

Performance Measure: ADAP: Application Determination

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 enrollment ¹ 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 enrollment ² received in the measurement year	
Exclusions:	 ADAP applications for new ADAP enrollment² that were incomplete or incorrectly filled out. Complete ADAP applications for new ADAP enrollment² received by ADAP within the last 14 days (two weeks) of the measurement year. 	
Data Element:	 Did the client apply for new ADAP enrollment² during the measurement year? (Y/N) If yes, was a determination on the application made by the ADAP program? (Y/N)	
Data Sources:	AIDS Drug Assistance Program Quarterly Data Report	
National Goals, Targets, or Benchmarks for Comparison:	Part B Collaborative ³ : 97% Part B Low Incidence Initiative ⁴ : 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.

US 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.

²New 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

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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 <u>ftp://ftp.hrsa.gov/hab/ADAP%20Instructions_Final%20_Feb%2022_08_.pdf</u>. Accessed July 17, 2009.]

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 HIV-1-infected adults and adolescents. Department of Health and Human Services. December 1, 2009; 1-161.. Available at <u>http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf</u>. Accessed December 7, 2009.

⁶ Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. February 23, 2009; pp 47. Available at <u>http://aidsinfo.nih.gov/ContentFiles/PediatricGuidelines.pdf.</u> Accessed September 9, 2009.

⁷ Perinatal HIV Guidelines Working Group. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. April 29, 2009; pp 1-90. Available at http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf. Accessed September 9, 2009.

⁸ 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. Available at: <u>http://www.cdc.gov/mmwr/pdf/rr/rr5804.pdf</u>. Accessed September 9, 2009.

⁹ Centers for Disease Control and Prevention. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. MMWR 2009;58(No. RR-11): 1-176. Available at: <u>http://aidsinfo.nih.gov/contentfiles/Pediatric_OI.pdf.</u> Accessed September 9, 2009.

Performance Measure: ADAP: Eligibility Recertification

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 eligibility ² at least two or more times which are at least 150 days apart in the measurement year.	
Denominator:	Number of clients enrolled in ADAP ³ in the measurement year.	
Patient Exclusions:	 Clients approved for new ADAP enrollment in the measurement year. Clients terminated from ADAP in the first 180 days of the measurement year. 	
Data Element:	 Was the client enrolled in ADAP during the measurement year? (Y/N) 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) If yes, list the dates of review. 	
Data Sources:	AIDS Drug Assistance Program Quarterly Data Report, Section 2: Annual Submission	
National Goals, Targets, or Benchmarks for Comparison:	Part B Collaborative ⁴ : 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"

US 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:

¹Includes all individuals, regardless of age.

² "Review for continued ADAP enrollment" (recertification) is a process for "confirming that a client receiving ADAPfunded 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". Available at

ftp://ftp.hrsa.gov/hab/ADAP%20Instructions_Final%20_Feb%2022_08_.pdf, page 20. Accessed July 17, 2009.]

³Clients 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. [Source: "Instructions for Completing The Drug Assistance Program Quarterly Data Report". Available at

Performance Measure: ADAP: Eligibility Recertification

ftp://ftp.hrsa.gov/hab/ADAP%20Instructions Final%20 Feb%2022 08 .pdf. Accessed July 17, 2009.]

⁴ Part B Collaborative measure reads: "Percent of ADAP enrollees recertified for ADAP eligibility criteria at least annually".

⁵The Ryan White HIV Treatment Modernization Act of 2006 (P.L. 109-415), Section 202(a).

⁶HRSA/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 HIV-1-infected adults and adolescents. Department of Health and Human Services. December 1, 2009; 1-161.. Available at <u>http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf</u>. Accessed December 7, 2009.

⁸ Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. February 23, 2009; pp 47. Available at <u>http://aidsinfo.nih.gov/ContentFiles/PediatricGuidelines.pdf. Accessed September 9</u>, 2009.

⁹Perinatal HIV Guidelines Working Group. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. April 29, 2009; pp 1-90. Available at http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf. Accessed September 9, 2009.

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. Available at: <u>http://www.cdc.gov/mmwr/pdf/rr/rr5804.pdf</u>. Accessed September 9, 2009.

¹¹Centers for Disease Control and Prevention. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. MMWR 2009;58(No. RR-11): 1-176. Available at: <u>http://aidsinfo.nih.gov/contentfiles/Pediatric_OI.pdf.</u> Accessed September 9, 2009.

Performance Measure: ADAP: Formulary

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.

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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:	1. 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 Element:	 Did the updated PHS Guidelines for the Use of Antiretroviral Agents in HIV-1- infected 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.

US Public Health Service Guidelines:

US Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and

Performance Measure: ADAP: Formulary

Adolescents¹ contains the list of classes of core antiretroviral therapeutics to be included in ADAP formularies.

References/Notes:

¹ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. December 1, 2009; 1-161.. Available at <u>http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf</u>. Accessed December 7, 2009.

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

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.

⁵ 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

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:	1. 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 Element:	 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.	

Performance Measure: ADAP: Inappropriate Antiretroviral Regimen Components Resolved by ADAP

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.

US Public Health Service Guidelines:

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

Components not recommended	Exceptions
Atazanavir + indinavir (AIII)	No exception
Didanosine + stavudine (AIII)	• When no other antiretroviral options are available and potential benefits outweigh the risks (BIII)
2-NNRTI combination (AII)	• No exception
Efavirenz in first trimester of pregnancy or in women with significant child-bearing potential (AIII)	• When no other antiretroviral options are available and potential benefits outweigh the risks (BIII)
Emtricitabine + lamivudine (AIII)	• No exception
Etravirine + Unboosted PI (AII)	No exception
Etravirine + ritonavir-boosted atazanavir or fosamprenavir (AII)	No exception
Etravirine + ritonavir-boosted tipranavir (AII)	No exception
Nevirapine in treament-naïve women with CD4 >250 or men with CD4 >400 (BI)	• If no other antiretroviral option available; if used patients should be closely monitored
Stavudine + zidovudine (AII)	• No exception
Unboosted darunavir, saquinavir, or tipranavir (AII)	No exception
Pediatric Patients: Antiretroviral Components Not Recomme	ended as Part of an Antiretroviral Regimen ²
Components not recommended	Exceptions
Atazanavir + indinavir	No exception
Dual NRTI combinations: • Lamivudine + Emtricitabine • Stavudine + Zidovudine • Stavudine + Didanosine	 No exception No exception May be considered for use in antiretroviral- experienced children who require therapy change
Efavirenz in first trimester of pregnancy or sexually active adolescent girls of childbearing potential.	• When no other antiretroviral options are available and potential benefits outweigh risks
Nevirapine initiation in adolescent girls with CD4 >250 cells/mm ³ or adolescent boys with CD4 >400 cells/mm ³	• Only if benefit clearly outweighs the risk
Unboosted saquinavir	• No exceptions

Performance Measure: ADAP: Inappropriate Antiretroviral Regimen Components Resolved by ADAP

References/Notes:

¹ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. December 1, 2009; 1-161.. Available at <u>http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf</u>. Accessed December 7, 2009.

² Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. February 23, 2009; pp 47. Available at http://aidsinfo.nih.gov/ContentFiles/PediatricGuidelines.pdf. Accessed September 9, 2009.