



Table of Contents

Performance Measure: ADAP Application Determination	2
Performance Measure: ADAP Eligibility Recertification	5
Performance Measure: ADAP Formulary	8
Performance Measure: ADAP Inappropriate Antiretroviral Regimen Components Resolved by ADAP	10



Performance Measure: ADAP Application Determination

National Quality Forum #: None

Description: Percent of ADAP applications¹ approved or denied for new ADAP enrollment² within 14 days (two weeks) of ADAP receiving a complete application in the measurement year

Numerator: Number of applications that were approved or denied for new ADAP enrollment¹ within 14 days (two weeks) of ADAP receiving a complete application in the measurement year

Denominator: Total number of complete ADAP applications for new ADAP enrollment² received in the measurement year

Exclusions:

1. ADAP applications for new ADAP enrollment² that were incomplete or incorrectly filled out.
2. Complete ADAP applications for new ADAP enrollment² received by ADAP within the last 14 days (two weeks) of the measurement year.

Data Elements:

1. Did the client apply for new ADAP enrollment² during the measurement year? (Y/N)
 - a. If yes, was a determination on the application made by the ADAP program? (Y/N)
 - i. If yes, list the date of receipt of the complete application and date of approval or denial.

Data Source: AIDS Drug Assistance Program Quarterly Data Report

National Goals, Targets, or Benchmarks for Comparison:

Part B Collaborative³: 97%

Part B Low Incidence Initiative⁴: 100%

Basis for Selection:

Timely review for ADAP eligibility can ensure timely access to medications. This quality measure has been used by the Part B Collaborative and Low Incidence Initiative to measure performance and to develop successful improvement projects to decrease the length of time to determine ADAP eligibility or ineligibility by the ADAP program.



U.S. Public Health Service Guidelines: This measure addresses the intent of HHS Treatment Guidelines for the use of antiretroviral agents and the prevention and treatment of opportunistic infections in HIV-infected individuals.⁵⁻⁹

References/Notes:

¹ Includes applications for all individuals, regardless of age.

² New ADAP enrollment “refers to individuals who applied to ADAP for the first time ever.... [This does not] include individuals who have been recertified as eligible or individuals who have been reinstated as enrolled clients after a period of having been decertified. Examples of clients who should **not** be included [as a new ADAP enrollment] are the following: 1) clients who have moved out of the State and then returned; and 2) clients who move on and off ADAP because of fluctuations in eligibility for a Medicaid/Medically Needy program, based on whether they met spend down requirements.”

[Source: “Instructions for Completing The Drug Assistance Program Quarterly Data Report”. Available at: TargetHIV.org Accessed May 8, 2019.

[HRSA’s Ryan White HIV/AIDS Program Part B: AIDS Drug Assistance Program](#)

[TargetHIV.org ADAP](#)

³ Part B Collaborative measure reads: “Percent of ADAP applicants approved or denied for ADAP enrollment within two weeks of ADAP receiving a complete application”.

⁴ Part B Low Incidence Initiative measure reads: “Percent of applying state ADAP clients approved/denied for ADAP services within two weeks of ADAP receiving a complete application”.

⁵ 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 [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV](#) . Accessed May 10, 2019.

⁶ Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#). Accessed May 10, 2019

⁷ Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United



States. Available at [Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States](#). Accessed May 10, 2019.

- 8 Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. MMWR 2009;58(No. RR-4): 1-216. Available at: [Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents](#). Accessed May 10, 2019.
- 9 Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at [Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children](#). Accessed May 10, 2019.



Performance Measure: ADAP Eligibility Recertification

National Quality Forum #: None

Description: Percentage of ADAP enrollees¹ who are reviewed for continued ADAP eligibility² two or more times in the measurement year.

Numerator: Number of ADAP enrollees who are reviewed for continued ADAP eligibility² at least two or more times which are at least 150 days apart in the measurement year.

Denominator: Number of clients enrolled in ADAP³ in the measurement year.

Patient Exclusions:

1. Clients approved for new ADAP enrollment in the measurement year.
2. Clients terminated from ADAP in the first 180 days of the measurement year

Data Element:

1. Was the client enrolled in ADAP during the measurement year? (Y/N)
 - a. If yes, was the client reviewed for continued ADAP eligibility¹ two or more times at least 150 days apart during the measurement year? (Y/N)
 - i. If yes, list the dates of review.

Data Sources: AIDS Drug Assistance Program Quarterly Report

National Goals, Targets, or Benchmarks for Comparison: Part B Collaborative⁴: 92%

Basis for Selection:

The Ryan White HIV Treatment Modernization Act of 2006 (P.L. 109-415)⁵ requires that the Ryan White HIV/AIDS Program be the payor of last resort. HAB Policy 07-03 specifies that “grantees must be capable of providing the HAB with documentation related to the use of funds as payor of last resort and the coordination of such funds with other local, State and Federal funds.⁶”



U.S. Public Health Service Guidelines: This measure addresses the intent of HHS Treatment Guidelines for the use of antiretroviral agents and the prevention and treatment of opportunistic infections in HIV infected individuals.⁷⁻¹¹

References/Notes:

- ¹ Includes all individuals, regardless of age.
- ² “Review for continued ADAP enrollment” (recertification) is a process for “confirming that a client receiving ADAP funded services is still eligible to receive those services.” Verification of ADAP eligibility includes verification of third party payor sources, such as Medicaid and Medicare. [Source: “Instructions for Completing The Drug Assistance Program Quarterly Data Report”. “[AIDS DRUG ASSISTANCE PROGRAM DATA REPORT \(ADA\) INSTRUCTION MANUAL 2018](#)”. Accessed May 2019.
- ³ Clients enrolled in ADAP: Refers to “the total number of individuals who are enrolled or certified as eligible to receive medications in...ADAP, regardless of whether they used ADAP services. “[AIDS Drug Assistance Program Data Report Instruction Manual 2018](#)”. Accessed May 2019.
- ⁴ Part B Collaborative measure reads: “Percent of ADAP enrollees recertified for ADAP eligibility criteria at least annually”.
- ⁵ [The Ryan White HIV Treatment Modernization Act of 2006](#) (P.L. 109-415), Section 202(a).
- ⁶ HRSA/HAB, Policy Notice-07-03, “[The Use of Ryan White HIV/AIDS Program, Part B \(formerly Title II\), AIDS Drug Assistance Program \(ADAP\) Funds for Access, Adherence and Monitoring Services](#)”, September 2007.
- ⁷ 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](#). Accessed May 2019.
- ⁸ Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#). Accessed May 2019
- ⁹ Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. [Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States](#). Accessed May 2019.



- 10 Centers for Disease Control and Prevention. [Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents](#). MMWR 2009; 58(No. RR-4): 1-216. Accessed May 2019.
- 11 Panel on Opportunistic Infections in HIV-Exposed Children. [Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children](#). Department of Health and Human Services. Accessed May 2019.



Performance Measure: ADAP Formulary

National Quality Forum #: None

Description: Percentage of new anti-retroviral classes that are included in the ADAP formulary within 90 days of the date of inclusion of new anti-retroviral classes in the PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents¹ during the measurement year.

Numerator: Number of new anti-retroviral classes included into the ADAP formulary within 90 days of the publication of updated PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents that include new anti-retroviral drug class during the measurement year.

Denominator: Total number of new antiretroviral classes published in updated PHS Guidelines during the measurement year.

Exclusions: PHS Guidelines for the Use of Antiretroviral Agents in HIV-1 infected Adults and Adolescents published in the last 90 days of the measurement year.

Data Elements:

1. Did the updated PHS Guidelines for the Use of Antiretroviral Agents in HIV-1infected Adults and Adolescents include any new anti-retroviral classes? (Y/N)

a. If yes, (for each new class) was the new class included into the ADAP formulary within 90 days of publication of updated PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents? (Y/N)

i. If yes, list the date of publication of PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents and date of inclusion in the ADAP formulary.

Data Sources:

- AIDS Drug Assistance Program Quarterly Data Report
- PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents

National Goals, Targets, or Benchmarks for Comparison: None available at this time



Basis for Selection:

The Ryan White HIV Treatment Modernization Act of 2006 (P.L. 109-415)² mandates that the state-operated ADAP programs “shall 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”. All ADAPs must include agents from each of the core antiretroviral classes listed in PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents^{3, 4}. These legislative and policy requirements have also been specified in the Part B ADAP Grant Application⁵.

U.S. Public Health Service Guidelines: US Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents¹ contains the list of classes of core antiretroviral therapeutics to be included in ADAP formularies. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV¹

References/Notes:

¹ 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](#). Accessed May 2019.

² [The Ryan White HIV Treatment Modernization Act of 2006 \(P.L. 109-415\), Section 202\(a\)](#).

³ HRSA/HAB, Policy Notice-07-03, “[The Use of Ryan White HIV/AIDS Program, Part B \(formerly Title II\), AIDS Drug Assistance Program \(ADAP\) Funds for Access, Adherence and Monitoring Services](#)”, September 2007. Accessed May 2019.

⁴ Deborah Parham Hopson, Ph.D., R.N., Assistant Surgeon General, Associate Administrator, HIV/AIDS Bureau, HRSA letter to Part B Grantees, February 1, 2008. HRSA/HAB Division of Service Systems Program Guidance: HIV Care Grant Program Part B: States/Territories Formula and Supplemental Awards and AIDS Drug Assistance Program Formula and Supplemental Awards, HRSA Announcement Numbers: HRSA 09-182 and 09-183.



Performance Measure: ADAP Inappropriate Antiretroviral Regimen Components Resolved by ADAP

National Quality Forum #: None

Description: Percent of identified inappropriate antiretroviral (ARV) regimen components prescriptions that are resolved by the ADAP program during the measurement year.

Numerator: Number of antiretroviral (ARV) regimen components prescriptions included in the US Public Health Service Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time”¹ and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”² that are resolved by the ADAP program during the measurement year.

Denominator: Number of inappropriate antiretroviral (ARV) regimen components prescriptions included in the US Public Health Service Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time”¹ and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”² that are identified by ADAP.

Patient Exclusions: For ADAP clients with multiple sources of funding for their medications, the ADAP program is responsible for identifying only ARV regimen components funded by ADAP.

Data Elements:

1. Was the prescribed antiretroviral (ARV) regimen components included in the US Public Health Service Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time”¹ and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”² identified by the ADAP program during the measurement year? (Y/N)
 - a. If yes, specify the components, the prescribing clinician and client.
 - b. In response to the ADAP program contacting the prescribing clinician, was the ARV regimen components prescription subsequently modified by the prescribing clinician to an ARV regimen components that is not included the US Public Health Service Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time”¹ and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”² or was the ARV regimen components clinically justified by the prescribing clinician? (Y/N)

Data Sources: ADAP Data Systems



National Goals, Targets, or Benchmarks for Comparison: None Available at this time

Basis for Selection and Placement: The US Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection specify antiretroviral regimens or components are not generally recommended because of suboptimal antiviral potency, unacceptable toxicities, or pharmacologic concerns.^{1, 2} ADAP programs are included as core medical services funded by the Ryan White HIV/AIDS Program, and are therefore, required to provide care and treatment consistent with PHS guidelines.

U.S. Public Health Service Guidelines:

Some antiretroviral regimens or components are not generally recommended because of suboptimal antiviral potency, unacceptable toxicities or pharmacologic concerns.

Adult and Adolescent Patients: Antiretroviral Regimens or Components That Should Not Be Offered At Any Time¹:

- Delavirdine (DLV)
- Didanosine (ddI)
- Indinavir (IDV)
- Nelfinavir (NFV)
- Stavudine (d4T)
- Monotherapy Regimens
- Dual-NRTI Regimens
- Triple-NRTI Regimens
- Atazanavir plus Indinavir
- Cobicistat plus Ritonavir as Pharmacokinetic Enhancers
- Didanosine plus Stavudine
- Didanosine plus Tenofovir Disoproxil Fumarate
- Two Non- Nucleoside Reverse Transcriptase Inhibitor Combinations
- Emtricitabine plus Lamivudine
- Etravirine plus Unboosted Protease Inhibitor
- Etravirine plus Fosamprenavir/Ritonavir
- Nevirapine Initiated in ARV-Naïve Women with CD4 Counts >250cells/mm³ or in ARV-Naïve Men with CD4 Counts >400cells/mm³
- Unboosted Darunavir, Saquinavir, or Tipranavir
- Stavudine plus Zidovudine
- Tenofovir Alafenamide plus Tenofovir Disoproxil Fumarate



Antiretroviral Therapy Regimens or Components Not Recommended for Initial Treatment of HIV infection in Children ²:

- Unboosted ATV- containing regimens in children
 - Rationale- Reduced Exposure
- BIC-based regimens
 - Rationale- Insufficient data to recommend
- Once-daily DRV- based regimens in children aged ≥ 3 years to 12 years
 - Rationale- Insufficient data to recommend
- Unboosted DRV
 - Rationale- Use without RTV has not been studied
- Dual (full-dose) PI regimens
 - Rationale- Insufficient data to recommend and potential for added toxicities
- Dual-NRTI combination of ABC plus TDF
 - Rationale- Insufficient data to recommend
- EFV-based regimens for children aged < 3 years
 - Rationale- Appropriate dose not determined
- ETR- based regimens
 - Rationale- Insufficient data to recommend
- LPV/r dosed once daily
 - Rationale- Reduced drug exposure
- MVC-based regimens
 - Rationale Insufficient data to recommend
- Regimens containing three drug classes
 - Rationale- Insufficient data to recommend
- Regimens containing only NRTIs
 - Inferior virologic efficacy
- Full-dose RTV or use of RTV as the sole PI
 - Rationale- GI intolerance and metabolic toxicity
- Regimens containing three NRTIs and one NNRTI
 - Rationale- Added cost and complexity outweighs any benefit
- TDF-containing regimens in children aged < 2 years
 - Rationale- Potential bone toxicity and appropriate dose has yet to be determined



Antiretroviral Therapy Regimens of Components Never Recommended for Treatment of HIV Infection in Children ²:

- One ARV Drug Alone (Monotherapy)
 - Exception Infants with perinatal HIV exposure and negative virologic tests who are receiving 4 weeks and 6 weeks of ZDV prophylaxis to prevent perinatal transmission of HIV
- Two NRTIs Alone
 - Not recommended for initial therapy
 - Some clinicians may opt to continue this treatment in patients who are currently on two NRTIs alone and who achieve virologic goals
- TDF plus ABC plus (3TC or FTC) as a Triple-NRTI Regimen
 - No exceptions
- TDF plus ddI plus (3TC or FTC) as a Triple-NRTI Regimen
 - No exceptions
- Dual-NNRTI Combinations
 - No exceptions
- Dual-NRTI Combination 3TC plus FTC
 - No exceptions
- Dual-NRTI Combination d4T plus ZDV
 - No exceptions
- NVP as Initial Therapy in Adolescent Girls with CD4 Cell Counts >250 cells/mm³ or Adolescent Boys with CD4 Cell Counts >400 cells/mm³
 - Only if benefit clearly outweighs risk

References/Notes:

¹ 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. Accessed May 17, 2019. (G-1 to G-2).

³ Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. [Guidelines for the Use of Retroviral Agents in Pediatric HIV Infection](#). Accessed May 17, 2019 (G-27 to G-28).

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