

## HAB HIV Performance Measures: ADAP: AIDS Drug Assistance Program

<b>Performance Measure: ADAP: Inappropriate Antiretroviral Regimen Components Resolved by ADAP</b>	
Percent of identified inappropriate antiretroviral (ARV) regimen components prescriptions that are resolved by the ADAP program during the measurement year.	
<b>Numerator:</b>	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” <sup>1</sup> and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children” <sup>2</sup> that are resolved by the ADAP program during the measurement year.
<b>Denominator:</b>	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” <sup>1</sup> and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children” <sup>2</sup> that are identified by ADAP.
<b>Patient Exclusions:</b>	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.
<b>Data Element:</b>	<ol style="list-style-type: none"> <li>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”<sup>1</sup> and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”<sup>2</sup> identified by the ADAP program during the measurement year? (Y/N)               <ol style="list-style-type: none"> <li>a. If yes, specify the components, the prescribing clinician and client.</li> <li>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”<sup>1</sup> and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children”<sup>2</sup> or was the ARV regimen components clinically justified by the prescribing clinician? (Y/N)</li> </ol> </li> </ol>
<b>Data Sources:</b>	<ul style="list-style-type: none"> <li>• ADAP data systems</li> </ul>
<b>National Goals, Targets, or Benchmarks for Comparison:</b>	None available at this time.

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#### 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.<sup>1,2</sup> 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 Time<sup>1</sup>

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 treatment-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 Recommended as Part of an Antiretroviral Regimen<sup>2</sup>

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 <sup>3</sup> or adolescent boys with CD4 >400 cells/mm <sup>3</sup>	• Only if benefit clearly outweighs the risk
Unboosted saquinavir	• No exceptions

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#### References/Notes:

<sup>1</sup> 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 <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed December 7, 2009.

<sup>2</sup> 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.