technivie)</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>simeprevir (Olysio)</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>sofosbuvir (Sovaldi)</td>
<td>15</td>
<td>13</td>
</tr>
</tbody>
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## ADAP Formulary Coverage Policies

<table>
<thead>
<tr>
<th>Policy</th>
<th>Full-Pay RX</th>
<th>Adap-Funded Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cap or maximum number of prescriptions/expenditures per client</td>
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<td>0</td>
</tr>
<tr>
<td>Cap or maximum number of clients to receive prescriptions or total expenditures</td>
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<td>0</td>
</tr>
<tr>
<td>Cap or maximum number of clients</td>
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</tr>
<tr>
<td>Fibrosis score restriction or prioritization (e.g., F3 or F4)</td>
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<td>1</td>
</tr>
<tr>
<td>Prior authorization</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Proof of denial by other payer (e.g., Medicaid)</td>
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<td>0</td>
</tr>
<tr>
<td>Sobriety requirement</td>
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<td>1</td>
</tr>
<tr>
<td>Specialist provider supervision requirement (e.g., hepatologist)</td>
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<td>1</td>
</tr>
<tr>
<td>No restrictions, open access</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>
Key Considerations for ADAPs
KEY CONSIDERATIONS FOR ADAPS

- HCV co-infection significantly impacts PLWH
- HRSA policy encourages ADAPs to include HCV DAA treatment on formularies
- ADAP clients’ uptake of HCV treatment, including DAAs, remains modest
  - Testing & surveillance
  - Navigating a challenging health care landscape
  - Provider capacity and attitudes regarding treatment
- ADAPs may use strategies to manage HCV DAA treatment utilization and expenditures
Related NASTAD Technical Assistance
RELATED NASTAD TECHNICAL ASSISTANCE

- National RWHAP Part B and ADAP Monitoring Project
  - RWHAP Part B and ADAP Monitoring Project *Annual Report*
  - National ADAP Formulary Database
- HRSA Cooperative Agreement for TA to ADAPs and RWHAP Part B programs
  - Peer exchange
  - Resources
Questions & Answers