Consultation Summary: Strategies to Increase Hepatitis C Treatment Within ADAPs

November 2016

Background & Purpose

NASTAD (the National Alliance of State & Territorial AIDS Directors) continues work to ensure that individuals co-infected with HIV and hepatitis C (HCV) can gain access to curative treatments for HCV via AIDS Drug Assistance Programs (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

Methods and Participation

Consultation participants included: ADAP and viral hepatitis program staff from jurisdictions in which one or more curative directly-acting antiviral (DAA) HCV medication has 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; and NASTAD staff. To maximize input across geographic regions, the consultation included both in-person and virtual participation. Twenty-six (26) and fourteen (14) participants joined the consultation in-person and virtually, respectively. A complete list of participants is attached to this summary.

Meeting Highlights

Federal Panel (CMS, HHS, HRSA, VA)

HHS: HHS staff provided a brief overview of the National Viral Hepatitis Action Plan, including activities related to HIV and HCV co-infection. Discussion ensued of current and future HHS initiatives that address access to testing, care, and treatment for HCV among people living with HIV (PLWH).

CMS: A CMS representative gave a brief overview of the CMS letter to state Medicaid programs on coverage restrictions for HCV medications, including responses received from states. This presentation also included current and future CMS efforts to increase access to testing, care, and treatment for HCV among PLWH.

HRSA/HAB: HRSA/HAB staff identified agency priorities related to HIV and HCV co-infection as well as current and future HRSA/HAB initiatives that address access to testing, care, and treatment for HCV among PLWH (e.g., AIDS Education and Training Center (AETC) Program). Of note, there is a need for improved data quality in tracking HIV/HCV co-infection rates among Ryan White HIV/AIDS Program (RWHAP) clients as well as updated guidance for HCV treatment in RWHAP clinics.

VA: A VA representative shared successes, lessons learned, and challenges faced by their National Viral Hepatitis Program in increasing access to testing, care, and treatment for HCV among all veterans as well as among veterans living with HIV. The VA identified evaluation, outmoded provider treatment requirements regarding alcohol and substance use, and medical transportation as key barriers. The representative also asserted the importance of integrated and multi-disciplinary treatment teams, incorporating substance use/mental health providers as well as support services staff (e.g., case managers) to ensure treatment adherence and completion.

Best Practice in ADAP HCV Treatment Utilization

ADAP Coverage of HCV Treatment as of May 2016

NASTAD asked states that have added one or more of the curative directly-acting antiviral (DAA) HCV treatment medications to complete an online request for information (RFI). The ADAP Hepatitis C Treatment Coverage RFI was produced as part of NASTAD's cooperative agreement with HRSA. NASTAD presented the key findings from the RFI and responded to related questions (see one pager attached).

State Examples: Arizona, Colorado, and Oklahoma

The following are examples from Arizona, Colorado, and Oklahoma ADAPs' approaches to adding one or more DAA HCV medication to their formulary, including relevant policies and utilization rates to-date.

- **Arizona:** Added the HCV drugs to the ADAP formulary as a result of last year's NASTAD Prevention and Care Technical Assistance (TA) meeting. With the support of the state's viral hepatitis prevention coordinator (VHPC), Arizona's ADAP has estimated that twelve (12) percent of RWHAP clients are co-infected with HIV and HCV. While some within the health department and community have expressed fears regarding the sustainability of the DAA inclusion, their concerns have been assuaged with low uptake and utilization. To date, Arizona's ADAP has treated twelve (12) clients, three (3) of whom have been cured. ADAP requires proof of a denial from Medicaid or private insurance before covering the full-cost of the medication. The reason for denial varies by insurer.

- **Colorado**: ADAP seen a cost saving following the implementation of the Affordable Care Act (ACA) and the availability of carryforward, rebate, and state dollars. ADAPs must quickly spend funds generated from rebates in order to avert losing some or all of the federal award, which is spent only after rebate funds are exhausted. State funds allow Colorado's ADAP to treat patients, including those that are mono-infected with HCV. ADAP maintains a formulary with the full breadth of HCV medications with no fibrosis requirements. To date ADAP has treated 132 individuals, only three (3) of whom did not have insurance (almost exclusively categorically ineligible for federal programs). The champions at the Denver Health hospital and telehealth have allowed for this success. ADAP has treated an estimated twenty (20) percent of the co-infected clients. The use of a prior authorization process enabled ADAP to quickly develop buy-in in the broader health department.
- **Oklahoma**: Is a low/moderate-incidence state with the majority of ADAP clients being served by the ADAP-funded insurance program. Thirty-one (31) co-infected ADAP clients have received a prescription for a DAA HCV medication, all through the ADAP-funded insurance program. Most of these individuals had already reached $0 co-payments, which resulted in low overall costs to the ADAP for covering the HCV treatment. Should co-payment or cost-sharing amounts increase, ADAP may face concerns regarding the inclusion of DAA HCV medications.

Round-Robin Discussion Among All Participants

Impediments and Opportunities within the Broader Health System

Participants discussed health system-level barriers to optimal HCV treatment uptake among ADAP clients including: how ADAPs assess and track the HCV care and treatment needs of their clients; ADAPs' ability to produce a continuum of care for HCV treatment among the clients they serve that are co-infected; and how ADAPs partner with other public health programs (e.g., Surveillance) and providers to bolster ADAP data specific to HCV (e.g., number of clients who are co-infected, number of clients who are cured).

- **Data on HIV/HCV Coinfection Among ADAP Clients:**
    - In Massachusetts, the health department completes an annual medical chart review for all clients treated for HCV. Many ADAP clients were treated to cure, yet were not captured in ADAP data. This may be due to clients' use of patient assistance programs in place of ADAP. In other states such as Virginia, HCV treatment data reporting is mostly generated by client self-report.
    - Many state hepatitis programs, including Arizona and Colorado, lost the Centers for Disease Control and Prevention (CDC) funding used to create and maintain a statewide HCV registry. These states' ADAPs then added a question regarding current HCV infection to the programs' application forms in order to capture this data.

    - Across all persons living with HCV, including ADAP clients, rates for confirmatory testing and linkage to care remain low among those who test positive for HCV screening tests.
- **Collaboration with Other Private and Public Payers:**
    - ADAPs may assess insurance plans for coverage of DAA HCV medications for their co-infected clients. Arizona and Virginia both added HCV treatment coverage to the plan-vetting process this year.
    - Several ADAPs will choose to cover the cost of DAA HCV treatments for clients denied by Medicaid or other payers (e.g., Arizona, Massachusetts). These ADAPs have continued to see low utilization, however. Both ADAP and provider consultation participants suggest that this may in part be attributed to a confusing payer landscape for clients and providers. Providers and their patients must contend with labyrinthine payer requirements (e.g., prior authorization) with high rates of coverage denial.
    - Many providers do not to capitalize on all of the available resources (e.g., ADAP). Instead, they default to relying on pharmaceutical companies' patient assistance programs (PAPs) to cover the cost of the medication. Gilead and Merck adopted PAP policies that restrict coverage to individuals whose insurance has denied them.
    - Even in the community pharmacy setting in which there is a more hands-on approach to interacting with clients, there is a notion that ADAPs only cover HIV antiretrovirals. Pharmacists will therefore not attempt to access coverage via ADAPs.

Clinical Management of HIV/HCV Co-Infection

Participants discussed providers' (including RWHAP providers) capacity for navigating complex diagnoses and treatment associated with HIV and HCV co-infection, including gaps and issues. Participants were also asked to identify particular providers and/or clinical settings that are the most or least effective in treating co-infected patients, including ADAP clients.

- **Sharing Clinical Best Practices Among Providers**: It can be difficult for providers to learn what others have done to operationalize treatment access, e.g. the diagnosis and management of cirrhosis. Having a central online hub for providers would allow better sharing of best practices.
- **Limited Availability of Providers in Low Resource States**: In rural or less-populous states, there may be very few doctors available to treat clients, creating long wait lists.
- **Lack of Capacity and Expertise to Treat HIV/HCV Among Providers:** RWHAP providers are referring clients to hepatologists due to requirements from insurance providers and a lack of confidence in treatment for HIV/HCV co-infection. Pre-DAA HCV treatments were extremely challenging for patients and the providers who managed them. Many providers may still be of the mindset that suicide ideation is an integral part of HCV treatment management, a

common side-effect of interferon-based regimens. As a result, providers may still default to referring patients to hepatologists. ADAPs and other key stakeholders should emphasize that initial screening at least can and should happen within the primary care setting.

- **Providing HCV Treatment for Sub-Populations (e.g., People with Active Substance Use):** There continues to be a persistent stigma regarding HCV and drug use. This manifests as an attitude that persons who have used or continue to use drugs are not "deserving" of treatment. ADAPs also face these attitudes as they work to add to these medications to their formularies. Providers should also not lose sight of non-injection-related HCV transmission. HCV acquisition may also occur via the sharing of crack pipes, straws, etc.
- **ADAP Communications with Provider Community:** The modes by which ADAPs share changes to their formulary coverage policies with providers varies by state and include webinars, in-person meetings, and updates to program websites. Some ADAPs post announcements regarding formulary changes to provider e-mail listservs, attaching new prior authorization paperwork or other documentation. ADAPs may also choose to share target specific provider groups, e.g., providers in correctional facilities. While the manner in which ADAPs may differ, all ADAP participants agreed that more expansive engagement regarding the role of ADAPs in treating HCV is necessary, particularly among non-RWHAP providers (e.g., hepatologists).

Policies and Procedures for HCV Treatment Among PLWH

Consultation participants addressed adaptations made to clinical settings in order to treat co-infected patients with DAA HCV medications, including the management of payers' prior authorization requirements, also identifying opportunities for ADAPs and other health department staff to bolster provider capacity to treat coinfection.

- **Non-Traditional Providers Supporting Access to HCV Treatment**:
    - At some clinics, pharmacists manage a registry of clinical criteria and insurance coverage and consult on possible drug-drug interactions. These dedicated pharmacists are thereby able to complete prior authorizations. Specialty pharmacies also have greater capacity to support clients through issues of adherence.
    - Nurse practitioners may also assist the client in navigating the prior authorization process.
    - Case managers are essential to facilitating the transfer of knowledge between primary care and specialist providers (e.g., hepatologists). They do so by assessing the needs of individual clients, including access to supportive services such as transportation.
    - ADAP coverage of drugs is not well understood by most hepatologists. ADAPs must adapt and work to communicate their role with non-traditional partners, including hepatologists. Professional societies like Infectious Diseases Society of America (IDSA) may also be helpful by

adding information regarding ADAP formulary coverage to the IDSA website.

- **ADAPs Assisting Providers in Navigating Restrictive Coverage Policies:** ADAPs must consider the best strategies to share timely information regarding coverage options. This is a major challenge for providers. A resource that outlines an algorithm may be one possibility. As well, it may be useful to develop a central prior authorization form or portal across payers (e.g., Medicaid, ADAP) to help providers in navigating payer restrictions.
- **ADAPs Educating Providers on Alternative Treatment Regimens**: Participants noted that many providers default to the treatments produced by Gilead (Sovaldi, Harvoni) or Merck (Zepatier), forgoing equally clinically effective and more cost-effective regimens. When Gilead or Merck refuse to provide support via their PAP for patients who were denied by their insurer, the patient is left without treatment and programs such as ADAP are left absorbing the total cost of the medication. ADAPs could better educate these providers on other regimens that are effective and available without these restrictions. This would also give ADAPs greater negotiation power with companies with more restrictive PAP and cost-sharing assistance program (CAP) policies.

Summary of Recommendations

ADAPs and Other Health Department Staff

- **Consider establishing a single prior approval form to be used across all payers, including ADAP and Medicaid.** Participants identified differing payer restrictions to be a key barrier to optimal HCV treatment uptake. A consolidated prior approval or prior authorization form across payers would alleviate administrative burden and confusion among providers and clients
- **Bolster communications regarding ADAP coverage of DAA HCV medications with a broad range of providers, including: case managers; pharmacists; hepatologists; and primary care providers.** There are a number of providers that operationalize HCV treatment access by navigating prior authorization processes, addressing issues of drug-drug interactions, and assisting clients in accessing supportive services that ensure high levels of adherence. Many of these providers lie outside of direct HIV care provision and/or RWHAP. As such, they may be unaware of the role of ADAP in providing access to HCV treatment and may therefore benefit from:
    - An overview of ADAPs and the breadth of services and treatments available to clients served
    - Education on the availability of comparably effective DAA HCV treatments
    - State-specific algorithms or decision trees regarding coverage of DAA HCV medications via various payers, including ADAP

- **Maximize available funding opportunities in order to expand access to DAA HCV medications (e.g., use of rebate funds).** This can include supporting positions and other elements of program infrastructure.

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- **Develop example "talking points" to be used by ADAP staff in generating buy-in for the addition of DAA HCV medications to the ADAP formulary.** ADAPs encounter stigmatizing attitudes as they work to add to these medications to their formularies. It would be helpful to have readily available talking points for ADAPs to use to respond to concerns regarding substance use, disease stage (i.e., fibrosis score), etc.
- **Assist ADAPs in communicating their role in providing access to a broad range of medications for their clients, inclusive of HCV treatment.**
- **To inform future technical assistance and advocacy efforts, gather data directly from ADAPs regarding:**
    - ADAPs' inclusion of DAA HCV medication coverage as part of plan assessment processes. While NASTAD routinely gathers qualitative data regarding ADAPs' plan selection processes for covering HIV antiretrovirals, no such data exists for DAA HCV treatments.
    - ADAP clients use of patient assistance and cost-sharing assistance programs for HIV antiretrovirals and DAA HCV medications. NASTAD has not surveyed ADAPs recently regarding ADAP clients' utilization of and experience with patient assistance and cost-sharing assistance programs for HIV and/or HCV treatment.
- **Continue to support peer exchanges between states in which ADAPs have added one or more DAA HCV medication to their formulary.** This engagement between ADAPs will allow for continual troubleshooting and sharing of best practices in order to maximize utilization among ADAPs covering one or more DAA HCV medication.
- **Continue technical assistance to states considering adding DAA HCV medications to their formulary.**

Other Key Stakeholders

- **AIDS Education and Training Centers (AETCs):** work closely with Project ECHO to capitalize on telemedicine. Secure continuing medical education (CME) credit for these activities.
- **Infectious Diseases Society of America (IDSA):** share data regarding ADAP formulary coverage of DAA HCV medications via website.
- **Project Inform:** share data regarding ADAP formulary coverage of DAA HCV medications via resource materials for patients and providers.

STRATEGIES TO INCREASE HEPATITIS C TREATMENT WITHIN ADAPS

AGENDA

This consultation is supported through a NASTAD cooperative agreement from Health Resources and Services Administration (HRSA).

THURSDAY, JUNE 9, 2016

8:30 AM – 9:00 AM	Breakfast
9:00 AM – 9:45 AM	Introductions, Meeting Expectations, and Opening Remarks *Speaker*: Britten Pund, NASTAD
9:45 AM – 10:45 AM	Federal Panel (CMS, HHS, HRSA, and VA)
10:45 AM – 11:00 AM	Break
11:00 AM – 11:45 AM	Case Study: Best Practice in ADAP HCV Treatment Utilization
11:45 PM – 1:00 PM	Working Lunch - Round Robin Discussion with Provider and Other Stakeholders Questions will be posed to provider stakeholders to kick off discussion with health department participants; action steps to be recommended. **Impediments and Opportunities: Health Systems**
1:00 PM – 1:15 PM	Break
1:15 PM – 2:15 PM	Round Robin Discussion with Provider and Other Stakeholders Questions will be posed to provider stakeholders to kick off discussion with health department participants; action steps to be recommended. **Clinical Management of HIV/HCV Co-Infection**
2:15 PM – 3:15 PM	Round Robin Discussion with Provider and Other Stakeholders Questions will be posed to provider stakeholders to kick off discussion with health department participants; action steps to be recommended.

	Policies and Procedures for HCV Treatment Among PLWH
3:15 PM – 4:00 PM	Wrap-up and Conclusion

NOTES

Strategies to Increase Hepatitis C Treatment Within ADAPs

June 9, 2016

Consultation Participant List

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ADAP Hepatitis C Treatment Coverage

June 2016

Background

NASTAD (the National Alliance of State & Territorial AIDS Directors) continues work to ensure that individuals co-infected with HIV and hepatitis C (HCV) can gain access to curative treatments for HCV via ADAP. NASTAD asked states that have added one or more of the directly-acting antiviral (DAA) HCV treatment medications to complete an online request for information (RFI). The ADAP Hepatitis C Treatment Coverage RFI was produced as part of NASTAD's cooperative agreement with the Health Resources and Services Administration (HRSA).

To date, twenty ADAPs have added one or more of the DAA HCV medications to their formulary; seventeen ADAPs responded to this RFI. **All responses to the RFI were reported as of May 1, 2016.**

Key Findings

ADAP Formulary Inclusion of DAA HCV Medications

Below is a summary of the numbers of ADAPs that cover each of the currently available DAA HCV medications. **To date, 324 ADAP clients have received a DAA HCV prescription via the full-pay prescription program. 283 ADAP clients have received a DAA HCV prescription via the ADAP-funded insurance program.**

ADAP FORMULARY COVERAGE		
DAA HCV Medication	**Full-Pay Prescription**	**ADAP-Funded Insurance**
daclatasvir (Daklinza)	10	9
dasabuvir, ombitasvir / paritaprevir / ritonavir (Viekira Pak)	15	12
elbasvir and grazoprevir (Zepatier)	9	9
ledipasvir and sofosbuvir (Harvoni)	16	13
ombitasvir, paritaprevir and ritonavir (Technivie)	10	9
simeprevir (Olysio)	9	11
sofosbuvir (Sovaldi)	15	13

ADAP Formulary Coverage Policies and Restrictions

ADAPs may have additional policies that are used to determine clients' eligibility to receive coverage for a DAA HCV medication. These policies may be determined by the ADAP directly or may be the result of either statewide policy or individual private insurance plan restrictions. The following tables summarize ADAPs' current use of policies to determine DAA HCV medication utilization and coverage under their full-pay prescription and ADAP-funded insurance programs.

ADAP FORMULARY COVERAGE POLICIES		
POLICY	**FULL-PAY RX**	**ADAP-FUNDED INSURANCE**
Cap or maximum number of prescriptions/expenditures per client	0	0
Cap or maximum number of clients to receive prescriptions or total expenditures	4	0
Cap or maximum number of clients	N/A	1
Fibrosis score restriction or prioritization (e.g., F3 or F4)	2[1]	1[2]
Prior authorization	10	4
Proof of denial by other payer (e.g., Medicaid)	6	0
Sobriety requirement	2	1
Specialist provider supervision requirement (e.g., hepatologist)	1	1
No restrictions, open access	2	8

ADAP Utilization of DAA HCV Medications

Full-Pay Prescription Program: 324 clients received a prescription for DAA HCV medication(s) via the ADAP full-pay prescription program as of May 1, 2016. Six ADAPs are able to report on the cure rate among their clients to receive a prescription; 105 clients have been reported cured.

ADAP-Funded Insurance Program: 283 clients received a prescription for DAA HCV medication(s) via the ADAP-funded insurance program as of May 1, 2016. Four ADAPs are able to report on the cure rate among their clients to receive a prescription; 40 clients have been reported as cured.

[1] One ADAP reported that they will restrict or prioritize treatment to individuals with fibrosis scores of F3 or F4. One ADAP reported that they will cover treatment for individuals with F2, F3, or F4.

[2] One ADAP reported that they will restrict or prioritize treatment to individuals with fibrosis scores of F2, F3, or F4.