Toward Pharmacoequity: ADAP Formulary Design to Meet the Comprehensive Treatment Needs of People with HIV

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Learning Objectives

By the end of this session, participants will be able to:

1. Apply principles of pharmacoequity as they apply to people with HIV and ADAP clients
2. Understand the comprehensive and evolving pharmacologic needs of people with HIV
3. Describe analyses of ADAP formulary coverage of prescription drug categories nationally and by U.S. region
4. Interpret ADAP formulary requirements and allowances

Presentation Roadmap

1. Pharmacoequity and the Evolving Pharmacologic Needs of People with HIV
2. ADAP Formulary Requirements and Allowances
3. Questions and Discussion

Pharmacoequity and the Evolving Pharmacologic Needs of People with HIV

Pharmacoequity

"Ensuring that all individuals, regardless of race and ethnicity, socioeconomic status, or availability of resources, have access to the highest-quality medications required to manage their health needs"[1]

Essential because of the important and growing role of prescription drugs in the management of both acute and chronic diseases

[1]Essien UR, et al. JAMA. 2021;326(18):1793-1794.

ADAPs Adopting Pharmacoequity Aligns with United States' HIV Initiatives and Plans

- Access to antiretroviral therapy (ART)
  - Ending the HIV Epidemic (EHE) Initiative: "Treat people with HIV rapidly and effectively to reach sustained viral suppression"[1]
  - National HIV/AIDS Strategy for the United States 2022–2025 (NHAS): "Improve HIV-Related Health Outcomes of People with HIV"[2]
- Access to non-HIV medications
  - NHAS: "Address … co-occurring conditions that impede access to HIV services"[2]
- Equity aspect
  - NHAS: "Reduce HIV-Related Disparities and Health Inequities"[2]

[1] HRSA. Ending the HIV Epidemic in the U.S. 2023.

[2] The White House. National HIV/AIDS Strategy for the United States 2022–2025. 2021.

Pharmacoequity for ADAP Clients: Socioeconomic Status

"Ensuring that all individuals, regardless of race and ethnicity, **socioeconomic status, or availability of resources**, have access to the highest-quality medications required to manage their health needs"[1]

ADAPs serve uninsured/underinsured people with HIV with low incomes

[1]Essien UR, et al. JAMA. 2021;326(18):1793-1794.

ADAPs Serve Uninsured/Underinsured People with HIV with Low Incomes

Nationally, **44%** ADAP clients have income less than 100% Federal Poverty Level (FPL).[1]

For **8** ADAPs, more than **50%** of ADAP clients less than 100% FPL.[1]

2023 FPL: 1 person - $14,580

4 people - $30,000

[1] Centers for Disease Control and Prevention (CDC). HIV Surveillance Supplemental Report, 2023; 28 (No.3).

[2] NASTAD. 2021-2022 National RWHAP Part B ADAP Monitoring Project Annual Report. 2022.

Pharmacoequity for ADAP Clients: Race/Ethnicity

"Ensuring that all individuals, regardless of **race and ethnicity**, socioeconomic status, or availability of resources, have access to the highest-quality medications required to manage their health needs"[1]

ADAPs serve large numbers of Black and Hispanic people with HIV

[1]Essien UR, et al. JAMA. 2021;326(18):1793-1794.

ADAPs Serve Large Numbers of Black and Hispanic People with HIV

Nationally, **40%** of people with HIV are Black people.[1]

For **11** ADAPs, more than **50%** of ADAP clients are Black people with HIV.[2]

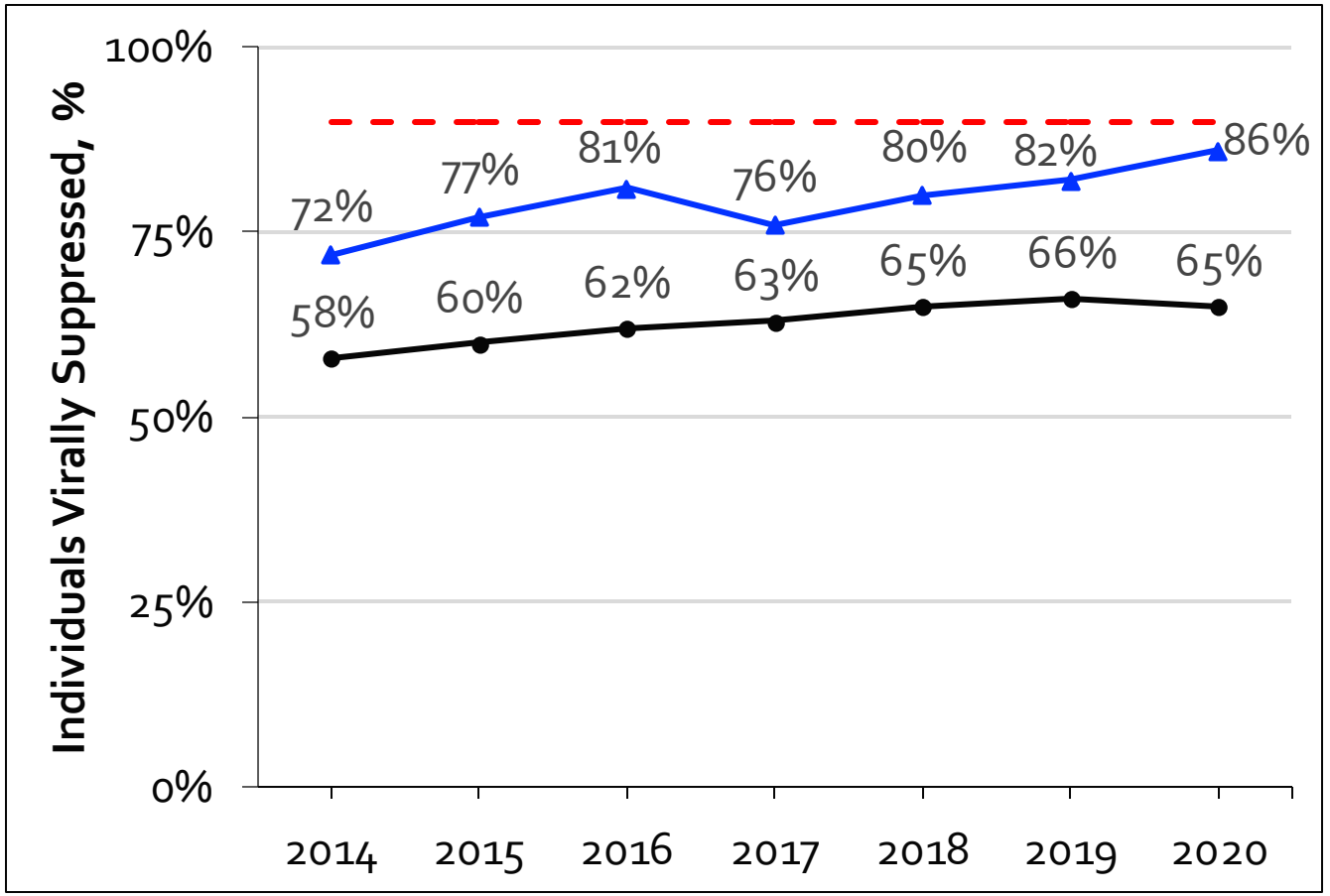
Nationally, **29%** of people with HIV are Hispanic people.[1]

For **9** ADAPs, more than **33%** of ADAP clients are Hispanic people with HIV.[2]

[1] CDC. HIV Surveillance Supplemental Report, 2023; 28 (No.3).

[2] NASTAD. 2021-2022 National RWHAP Part B ADAP Monitoring Project Annual Report. 2022.

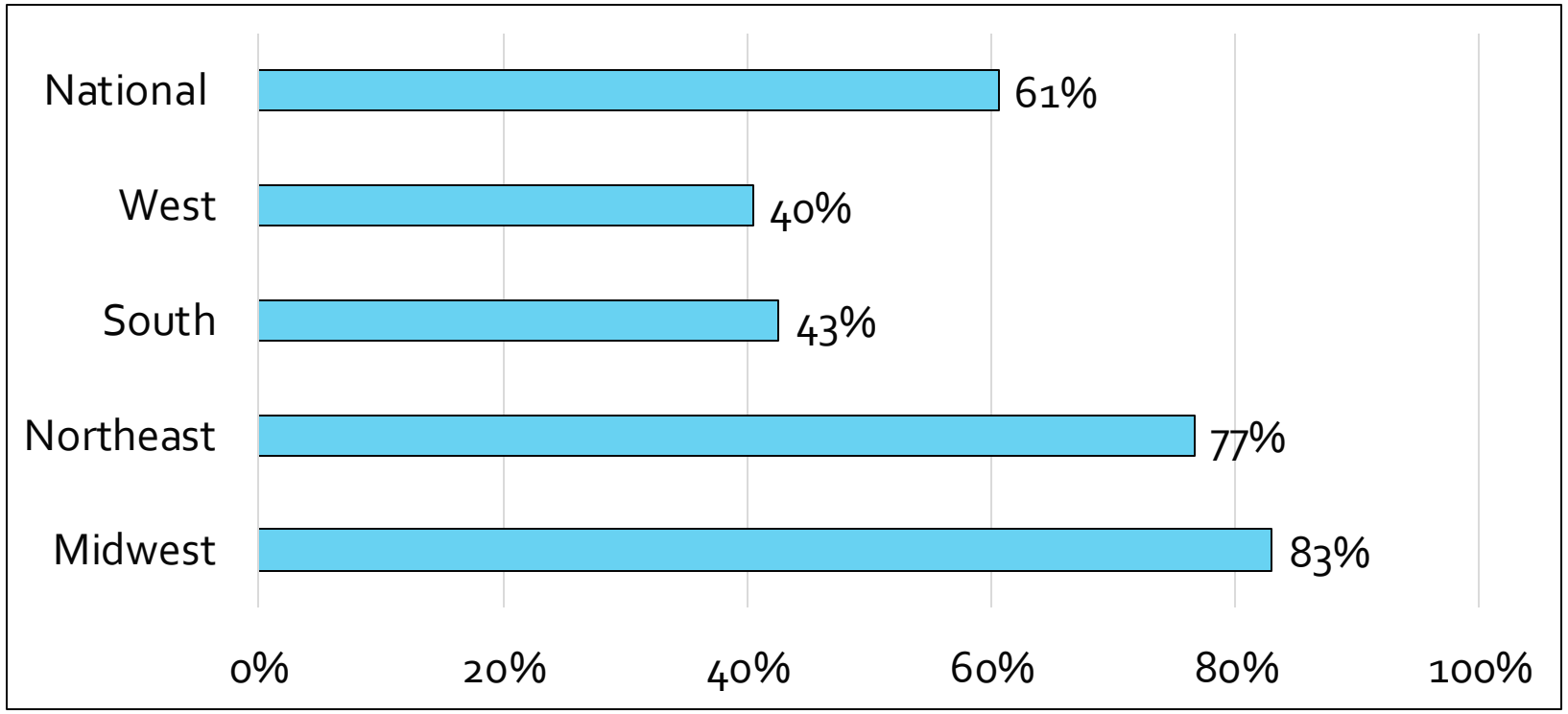
ADAPs Deliver Excellent HIV Outcomes for a Vulnerable Population



[1] NASTAD. National RWHAP Part B ADAP Monitoring Project Annual Reports.

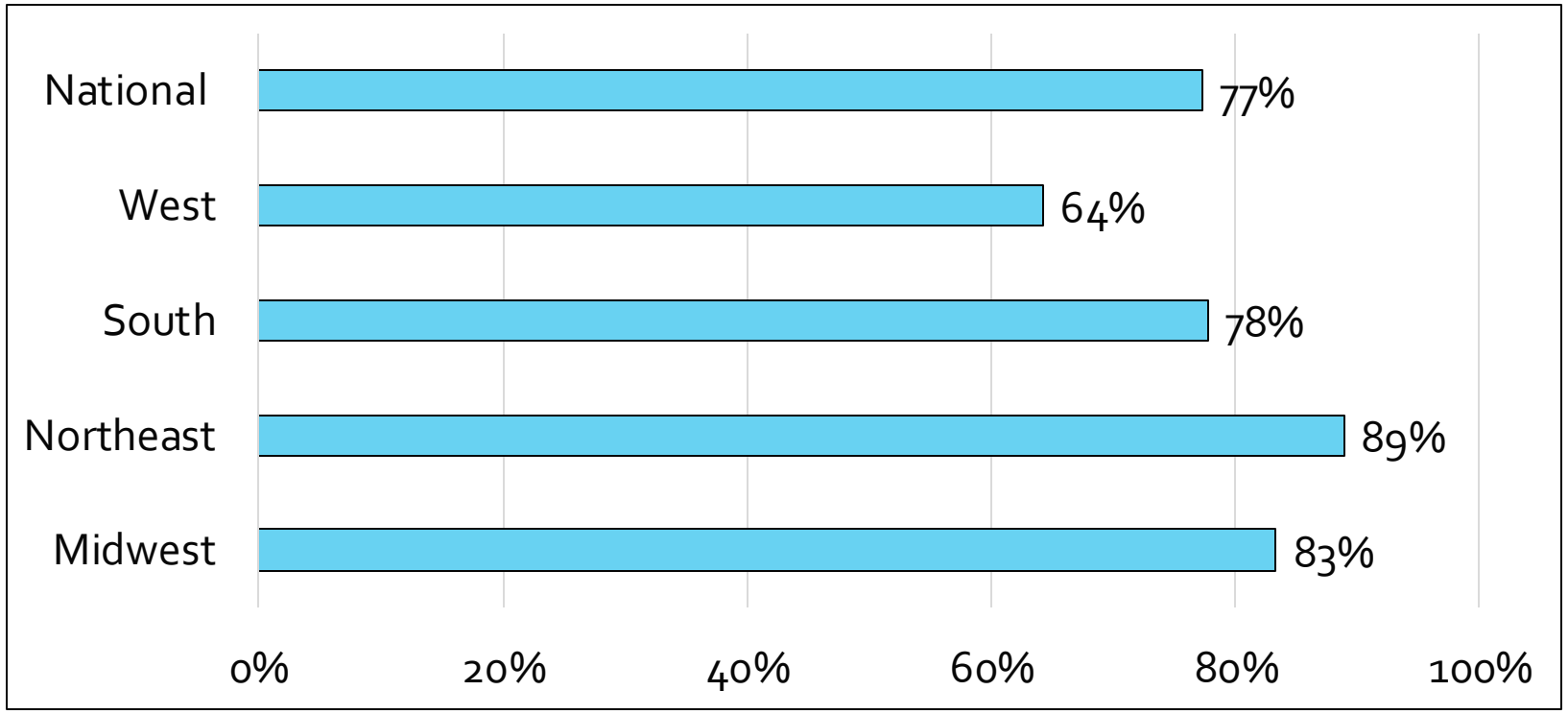
[2] CDC. NCHHSTP AtlasPlus.

ADAP Formulary Coverage of 47 Branded Antiretroviral Therapy Medications, Nationally and by Region, 2023[1]



[1] NASTAD. 2023 National ADAP Formulary Database. 2023. Data note: 50 States, DC, Guam, and Puerto Rico are included. Guam was considered a "Western" jurisdiction. Puerto Rico was considered a "Southern" jurisdiction.

ADAP Formulary Coverage of Cabotegravir/Rilpivirine, Nationally and by Region, 2023[1]



[1] NASTAD. 2023 National ADAP Formulary Database. 2023.

Evolving Pharmacologic Needs and Increased ADAP Resources

- Evolving pharmacologic needs of people with HIV
  - Aging
  - Increased diagnosis of co-morbid conditions
  - Increased appreciation of importance of whole-person care

- Increased ADAP Resources
  - No recent waitlists
  - Robust addition of non-HIV medications

High Impact Medications for ADAP Formulary Design and Pharmacoequity

- Mental health
- Substance use disorder and overdose prevention
- Gender-affirming therapy
- Comorbidities associated with aging with HIV

Mental Health and HIV

- Prevalence of depression among people with HIV: estimated to be **15-40%** [1]
  - Much higher prevalence in people with HIV compared with general population

- From Medical Monitoring Project, estimated prevalence based on symptoms during the past 2 weeks:[2]
  - **15%** depression
  - **21%** anxiety

[1] Angelino AF, et al. Clin Infect Dis. 2001;33(6):847.

[2] CDC. HIV Surveillance Special Report 32. 2023.

Depression, HIV, and ART

- Progression of HIV disease is associated with increased risk for developing depression through[1]
  - direct damage to subcortical brain areas
  - chronic neuroinflammation induced by HIV
- Some ART is associated with depression[2]
  - efavirenz
  - rilpivirine
  - cabotegravir
  - integrase inhibitors, especially dolutegravir

[1] Benatti C, et al. CNS Neurol Disord Drug Targets. 2016;15(4):414.
[2] Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. 2023.

Why Cover Medications Related to Mental Health? HIV-Related Benefits

- Depression negatively impacts HIV outcomes
  - Associated with non-adherence to HIV treatment[1]
  - Increased risk of HIV disease progression and mortality[2]

- Treatment of depression for people with HIV is associated with increased viral suppression, which is likely attributable to increased uptake and adherence to ART.[3]

[1] van Servellen G, et al. AIDS Patient Care STDS. 2002;16(6):269.

[2] Ickovics JR, et al. JAMA. 2001;285(11):1466.

[3] Tsai AC et al. Arch Gen Psychiatry. 2010;67(12):1282-1290.

Why Cover Medications Related to Mental Health? Non-HIV Benefits

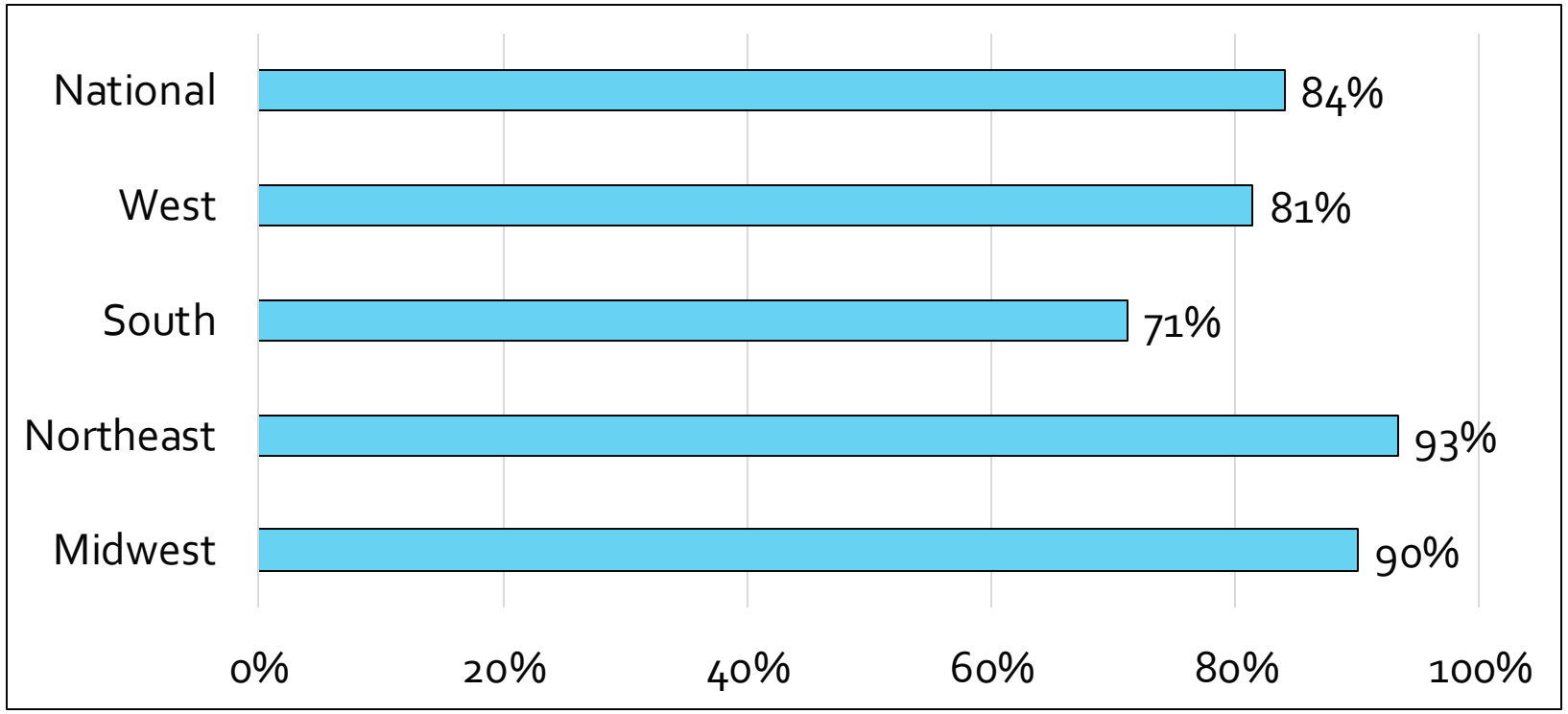
- Meta-analysis: treating depression with a selective serotonin reuptake inhibitor (SSRI) results in improved quality of life. [1]

- People who start antidepressant treatment experience significant improvement in depression as well as function and disability. [2]

[1] Hoffman SG et al. Cogn Behav Ther. 2017 Jun; 46(4): 265–286..

[2] Kunik ME et al. Psychol Med. 2008;38(3):385–96.

ADAP Formulary Coverage of 5 SSRIs[1] with Indication for Depression, Nationally and by Region, 2023[2]



[1] Citalopram, Escitalopram, Fluoxetine, Paroxetine, Sertraline

[2] 2023 National ADAP Formulary Database. NASTAD. 2023.; Data note: Guam was considered a "Western" jurisdiction. Puerto Rico was considered a "Southern" jurisdiction.

HIV, Substance Use Disorder (SUD), and Overdoses

- SUD Prevalence in Past Year : **11.1%** among people with HIV compared with **7.4%** among general population[1]
- From Medical Monitoring Project, estimated prevalence of nonmedical use of noninjection or injection drugs in the past 12 months: **48%**[2]
- Meta-analysis: people who use drugs have a **74%** greater risk of overdose if they have HIV compared with their counterparts who do not have HIV[3]

[1] Substance Abuse and Mental Health Services Administration (SAMHSA). Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders. 2020.
[2] CDC. HIV Surveillance Special Report 32. 2023.
[3] Green TC et al. AIDS. 2012 Feb 20; 26(4): 403–417.

Why Cover Medications Related to Substance Use Treatments and Overdose Prevention? HIV-Related Benefits

- Prospective multisite cohort study: people with HIV, who started buprenorphine/naloxone and stayed on it, were more likely to initiate ART[1]
- For people with HIV, buprenorphine treatment improved adherence to ART [2,3]
- People with HIV with Opioid Use Disorder (OUD) starting buprenorphine had an increase in the probability of being virally suppressed [4]

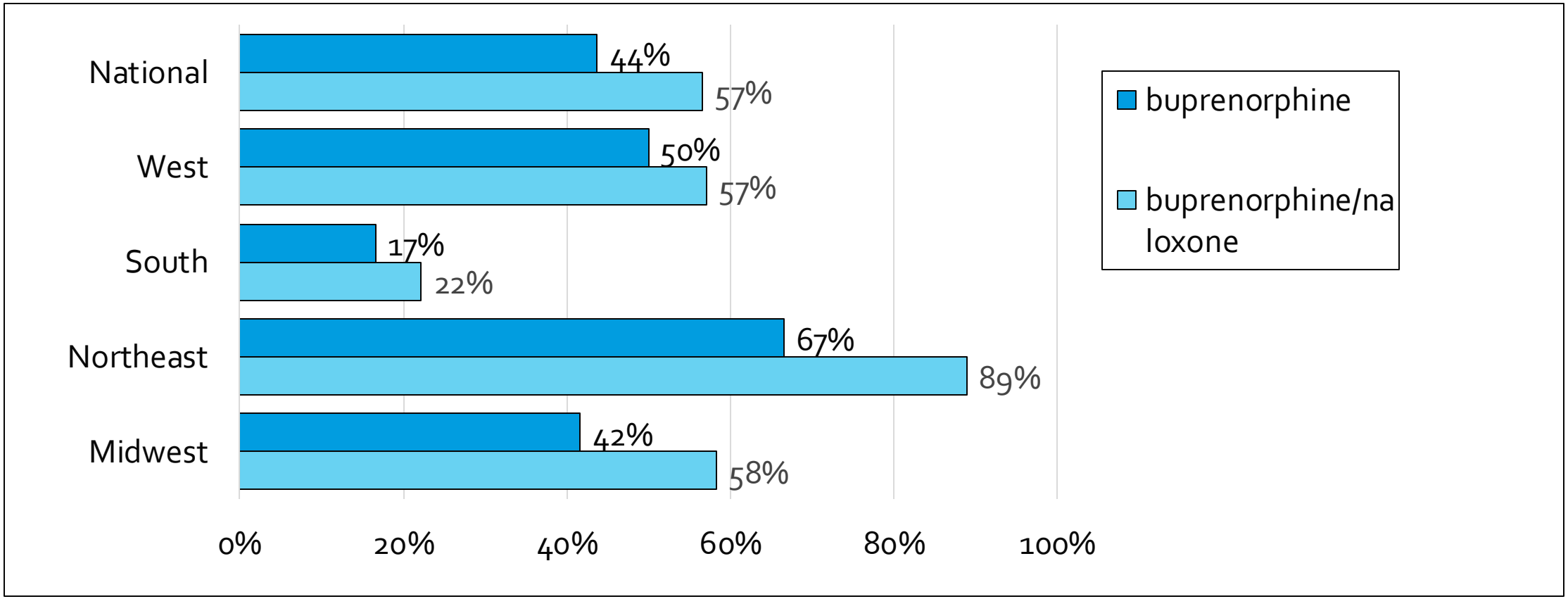
[1] Altice FL et al. J Acquir Immune Defic Syndr 2011; 56 Suppl 1:S22–32.
[2] Moatti JP et al. AIDS 2000; 14:151–5.
[3] Mazhnaya A et al. J Acquir Immune Defic Syndr 2018; 79:288–95.
[4] Kim J, et al. Clin Infect Dis. 2021 Dec 1; 73(11): 1951–1956.

Why Cover Medications Related to Substance Use Treatments and Overdose Prevention? Non-HIV Benefits

- Meta-analysis: For people with OUD, treatment with opioid agonists was associated with a lower risk of all-cause mortality compared with no opioid agonist use [1]
- Communities that increase access to naloxone experience a significant reduction in opioid overdose deaths [2]
- Increased access to naloxone through community-based programs can also help reduce opioid overdose deaths and improve access to addiction treatment and other healthcare services[3]

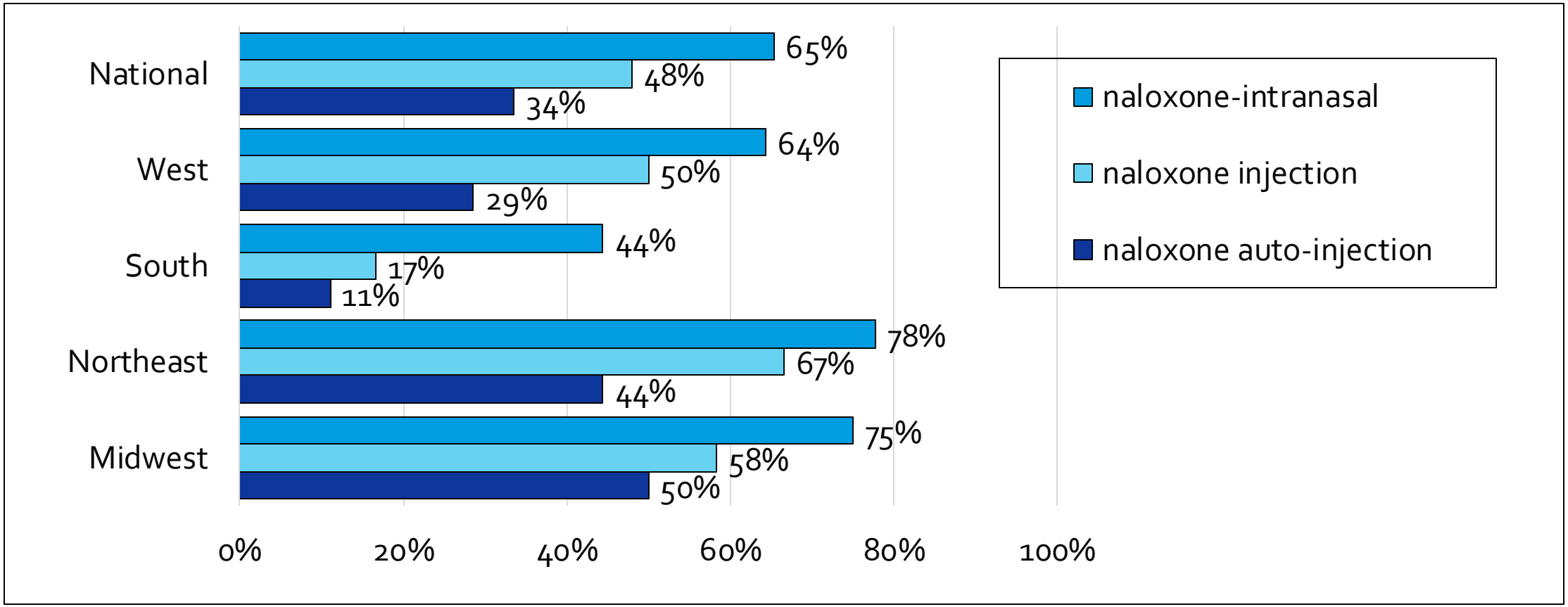
[1] Santo T Jr et al. JAMA Psychiatry. 2021;78(9):979.
[2] Walley AY et al. BMJ 2013; 346: f174.
[3] Lambdin BH et al. MMWR. 69(33), 1117–1121.

ADAP Formulary Coverage of Buprenorphine and Buprenorphine/Naloxone, Nationally and by Region, 2023[1]



[1] 2023 National ADAP Formulary Database. NASTAD. 2023.

ADAP Formulary Coverage of Naloxone Formulations, Nationally and by Region, 2023[1]



[1] 2023 National ADAP Formulary Database. NASTAD. 2023.

HIV and Gender-Affirming Therapy

- Meta-analysis: estimate of HIV prevalence: 14% among transgender women and 2% among transgender men.
  - Highest prevalence is among Black (44%) and Hispanic/Latino (26%) transgender women.
- Recent CDC study: found stark differences in HIV prevalence by race/ethnicity:
  - 62% of Black transgender women
  - 35% of Hispanic/Latina transgender women
  - 17% of White transgender women.

[1] Becasen JS et al. Am J Public Health. 2018:e1-e8.
[2] CDC. HIV Surveillance Special Report 2021 April;27 (No. 1).

Why Cover Hormonal Agents for Gender-Affirming Therapy? HIV-Related benefits

- People are more likely to engage in HIV care when gender affirmation needs are met.[1,2]
- Adherence to hormone therapy correlates with adherence to ART[3,4] and higher rates of viral suppression[4]

[1] Sevelius JM. Sex Roles. 2013;68(11-12):675-689.
[2] Dowshen N et al. Transgend Health. 2017;2(1):81-90.
[3] Crosby RA et al. Transgend Health. 2018;3(1):141-146.
[4] Sevelius JM et al. AIDS Care. 2014;26(8):976-982.

Why Cover Hormonal Agents for Gender-Affirming Therapy? Psychosocial Benefits – Part 1

- Meta-analysis:[1] gender-affirming treatment that included hormones demonstrated that hormonal therapy results in significant improvement in:
  - gender dysphoria symptoms
  - psychological functioning
  - sexual function
  - overall quality of life

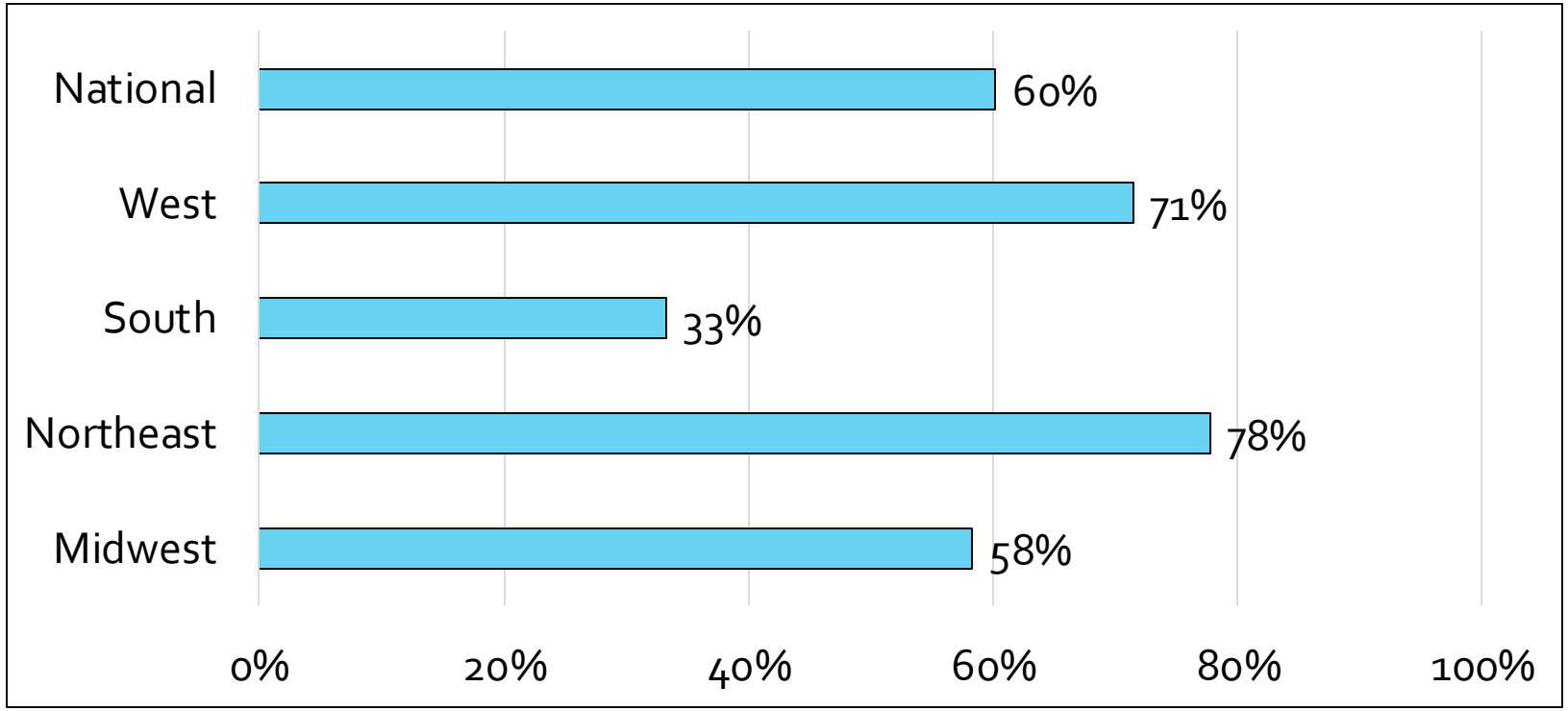
[1] Murad MH et al. Clin Endocrinol (Oxf). 2010;72(2):214.

Why Cover Hormonal Agents for Gender-Affirming Therapy? Psychosocial Benefits – Part 2

- Meta-analysis:[1] gender-affirming hormonal therapy was associated with:
  - Improvement in quality of life
  - Decrease in depression
  - Decrease in anxiety
- Associations were similar across gender identity and age.

[1] Baker KE et al. J Endocr Soc. 2021;5(4):bvab011.

ADAP Formulary Coverage of Sex Hormones for Gender-Affirming Therapy, Nationally and by Region, 2023[1]



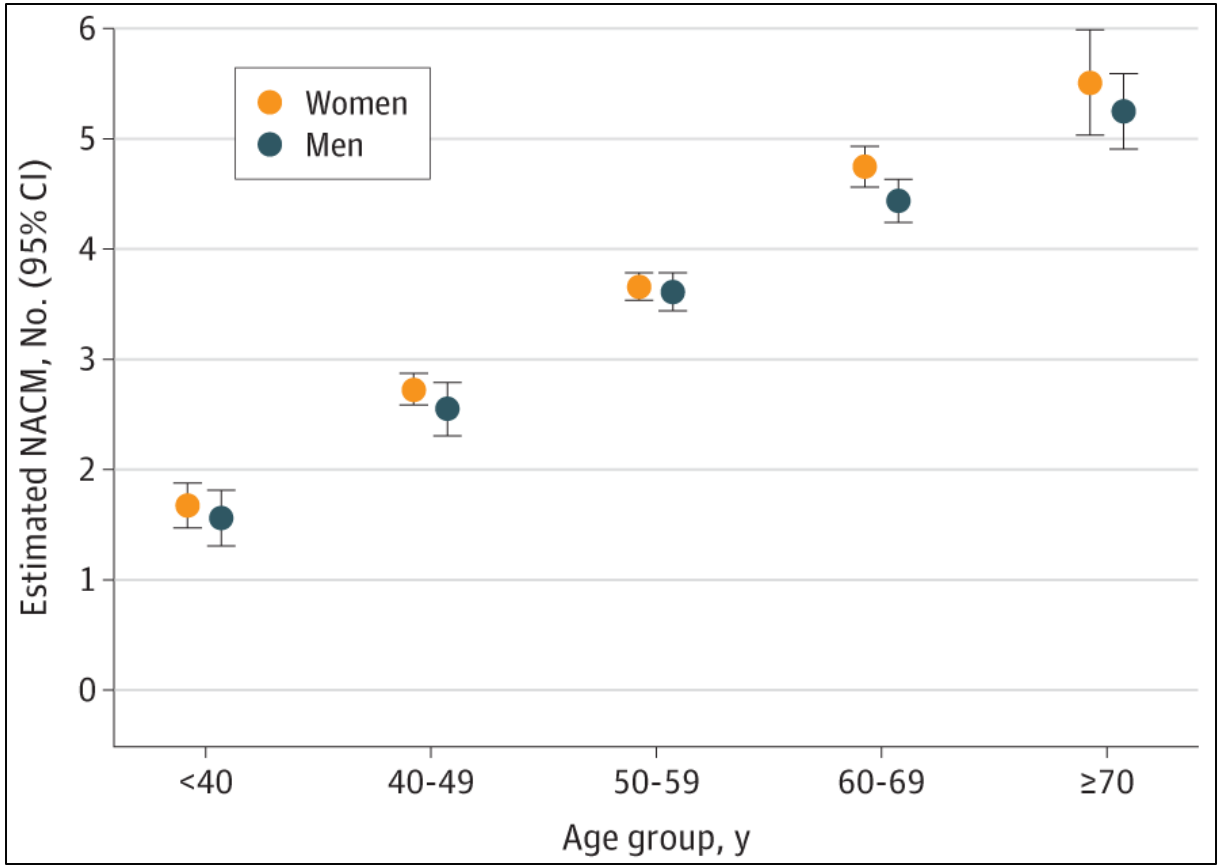
[1] NASTAD. 2023 National ADAP Formulary Database. 2023.

HIV and Co-morbidities

- Comorbidities represent a growing health issue for people with HIV, especially ones that are aging-related [1]
- Prevalence of people with HIV with more than 2 comorbidities was similar to that of the people in the general population who were 10 years older. [2,3]
  - Risk factors: having low CD_4 counts, more time taking ART [2]

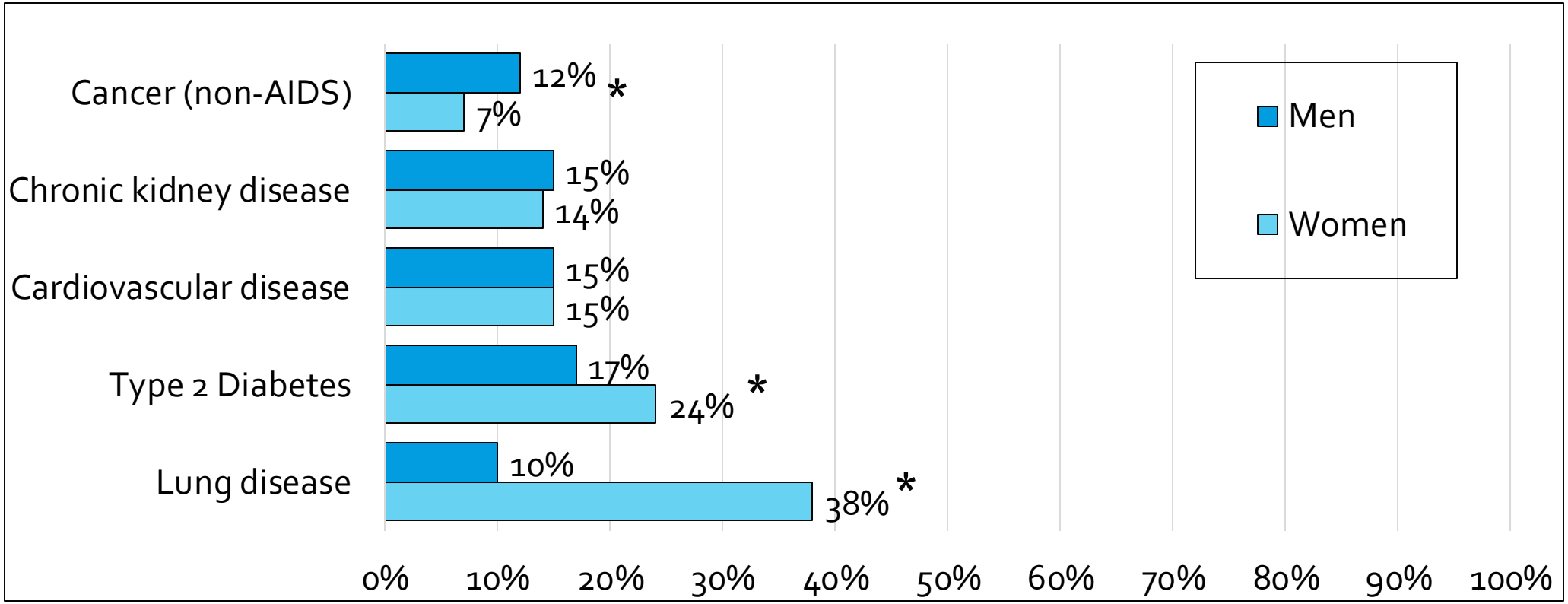
[1] Gallant J et al. J Infect Dis. 2017;216(12):1525-1533.
[2] Guaraldi G et al. Clin Infect Dis. 2011;53(11):1120-1126.
[3] Nanditha NGA et al. BMJ Open. 2021;11(1):e041734.

Mean Number of Non-AIDS Comorbidities Among People with HIV, Stratified by Sex and Age Group[1]



[1] Collins, LF et al. JAMA Netw Open 2023 Aug 1;6(8):e2327584

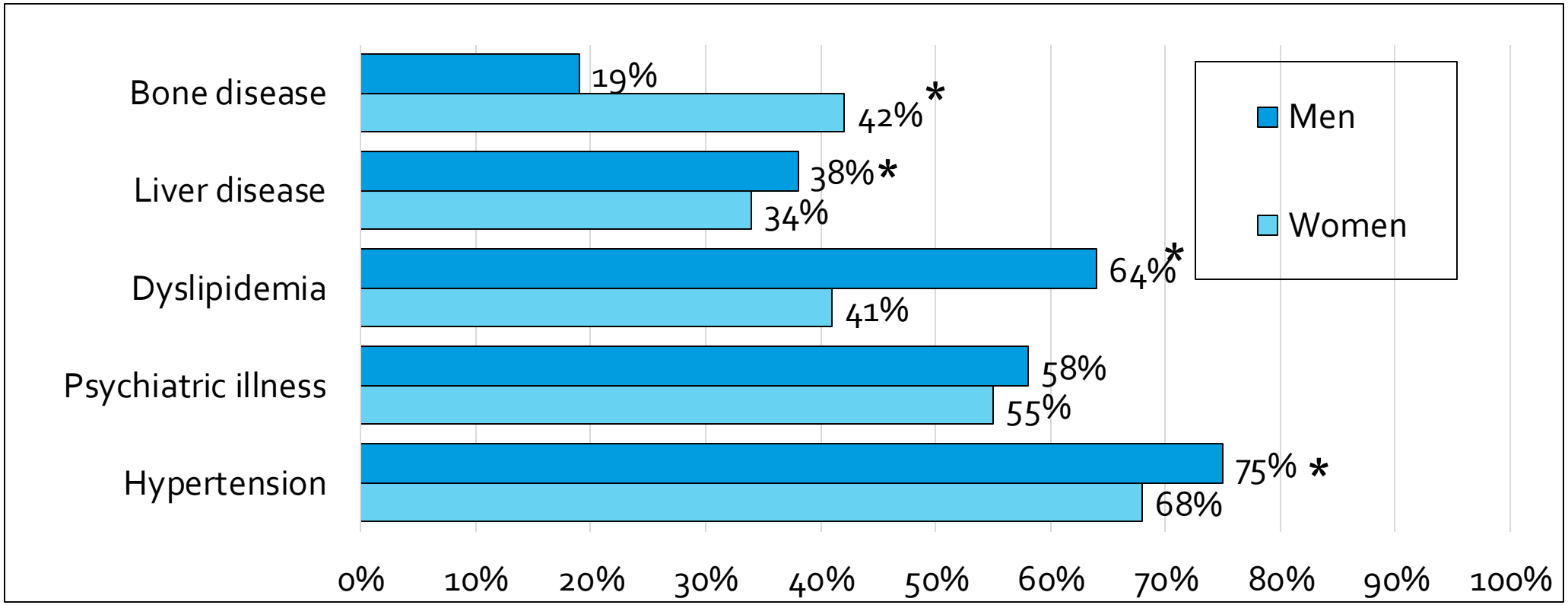
Prevalence of Non-AIDS Comorbidities Among Women and Men, 2019[1] – Part 1



[1] Collins, LF et al. JAMA Netw Open 2023 Aug 1;6(8):e2327584.

* Statistically significant difference in prevalence between men and women

Prevalence of Non-AIDS Comorbidities Among Women and Men, 2019[1] – Part 2



[1] Collins, LF et al. JAMA Netw Open 2023 Aug 1;6(8):e2327584.

* Statistically significant difference in prevalence between men and women

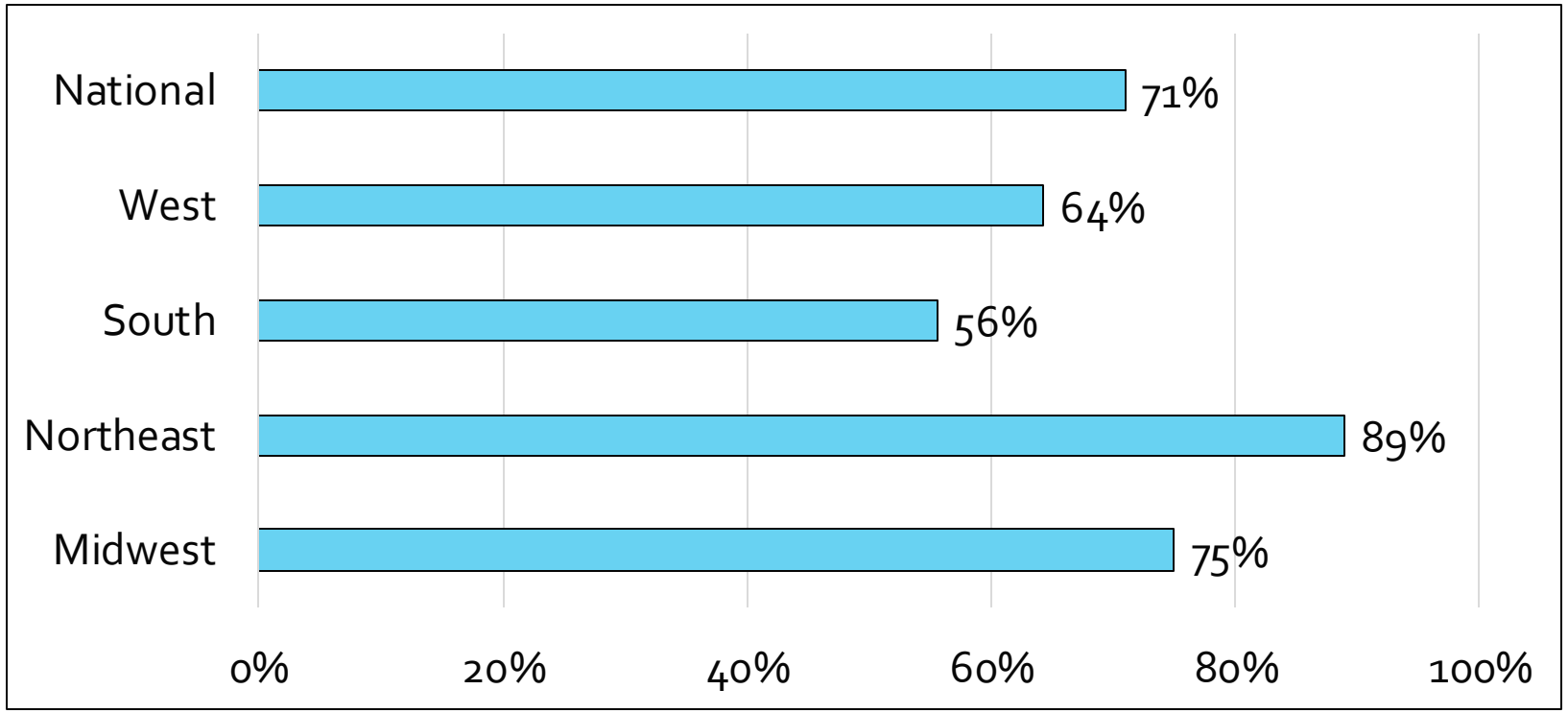
Why Cover Medications Related to Treating Co-morbidities Related to Aging?

- Increased comorbidity burden has negative consequences for people with HIV:
  - Reduced quality of life [1]
  - Premature mortality [1]
  - Increased health care utilization [1,2]- up to **5** times
  - Increased cost [2]- **$300-$5000** more per person-month for a person with HIV who has comorbidities than for a person with HIV who does not have comorbidities

[1] Rajasuriar R et al. AIDS. 2017;31(10):1393-1403.
[2] Gallant J et al. Curr Med Res Opin. 2018;34(1):13-23.

ADAP Formulary Coverage of Bronchodilator / Respiratory Inhalants, Nationally and by Region, 2023[1]

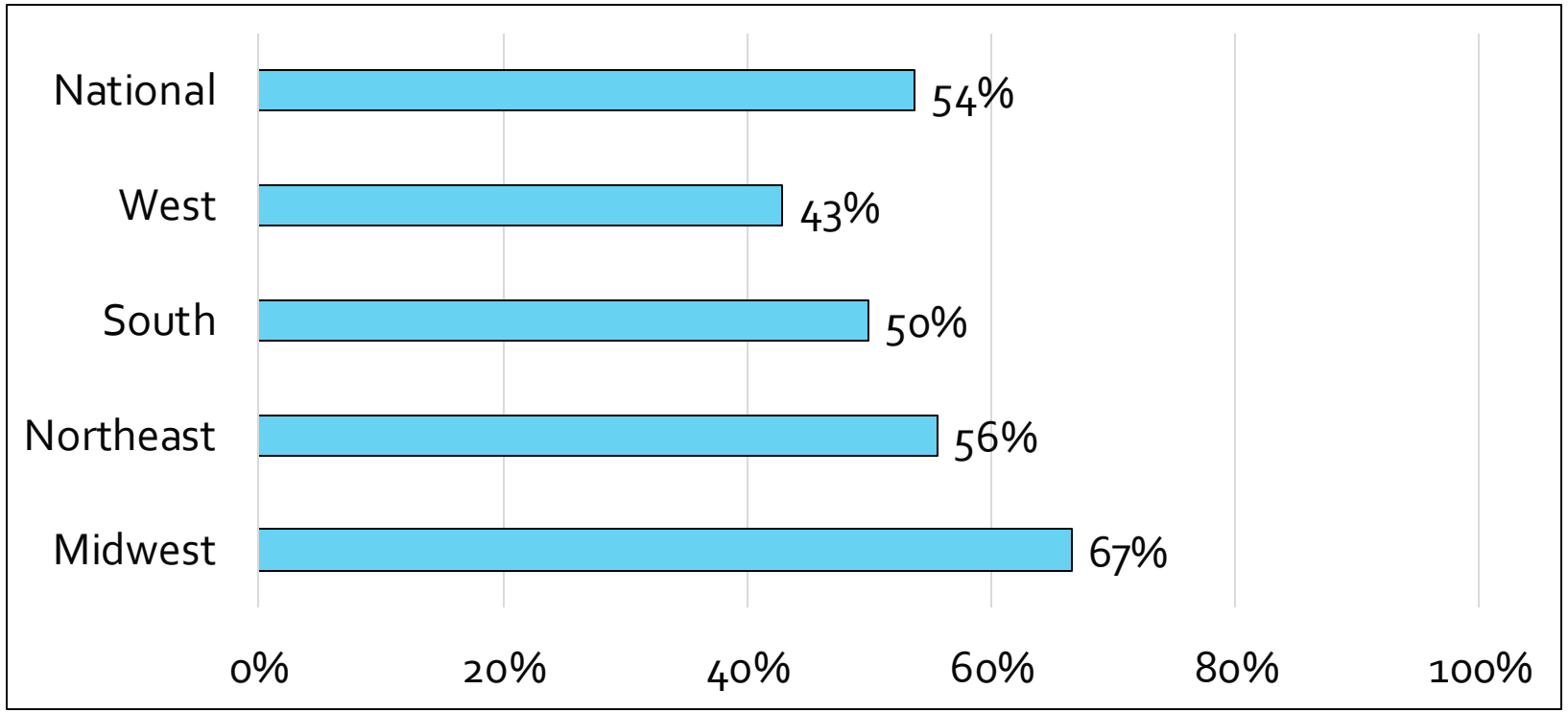
Formulary Decision Disproportionately Affects Women ADAP Clients



[1] NASTAD. 2023 National ADAP Formulary Database. 2023.

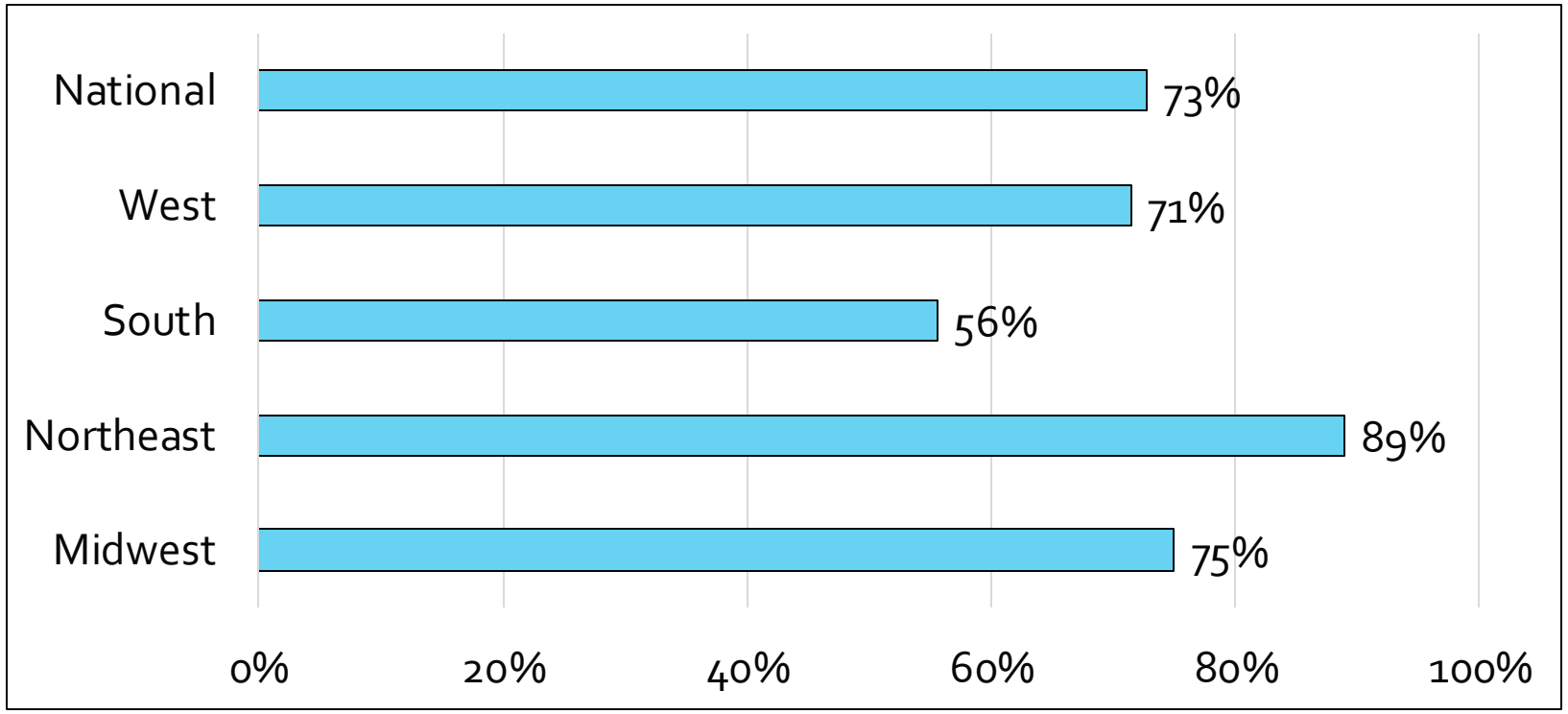
ADAP Formulary Coverage of Bisphosphonates, Nationally and by Region, 2023[1]

Formulary Decision Disproportionately Affects Women ADAP Clients



[1] NASTAD. 2023 National ADAP Formulary Database. 2023.

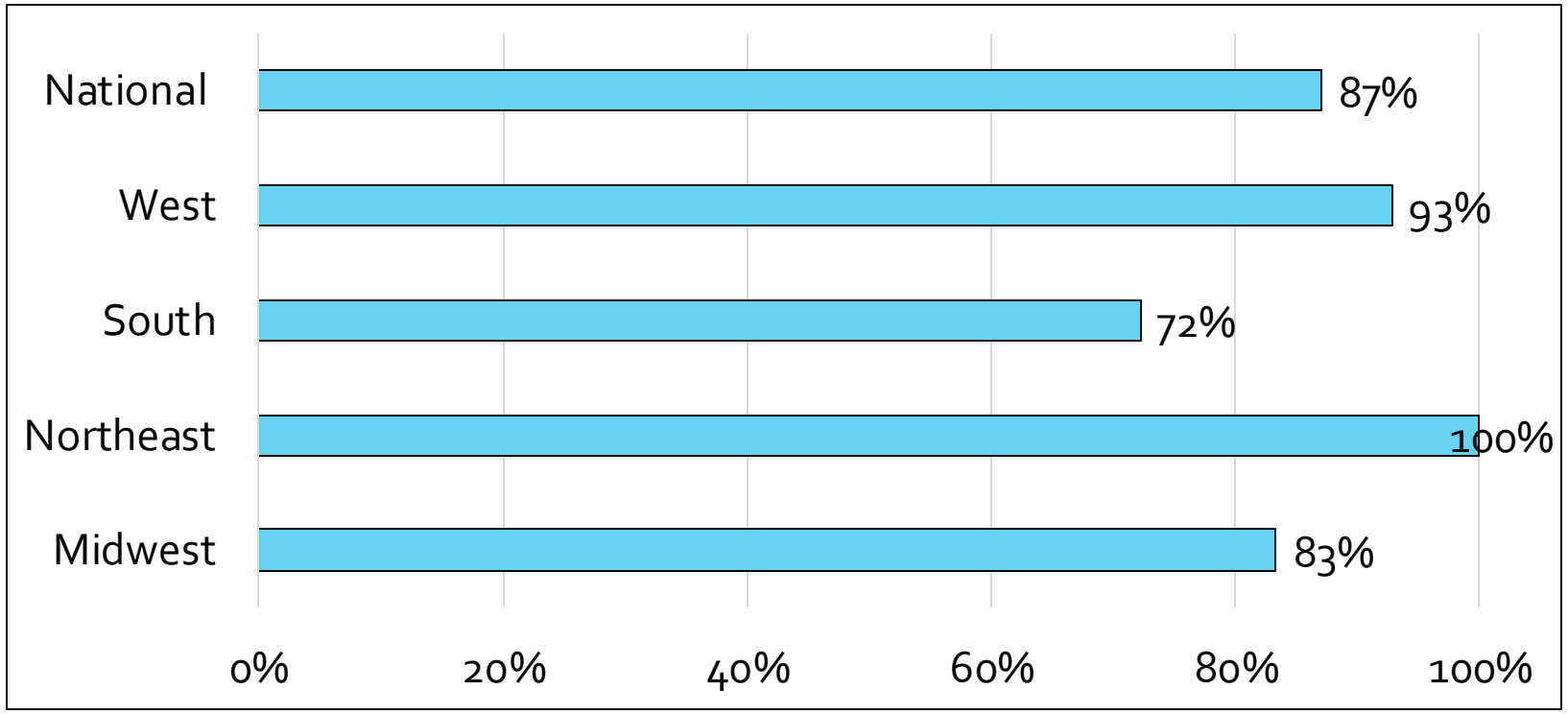
ADAP Formulary Coverage of Cardiac Medications[1], Nationally and by Region, 2023[2]



[1] Includes cardioselective beta-blockers and / or cardiovascular agents

[2] NASTAD. 2023 National ADAP Formulary Database. 2023.

ADAP Formulary Coverage of Metabolic Medications[1], Nationally and by Region, 2023[2]



[1] Includes cholesterol absorption inhibitors, hyperlipidemia medications, and insulin

[2] NASTAD. 2023 National ADAP Formulary Database. 2023.

ADAP Formulary Design and Incorporating Pharmacoequity

- Review ADAP client data to assess populations
- Assess formulary for access to medications for
  - Mental health
  - Substance use disorder and overdose prevention
  - Gender-affirming therapy
  - Comorbidities associated with aging with HIV
- Discuss available resources and medication cost-effectiveness to determine if medications can be added

ADAP Formulary Requirements and Allowances

RWHAP Legislation – Key Provisions

Section 2616(c) of the Public Health Service Act (42 U.S.C. 300ff-26(c)).

(a) IN GENERAL.— A State shall use a portion of the amounts provided under a grant awarded under section 2611 to establish a program under section 2612(b)(3)(B) to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.

RWHAP Legislation – Key Provisions (continued)

(c) STATE DUTIES.— In carrying out this section the State shall—

(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;

(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;

HRSA HAB Policies

An ADAP formulary must include at least one drug from each class of HIV antiretroviral medications

1. Nucleoside reverse transcriptase inhibitors
2. Non-nucleoside reverse transcriptase inhibitors
3. Protease inhibitors
4. Integrase strand transfer inhibitors
5. Fusion Inhibitors
6. CCR5 antagonists
7. CD4-directed post-attachment inhibitors
8. GP120-director attachment inhibitors
9. Capsid inhibitors

HHS. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv

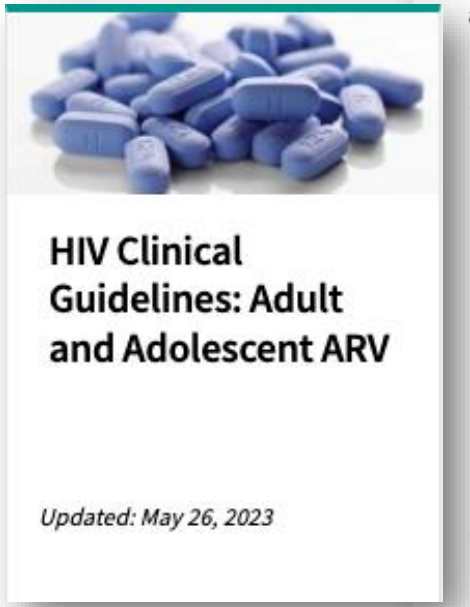
HRSA HAB Policies (continued – 1)

RWHAP funds may only be used to purchase medications approved by the U.S. Food and Drug Administration (FDA) and the devices needed to administer them

- May include FDA-approved prescription versions of medications available over-the-counter (e.g., acetaminophen)
- Supplements and vitamins coverage not allowable uses of federal funds

HRSA HAB Policies (continued – 2)

ADAP formulary must be consistent with the most recent HHS treatment guidelines



- The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) classifies the regimens below (in alphabetical order) as *Recommended Initial Regimens for Most People with HIV.*

For people with HIV who do not have a history of using long-acting cabotegravir (CAB-LA) as pre-exposure prophylaxis (PrEP), the following regimens are recommended:

- Bictegravir/tenofovir alafenamide (TAF)/emtricitabine (FTC) **(AI)**[a]
- DTG/abacavir/3TC—**only** for individuals who are HLA-B*5701 negative and without chronic hepatitis B virus (HBV) coinfection **(AI)**
- DTG plus (TAF or tenofovir disoproxil fumarate [TDF])[b] plus (FTC or 3TC) **(AI)**
- DTG/3TC **(AI)**—except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or when ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available

For people with HIV and a history of using CAB-LA as PrEP, INSTI genotypic resistance testing should be done before the start of ART. If treatment is begun prior to results of genotypic testing, the following regimen is recommended:

- Boosted darunavir plus (TAF or TDF)[b] plus (FTC or 3TC)—pending the results of the genotype test **(AIII).**

HHS. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv

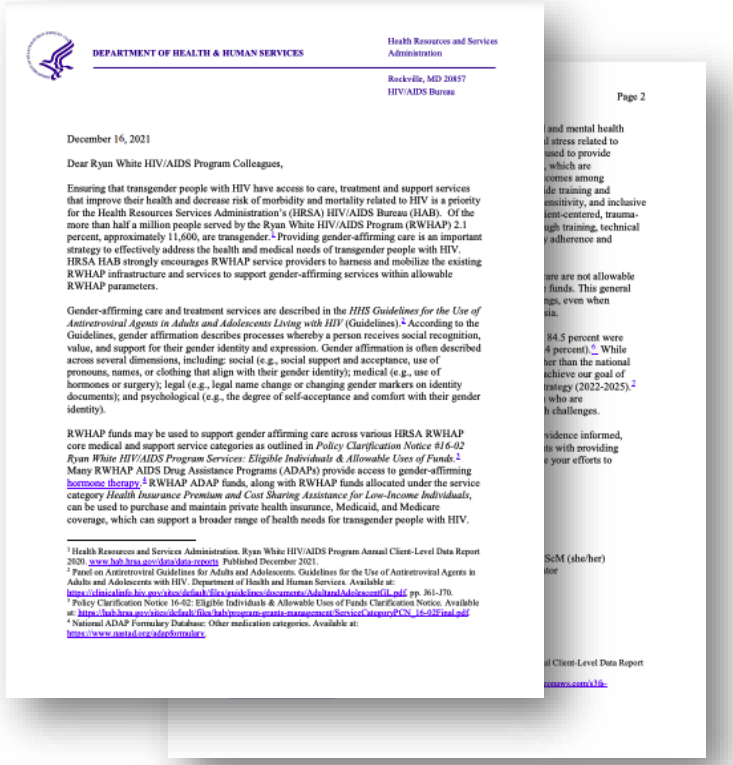
HRSA HAB Policies (continued – 3)

All formulary medications and ADAP-funded services must be equally and consistently available to all eligible enrolled people throughout the state or territory

- Access to medicines on ADAP formulary must be equitable for all clients

Each ADAP determines the composition of its medication formulary, which may also include vaccines and medications for the prevention and treatment of opportunistic infections, and for the treatment of chronic medical and mental health conditions, including co-morbidities such as hepatitis

HRSA HAB Program Letters of Interest



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
HIV/AIDS Bureau

December 16, 2021

Dear Ryan White HIV/AIDS Program Colleagues,

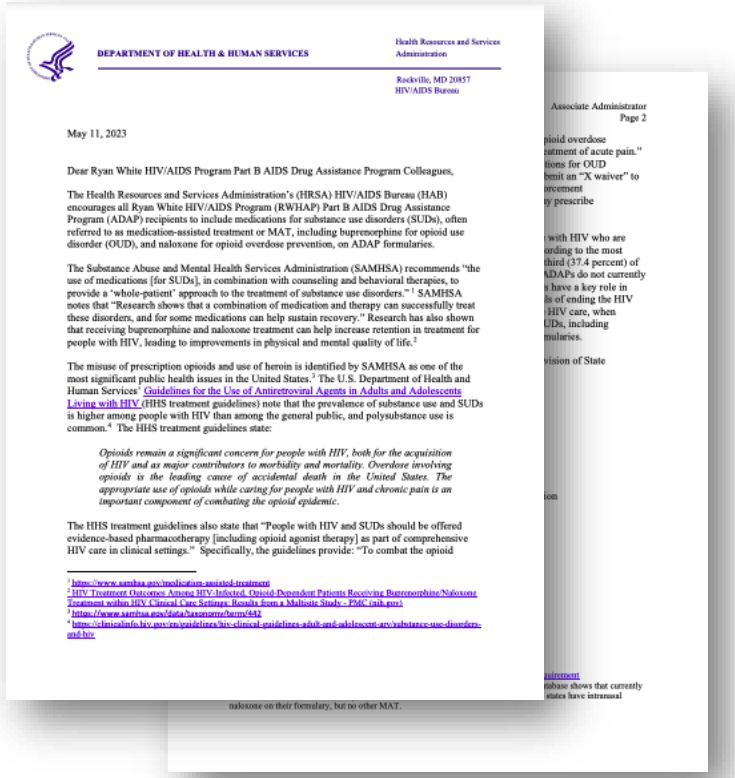
Ensuring that transgender people with HIV have access to care, treatment and support services that improve their health and decrease risk of morbidity and mortality related to HIV is a priority for the Health Resources Services Administration's (HRSA) HIV/AIDS Bureau (HAB). Of the more than half a million people served by the Ryan White HIV/AIDS Program (RWHAP) 2.1 percent, approximately 11,600, are transgender.[1] Providing gender-affirming care is an important strategy to effectively address the health and medical needs of transgender people with HIV. HRSA HAB strongly encourages RWHAP service providers to harness and mobilize the existing RWHAP infrastructure and services to support gender-affirming services within allowable RWHAP parameters.

Gender-affirming care and treatment services are described in the *HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (Guidelines).[2] According to the Guidelines, gender affirmation describes processes whereby a person receives social recognition, value, and support for their gender identity and expression. Gender affirmation is often described across several dimensions, including: social (e.g., social support and acceptance, use of pronouns, names, or clothing that align with their gender identity); medical (e.g., use of hormones or surgery); legal (e.g., legal name change or changing gender markers on identity documents); and psychological (e.g., the degree of self-acceptance and comfort with their gender identity).

RWHAP funds may be used to support gender affirming care across various HRSA RWHAP core medical and support service categories as outlined in *Policy Clarification Notice #16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*.[3] Many RWHAP AIDS Drug Assistance Programs (ADAPs) provide access to gender-affirming hormone therapy.[4] RWHAP ADAP funds, along with RWHAP funds allocated under the service category *Health Insurance Premium and Cost Sharing Assistance for Low-Income Individuals*, can be used to purchase and maintain private health insurance, Medicaid, and Medicare coverage, which can support a broader range of health needs for transgender people with HIV.

[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2020. www.hab.hrsa.gov/data/data-reports Published December 2021.
[2] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultAndAdolescentGL.pdf pp. J61-J70.
[3] Policy Clarification Notice 16-02: Eligible Individuals & Allowable Uses of Funds Clarification Notice. Available at: https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf
[4] National ADAP Formulary Database: Other medication categories. Available at: https://www.nastad.org/aidsformulary.

Gender-Affirming Care in RWHAP



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
HIV/AIDS Bureau

May 11, 2023

Dear Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Program Colleagues,

The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) encourages all Ryan White HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Program (ADAP) recipients to include medications for substance use disorders (SUDs), often referred to as medication-assisted treatment or MAT, including buprenorphine for opioid use disorder (OUD), and naloxone for opioid overdose prevention, on ADAP formularies.

The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends "the use of medications [for SUDs], in combination with counseling and behavioral therapies, to provide a 'whole-patient' approach to the treatment of substance use disorders."[1] SAMHSA notes that "Research shows that a combination of medication and therapy can successfully treat these disorders, and for some medications can help sustain recovery."[2] Research has also shown that receiving buprenorphine and naloxone treatment can help increase retention in treatment for people with HIV, leading to improvements in physical and mental quality of life.[3]

The misuse of prescription opioids and use of heroin is identified by SAMHSA as one of the most significant public health issues in the United States.[3] The U.S. Department of Health and Human Services' Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (HHS treatment guidelines) note that the prevalence of substance use and SUDs is higher among people with HIV than among the general public, and polysubstance use is common.[4] The HHS treatment guidelines state:

> *Opioids remain a significant concern for people with HIV, both for the acquisition of HIV and as major contributors to morbidity and mortality. Overdose involving opioids is the leading cause of accidental death in the United States. The appropriate use of opioids while caring for people with HIV and chronic pain is an important component of combating the opioid epidemic.*

The HHS treatment guidelines also state that "People with HIV and SUDs should be offered evidence-based pharmacotherapy [including opioid agonist therapy] as part of comprehensive HIV care in clinical settings."[4] Specifically, the guidelines provide: "To combat the opioid

[1] https://www.samhsa.gov/medication-assisted-treatment
[2] HIV Treatment Outcomes Among HIV-Infected, Opioid-Dependent Patients Receiving Buprenorphine/Naloxone Treatment within HIV Clinical Care Settings: Results from a Multisite Study - PMC (nih.gov)
[3] https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2020-NSDUH-tables
[4] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/substance-use-disorders-and-hiv

Substance Use Disorders

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
HIV/AIDS Bureau

April 26, 2023

Dear Ryan White HIV/AIDS Program Colleagues:

As sexually transmitted infections (STIs), including the recent mpox outbreak, continue to have a disproportionate impact on people with HIV, the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau's (HAB) Ryan White HIV/AIDS Program (RWHAP) plays a critical role in addressing STIs for people with HIV. This includes access to treatment for STIs through RWHAP AIDS Drug Assistance Program (ADAP) formularies.

ADAPs ensure that eligible people with HIV can access medications that improve individual health outcomes and reduce HIV transmission. Similarly, affordable access to STI treatment decreases the potential for STI transmission. While many ADAP formularies may already provide access to medications used to treat STIs, ADAPs are encouraged to review their formulary to ensure that all preferred and second line medications recommended in the STI treatment guidelines are included, especially in jurisdictions with higher STI prevalence.

The 2022-2025 National HIV/AIDS Strategy (NHAS)[1] identifies HIV and STIs as syndemic conditions that adversely interact with each other and contribute to a greater impact of disease and ongoing health disparities and inequities. Rates of STIs are higher among people with HIV than people without HIV, and people with HIV who have one or more STI are more likely to transmit HIV to a partner. Furthermore, people without HIV with one or more STIs are more likely to contract HIV.[2] Overall, STI rates have increased across the U.S. since 2017, posing an alarming risk both for people with HIV and for new HIV infections,[3] especially impacting NHAS priority populations including communities of color, men who have sex with men (MSM), heterosexual women, and youth.[4]

Per the RWHAP statute, RWHAP recipients and subrecipients are required to follow the federally approved HIV clinical practice guidelines, including the Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV, which cover the treatment of STIs. In addition, the 2021 STI Treatment Guidelines[5] from the Centers for Disease Control and Prevention (CDC) include updated treatment recommendations and expanded risk factor-based testing for select STIs. When implemented as recommended, the revised guidelines can reduce barriers to STI treatment, decrease transmission rates, and improve cure rates.

[1] National HIV/AIDS Strategy for the United States 2022-2025
[2] Sexually transmitted infections and HIV in the era of antiretroviral treatment and prevention: the biologic basis for epidemiologic synergy.
[3] https://www.cdc.gov/nchhstp/stdfact-std-hiv-detailed.htm
[4] National HIV/AIDS Strategy for the United States 2022-2025
[5] CDC Releases 2021 STI Treatment Guidelines

Sexually Transmitted Infections and Mpox

https://ryanwhite.hrsa.gov/grants/program-letters

Questions and Discussion

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