NATIONAL PARAMETER STREAMENT



Leveraging RWHAP Services to Optimize Treatment Access for HIV/HCV Co-infection

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Agenda

- Background
- National RWHAP Part B and ADAP Monitoring Project: HCV Coverage
- NASTAD Consultation: Strategies to Increase Hepatitis C Treatment Within ADAPs
- Key Considerations for ADAPs
- Strategies to Increase Access to HCV Treatment within ADAPs: Provider Decision Tree
- Related NASTAD Technical Assistance
- Questions & Answers





Background

HRSA Policy

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 <u>letter</u> 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 RWHAP Part B and ADAP Monitoring Project: HCV Coverage

National RWHAP Part B and ADAP Monitoring Project

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 Ryan White HIV/AIDS Program Part B and ADAP Monitoring Project Annual Report (The Report)
- National ADAP Formulary Database



National ADAP Formulary Database: HCV

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, 2018.

- Annual comprehensive National ADAP Formulary Survey
- Monthly update surveys



National ADAP Formulary Database: HCV

As of August 1, 2018:

- 39 ADAPs cover one or more HCV treatment medication
- Among directly-acting antiviral (DAA) HCV treatment medications:
 - 27 ADAPs cover daclatasvir (Daklinza)
 - 33 ADAPs cover dasabuvir, ombitasvir, paritaprevir, ritonavir (Viekira Pak XR)
 - 33 ADAPs cover elbasvir and grazoprevir (Zepatier)
 - 26 ADAPs cover glecaprevir and pibrentasvir (Mavyret)
 - 32 ADAPs cover ledipasvir and sofosbuvir (Harvoni)
 - 26 ADAPs cover ombitasvir, paritaprevir and ritonavir (Technivie)
 - 28 ADAPs cover sofosbuvir (Sovaldi)
 - 26 ADAPs cover sofosbuvir, velpatasvir (Epclusa)
 - 19 ADAPs cover sofosbuvir, velpatasvir and voxilaprevir (Vosevi)



National RWHAP Part B & ADAP Monitoring Project Annual Report

In calendar year 2016, over 1,000 clients (2%) across 15 ADAPs were reported as being co-infected with HCV at some point during the year

- 336 (32%) of these clients received HCV treatment
 - 160 (48%) were reported as cured.

These values likely indicate underreporting as a result of limited data available to ADAPs





NASTAD Consultation: Strategies to Increase Hepatitis C Treatment Within ADAPs

Background and Purpose

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



Request for Information (RFI) Findings

- 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.



Request for Information (RFI) Findings

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	



Request for Information (RFI) Findings

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	
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	





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





Strategies to Increase Access to HCV Treatment within ADAPs: Provider Decision Tree

Background

Following a June 2016 consultation to explore strategies to increase uptake of HCV direct acting antivirals (DAAs) treatment, NASTAD developed <u>"Strategies to Increase Access to Hepatitis C (HCV) Treatment within ADAPs: Provider Decision Tree,"</u> a resource for providers to illustrate and clarify the myriad treatment coverage options available to people living with HIV and HCV, including ADAP

- Printable, PDF version
- Interactive, web-based version

ADAPs are encouraged to share this resource with local HIV/HCV service providers, including those who work outside of the RWHAP

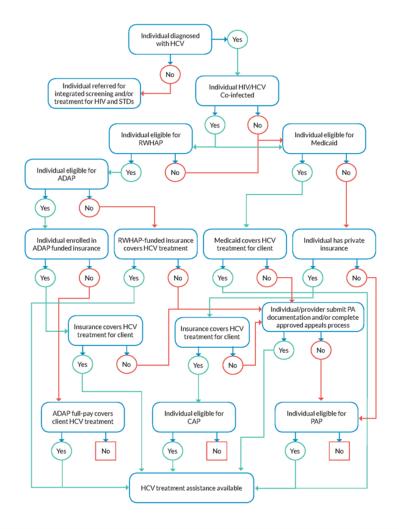


Resource Highlights

- Overview of key payers and considerations
 - Private insurance
 - Medicaid
 - ADAP
 - RWHAP Parts A, B, C, and D
 - Patient assistance programs (PAPs)
 - Cost-sharing assistance programs (CAPs)
- Decision tree
- Resources



Printable PDF Version







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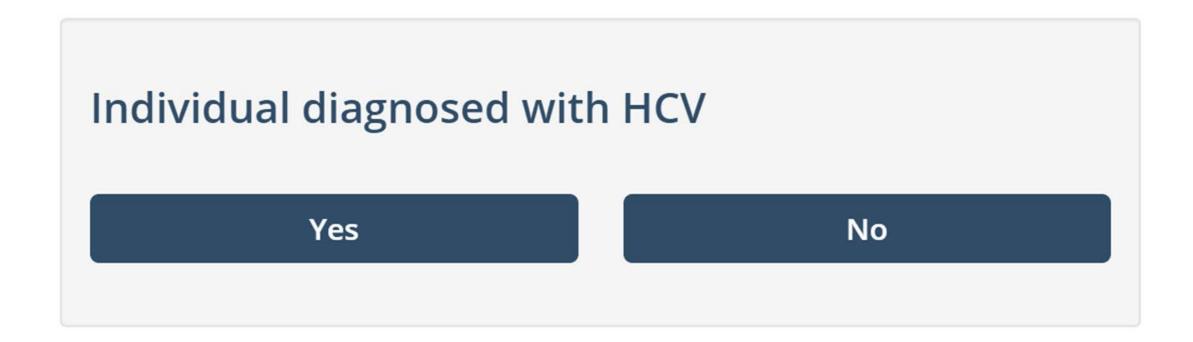
REQUEST TRAINING & TA

ADAP HCV DECISION TREE

NASTAD continues work to ensure that individuals coinfected with HIV and hepatitis C virus (HCV) can gain access to curative treatments for HCV via the Health Resources and Services Administration's (HRSA) Ryan White HID/AIDS Program's (RWHAP) AIDS Drug Assistance Programs (ADAPs). While the number of ADAPs that include one or more direct-acting antiviral (DAA) HCV treatments on their formulary continues to increase, many ADAPs still face challenges in optimizing uptake of HCV treatment among HIV/HCV coinfected clients.

Utilization data suggests that the broader HCV health care landscape remains confusing for clients and providers to navigate. Many providers do not maximize all available HCV treatment opportunities, instead relying solely on pharmaceutical companies' patient assistance and cost-sharing assistance programs. NASTAD has developed a decision tree for providers to illustrate and clarify the myriad treatment coverage options available to people living with HIV and HCV including ADAP Please note: If the decision tree doesn't load immediately please refresh the







Individual HIV/HCV co-infected

Yes

No



Restart





Individual is eligible for RWHAP and/or Medicaid

RWHAP only

Medicaid only

Eligible for both RWHAP and Medicaid Eligible for neither RWHAP or Medicaid



Restart







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



Contact Information

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