NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0406 NQF Project: Infectious Disease Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Jul 31, 2008 Most Recent Endorsement Date: Jul 31, 2008 Last Updated Date: Aug 23, 2012

BRIEF MEASURE INFORMATION

De.1 Measure Title: HIV/AIDS: Adolescent and Adult Patients who are Prescribed Potent Antiretroviral Therapy

Co.1.1 Measure Steward: National Committee for Quality Assurance

De.2 Brief Description of Measure: Percentage of patients with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit: aged 13 years and older who have a history of a CD4 count less than or equal to 500 cells/mm3; aged 13 years and older who have a history of an AIDS-defining illness, regardless of CD4 count; or who are pregnant, regardless of CD4 count or age, who were prescribed potent antiretroviral therapy

2a1.1 Numerator Statement: Patients who were prescribed potent antiretroviral* therapy

*Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials

- 2a1.4 Denominator Statement: A. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history of a CD4 count less than or equal to 500 cells/mm3; and
- B. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history an AIDS-defining illness**, regardless of CD4 count; and
- C. All patients with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who are pregnant, regardless of CD4 count or age.
- **The most commonly used case definition for AIDS is the 1993 Revised Surveillance Case Definition from the CDC. It includes: Candidiasis of bronchi, trachea, or lungs; candidiasis, esophageal; cervical cancer, invasive; coccidiodomycosis, disseminated or extrapulmonary; cryptococcosis, extrapulmonary; crytosporidiosis, chronic intestinal (greater than 1 month's duration); cytomegalovirus disease (other than liver, spleen, or nodes); cytomegalovirus retinitis (with loss of vision); encephalopathy, HIV-related; herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis; histoplasmosis, disseminated or extrapulmonary; isosporiasis, chronic intestinal (greater than 1 month's duration); Kaposi's sarcoma; lymphoma, Burkitt's (or equivalent term); lymphoma, immunoblastic (or equivalent term); lymphoma, primary, of brain; mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary; mycobacterium tuberculosis, any site (pulmonary or extrapulmonary); mycobacterium, other species or unidentified species, disseminated or extrapulmonary; pneumocystis carinii pneumonia; pneumonia, recurrent; progressive multifocal leukoencephalopathy; salmonella septicemia, recurrent; toxoplasmosis of brain; wasting syndrome due to HIV. (Aberg, 2009; National Center for Infectious Diseases Division of HIV/AIDS)

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

Note: For potent antiretroviral therapy recommendations refer to current DHHS quidelines available at www.aids.gov

Aberg JA, Kaplan JE, Libman H, Emmanuel P, Anderson JR, Stone VE, Oleske JM, Currier JS, Gallant JE; HIV Medicine Association of the Infectious Diseases Society of America. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2009 Sep 1;49(5):651-81. Available at

http://www.uphs.upenn.edu/bugdrug/antibiotic manual/idsahivprimarycare2009.pdf. Accessed May 25, 2012.

National Center for Infectious Diseases Division of HIV/AIDS. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMRW Recomm Rep. 1992;41(RR-17):1-19.

2a1.8 Denominator Exclusions: None

1.1 Measure Type: Process

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Laboratory, Electronic Clinical

Data: Pharmacy

2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):

N/A

STAFF NOTES (issues or questions regarding any criteria)
Comments on Conditions for Consideration:
Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (<i>check De.5</i>): 5. Similar/related endorsed or submitted measures (<i>check 5.1</i>): Other Criteria:
Staff Reviewer Name(s):
1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.

Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. Hi	gh Impact:	H	l M	L	

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Infectious Diseases, Infectious Diseases: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS)

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: A leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Approximately 1.2 million people in the U.S. age 13 and older are estimated to be living with HIV and as many as 20 percent of them are undiagnosed. (CDC, 2012) Despite strong efforts that have prevented significant increases in new cases of HIV/AIDS since 2006, an average of 50,000 people are newly infected each year, (CDC, Aug 2011) and although the number of deaths due to HIV/AIDS infection declined 7 percent from 2006-2009, (CDC, Feb 2011) it is still one of the top leading causes of death for black males and females and Hispanic/Latina females in the 35–44 age group. (CDC, 2012) These steady incidence rates and declining mortality rates mean more people than ever are living with HIV/AIDS; ensuring they receive recommended, high-quality care supports prevention efforts and significantly affects their ability to lead healthier lives. Preventing HIV and its related illness and death is a significant national health policy objective and 18 of the U.S. Healthy People 2020 goals are related to HIV prevention and treatment. (USDHHS, 2012)

Untreated HIV infection is characterized by progressive depletion of CD4 T lymphocyte (CD4) count leading to the development of AIDS-defining conditions, and more recent data suggest that HIV is also associated with an increased risk of serious non-AIDS diseases like cardiovascular, renal, and liver diseases, and cancers. (Babiker, et al., 2012) Significant declines in morbidity and mortality in the last twenty years due to AIDS are attributable to the use of intensive antiretroviral therapy (ART). (Palella, et al., 1998) Studies have found that starting ART early in a patient's diagnosis results in lower viral loads, higher CD4 counts, less AIDS progression, lower mortality, and less risk of developing a non-AIDS defining illness. (Zolopa, et al., 2009; Baker, et al., 2008) ART therapy for pregnant women is especially crucial as it can reduce mother-to-child transmission of HIV either by lowering plasma viral load in pregnant women or through post-exposure prophylaxis in their newborns. (Siegfried, et al., 2011) Providing appropriate ART for patients with HIV can significantly impact transmission and prevalence of the disease and reduce mortality. In addition, ART has been found to be highly cost-effective for patients with HIV/AIDS. (Walensky, et al. 2007)

1a.4 Citations for Evidence of High Impact cited in 1a.3: Babiker AG, Emery S, Fätkenheuer G, et al. Considerations in the rationale, design and methods of the Strategic Timing of AntiRetroviral Treatment (START) study. Clin Trials. 2012 Apr 30; Epub ahead of print.

Baker JV, Peng G, Rapkin J, et al. CD4+ count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS. 2008 Apr 23;22(7):841-8.

Centers for Disease Control and Prevention (CDC). HIV in the United States: At a Glance. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Division of HIV/AIDS Prevention. Last Updated March 12, 2012. Accessed May 14, 2012. http://www.cdc.gov/hiv/resources/factsheets/us.htm

Centers for Disease Control and Prevention (CDC). Estimates of New HIV Infections in the United States, 2006–2009. CDC Fact Sheet, August 2011. Accessed May 14, 2012. http://www.cdc.gov/nchhstp/newsroom/HIVIncidenceResources.html

Centers for Disease Control and Prevention (CDC). HIV Surveillance Report, 2009; vol. 21. Published February 2011. Accessed May 14, 2012. http://www.cdc.gov/hiv/surveillance/resources/reports/2009report/

Palella FJ Jr, Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. HIV Outpatient Study Investigators. N Engl J Med. 1998 Mar 26; 338(13):853-60.

Siegfried N, van der Merwe L, Brocklehurst P, Sint TT. Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection. Cochrane Database Syst Rev. 2011 Jul 6;(7):CD003510.

USDHHS. Healthy People 2020 Topics and Objectives Index. Last updated May 1, 2012. http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx.

Walensky RP, Freedberg KA, Weinstein MC, Paltiel, AD. Cost-Effectiveness of HIV Testing and Treatment in the United States. Clin Infect Dis. (2007) 45 (Supplement 4): S248-S254.

Zolopa A, Andersen J, Powderly W, et al. Early antiretroviral therapy reduces AIDS progression/death in individuals with acute opportunistic infections: a multicenter randomized strategy trial. PLoS One. 2009; 4(5):e5575. 1b. Opportunity for Improvement: H M L I (There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

Physicians provide antiretroviral therapy (ART) to patients to decrease plasma viral load, increase CD4 counts, and prevent disease progression and mortality. Researchers note that ART has dramatically reduced morbidity and mortality worldwide. (Wong, et al., 2012) In spite of this knowledge a recent literature review found that anywhere from 45 to 55 percent of patients with known HIV do not receive any medical care over a 12-month period (Gardner, et al., 2011). Ensuring higher use of ART can reduce morbidity and mortality due to HIV.

Gardner EM, McLees MP, Steiner JF, et al. The Spectrum of Engagement in HIV Care and its Relevance to Test-and-Treat Strategies for Prevention of HIV Infection. Clin Infect Dis. 2011 March 15; 52(6): 793–800.

Wong WC, Luk CW, Kidd MR. Early Mortality in Adults Initiating Antiretroviral Therapy (ART) in Low- and Middle-Income Countries (LMIC): A Systematic Review and Meta-Analysis. Sex Transm Infect. 2012 Mar; 88(2):125-31.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

CMS Physician Quality Reporting System:

This measure was used in the 2009 and 2010 CMS Physician Quality Reporting System (2011 data has been requested from CMS). For this measure, the average performance rate per eligible professional was 90.3% in 2009 and 97.2% in 2010. These numbers are based on a small numbers of providers (60 in 2009, 61 in 2010). Data from a much larger source, the HIVQUAL-US reporting program, indicate that there is a gap in care with room for improvement.

HIVQUAL-US is a program designed to improve care for people living with HIV/AIDS through quality improvement, performance measurement, and infrastructure/capacity building. It is funded through a cooperative agreement administered by the Health Resources & Services Administration's HIV/AIDS Bureau. Ryan White HIV/AIDS Part C and Part D Programs are eligible to participate. It has several viral load control measures, including: 1) last viral load undetectable or <200, among patients on antiretroviral therapy >12 weeks, and; 2) viral load always undetectable or <200, among patients on antiretroviral therapy >12 weeks.

There were 202 facilities that reported this measure in 2009 (covering 9,153 patients). The facility means were 75.2% and 64.2%, respectively.

1b.3 Citations for Data on Performance Gap: [For Maintenance - Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included Centers for Medicare & Medicaid Services. 2010 Reporting Experience: Including Trends (2007-2011). Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program. February 22, 2012. Accessed June 28, 2012. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/pgrs

JSI. HIVQUAL-US Performance Data Report. Ryan White Part C and Part D Funded Programs. October 2011. pp: 1-20.

1b.4 Summary of Data on Disparities by Population Group: [For Maintenance – Descriptive statistics for performance results for this measure by population group]

The measure is not stratified by patient groups or cohorts that could potentially be affected by disparities in care. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data is not coded in a standard manner and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, and employer) should capture and report this data. While "requiring" reporting of the data could push

the field forward, it has been our position that doing so would create substantial burden without generating meaningful results. We believe that the measure specifications should not require this unless absolutely necessary since the data needed to determine disparities cannot be ascertained from the currently available sources.							
1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] N/A							
1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.) Is the measure focus a health outcome? Yes No If not a health outcome, rate the body of evidence.							
Quantity:	H M		Quality: H M L	I ☐ Consistency: H☐ M☐ L☐ I ☐			
Quantity	Quality	Consistency	Does the measure pass s	subcriterion1c?			
М-Н	M-H	M-H	Yes				
L	М-Н	M	Yes IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No				
М-Н	L	М-Н	Yes IF potential benefits to patients clearly outweigh potential harms: otherwise No				
L-M-H	L-M-H	L	No 🗌				
Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service Does the measure pass subcriterion1c? Yes□ IF rationale supports relationship							
1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome): This is a process measure. Prescribe potent antiretroviral therapy (ART) to HIV patients >> Increased CD4 counts, decreased plasma viral load >> Prevention of disease progression >> Decreased morbidity and mortality							
1c.2-3 Type of Evidence (Check all that apply): Clinical Practice Guideline							
1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population): The Department of Health and Human Services guidelines recommend initiating antiretroviral therapy (ART) in all patients with HIV who are pregnant, have a history of an AIDS-defining illness or with a CD4 count less than 350 cells/mm3 (A-I). The panel also recommends initiating antiretroviral therapy in all patients with HIV whose CD4 count is between 350 and 500 cells/mm3 (A-II).							
1c.5 Quantity of Studies in the Body of Evidence (<i>Total number of studies, not articles</i>): The DHHS guidelines include 45 studies supporting its recommendations. They cite 20 randomized control trials involving 19, 678 patients and more than 25 cohort studies of 87,000 patients.							
1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): The DHHS guidelines state that "randomized controlled trials provide definitive evidence supporting the benefit of ART in patients with CD4 counts <350 cells/mm3. Results from multiple observational cohort studies demonstrate benefits of ART in reducing AIDS- and non-AIDS associated morbidity and mortality in patients with CD4 counts ranging from 350 to 500 cells/mm3." (p. E-1)							

- 1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): The evidence cited in the DHHS guidelines is consistent in showing the benefits of initiating ART in all patients with HIV who are pregnant, have a history of an AIDS-defining illness, with a CD4 count less than 350 cells/mm3, or with a CD4 count between 350 and 500 cells/mm3.
- 1c.8 **Net Benefit** (*Provide* estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit benefit over harms):

Preliminary data indicate that treatment of acute HIV infection with combination antiretroviral therapy (ART) has a beneficial effect on laboratory markers of disease progression. Theoretically, early intervention could decrease the severity of acute disease; alter the initial viral setpoint, which can affect disease progression rates; reduce the rate of viral mutation as a result of suppression of viral replication; preserve immune function; and reduce the risk of viral transmission during this highly infectious stage of disease. Additionally, although data are limited and the clinical relevance is unclear, the profound loss of gastrointestinal lymphoid tissue that occurs during the first weeks of infection may be mitigated by the early initiation of ART. (DHHS, 2012)

Earlier studies definitively showed that potent combination ART improves survival and reduces acquired immune deficiency syndrome (AIDS)-related complications in patients with advanced HIV disease. There is now increasing evidence demonstrating the benefits of viral suppression and immunologic responses on reducing mortality and non-AIDS-related complications in patients with higher pretreatment CD4 counts. (DHHS, 2012)

Clinical studies have demonstrated that sustaining viral suppression and maintaining higher CD4 count, mostly as a result of effective combination antiretroviral therapy, delay or prevent some non-AIDS-defining complications, such as HIV-associated kidney disease. Sustained viral suppression and immune recovery may also delay or prevent other disorders, such as liver disease, cardiovascular disease, and malignancies. (DHHS, 2012)

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. March 2012. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/contentfiles/lyquidelines/adultandadolescentgl.pdf. Accessed June 11, 2012.

- 1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes
- 1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: These guidelines were developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents (a Working Group of the Office of AIDS Research Advisory Council). The Panel is composed of more than 30 voting members who have expertise in HIV care and research. The U.S. government representatives include at least 1 representative from each of the following DHHS agencies: CDC, FDA, HRSA, and NIH. These members are appointed by their respective agencies. Approximately 2/3 of the Panel members are nongovernmental scientific members. There are 4–5 community members with knowledge in HIV treatment and care. Members who do not represent U.S. government agencies are selected after an open announcement to call for nominations. Each member serves on the Panel for a 4-year term, with an option to be reappointed for an additional term. All members of the Panel submit a written financial disclosure annually reporting any association with manufacturers of antiretroviral drugs or diagnostics used for management of HIV infections.
- 1c.11 System Used for Grading the Body of Evidence: Other
- 1c.12 If other, identify and describe the grading scale with definitions: Strength of Recommendation: A: Strong recommendation for the statement; B: Moderate recommendation for the statement; C: Optional recommendation for the statement. Quality of Evidence: I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III: Expert opinion
- 1c.13 Grade Assigned to the Body of Evidence: A-I and A-II

1c.14 Summary of Controversy/Contradictory Evidence: There is some controversy as to whether patients should be initiated on potent ART regardless of CD4 count. Currently, some experts recommend beginning ART earlier in the course of HIV, when the CD4 count is still greater than 500 cells/mm3; this is a moderate recommendation based on expert opinion. There are no randomized controlled trials with definitive data proving a clear benefit to initiating ART in patients with a CD4 count greater than 500 cells/mm3. Additionally, observational cohort studies have shown mixed results. As stated in the DHHS treatment guidelines, "potential risks of short- or long-term drug-related complications and nonadherence to long-term therapy in asymptomatic patients may offset possible benefits of earlier initiation of therapy." (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2012)

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below): N/A

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #): [Strength of recommendation and quality of evidence are in parentheses, following each recommendation]

DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents (2012):

Antiretroviral therapy (ART) is recommended for all HIV-infected individuals. The strength of this recommendation varies on the basis of pretreatment CD4 cell count:

- CD4 count <350 cells/mm3 (A-I)
- CD4 count 350 to 500 cells/mm3 (A-II)
- CD4 count >500 cells/mm3 (B-III)

Regardless of CD4 count, initiation of ART is strongly recommended for individuals with the following conditions:

- Pregnancy (A-I)
- History of an AIDS-defining illness (A-I)
- HIV-associated nephropathy (HIVAN) (A-II)
- HIV/hepatitis B virus (HBV) coinfection (A-II)

Effective ART also has been shown to prevent transmission of HIV from an infected individual to a sexual partner; therefore, ART should be offered to patients who are at risk of transmitting HIV to sexual partners (A-I [heterosexuals] or A-III [other transmission risk groups]).

The recommendation to initiate therapy at CD4 count >500 cells/mm3 (B-III) is based on growing awareness that untreated HIV infection or uncontrolled viremia may be associated with development of many non-AIDS-defining diseases, including cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancy; availability of ART regimens that are more effective, more convenient, and better tolerated than earlier ART combinations no longer widely used; and evidence from one observational cohort study that showed survival benefit in patients who started ART when their CD4 counts were >500 cells/mm3.

Tempering the enthusiasm to treat all patients regardless of CD4 count is the absence of randomized data that definitively demonstrate a clear benefit of ART in patients with CD4 count >500 cells/mm3 and mixed results on the benefits of early ART from observational cohort studies. In addition, potential risks of short- or long-term drug-related complications and nonadherence to long-term therapy in asymptomatic patients may offset possible benefits of earlier initiation of therapy. When resources are not available to initiate ART in all patients, treatment should be prioritized for patients with the lowest CD4 counts and those with the following clinical conditions: pregnancy, history of an AIDS-defining illness, HIV-associated nephropathy (HIVAN), or HIV/hepatitis B virus (HBV) coinfection.

Patients starting ART should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence (A-III). Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors.

1c.17 Clinical Practice Guideline Citation: Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. March 2012. Department of Health and Human Services. Available

NQF #0406 HIV/AIDS: Adolescent and Adult Patients who are Prescribed Potent Antiretroviral Therapy, Last Updated Date: Aug 23, 2012 at http://www.aidsinfo.nih.gov/contentfiles/lyquidelines/adultandadolescentgl.pdf. Accessed June 11, 2012. 1c.18 National Guideline Clearinghouse or other URL: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf 1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes 1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: DHHS Adult/ Adolescent Guidelines; expert consensus with evidence review 1c.21 System Used for Grading the Strength of Guideline Recommendation: Other 1c.22 If other, identify and describe the grading scale with definitions: Strength of Recommendation: A: Strong recommendation for the statement; B: Moderate recommendation for the statement; C: Optional recommendation for the statement. Quality of Evidence: I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III: Expert opinion 1c.23 Grade Assigned to the Recommendation: A-I and A-II 1c.24 Rationale for Using this Guideline Over Others: It is NCQA policy to use guidelines that are evidence-based, applicable to physicians and other healthcare providers, and developed by a national specialty organization or government agency. NCQA and PCPI convened an expert panel of diverse stakeholders to review the quidelines and evidence for this measure. The panel determined the measure was scientifically sound using the full body of evidence and guidelines for this measure concept. Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence? 1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High 1c.28 Attach evidence submission form: 1c.29 Attach appendix for supplemental materials: Was the threshold criterion, Importance to Measure and Report, met? (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria: For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated. 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria) Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing. S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable Created on: 08/24/2012 at 12:28 PM

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

assn.org/apps/listserv/x-check/gmeasure.cgi?submit=PCPI

S.2 If yes, provide web page URL: The NQF endorsed measure is available on AMA's website: http://www.ama-

- **2a1.** Precise Measure Specifications. (The measure specifications precise and unambiguous.)
- 2a1.1 **Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome): Patients who were prescribed potent antiretroviral* therapy
- *Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials
- 2a1.2 **Numerator Time Window** (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): 12-month measurement period
- 2a1.3 **Numerator Details** (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses: Patients who were prescribed potent antiretroviral* therapy*
- *Potent antiretroviral therapy is described as any antiretroviral therapy that has demonstrated optimal efficacy and results in durable suppression of HIV as shown by prior clinical trials

Report the CPT® Category II code: 4276F - Potent antiretroviral therapy prescribed

- 2a1.4 **Denominator Statement** (Brief, narrative description of the target population being measured):
- A. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history of a CD4 count less than or equal to 500 cells/mm3; and
- B. All patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who have a history an AIDS-defining illness**, regardless of CD4 count; and
- C. All patients with a diagnosis of HIV/AIDS, with at least two medical visits during the measurement year, with at least 90 days between each visit, who are pregnant, regardless of CD4 count or age.
- **The most commonly used case definition for AIDS is the 1993 Revised Surveillance Case Definition from the CDC. It includes: Candidiasis of bronchi, trachea, or lungs; candidiasis, esophageal; cervical cancer, invasive; coccidiodomycosis, disseminated or extrapulmonary; cryptococcosis, extrapulmonary; crytosporidiosis, chronic intestinal (greater than 1 month's duration); cytomegalovirus disease (other than liver, spleen, or nodes); cytomegalovirus retinitis (with loss of vision); encephalopathy, HIV-related; herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis; histoplasmosis, disseminated or extrapulmonary; isosporiasis, chronic intestinal (greater than 1 month's duration); Kaposi's sarcoma; lymphoma, Burkitt's (or equivalent term); lymphoma, immunoblastic (or equivalent term); lymphoma, primary, of brain; mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary; mycobacterium tuberculosis, any site (pulmonary or extrapulmonary); mycobacterium, other species or unidentified species, disseminated or extrapulmonary; pneumocystis carinii pneumonia; pneumonia, recurrent; progressive multifocal leukoencephalopathy; salmonella septicemia, recurrent; toxoplasmosis of brain; wasting syndrome due to HIV. (Aberg, 2009; National Center for Infectious Diseases Division of HIV/AIDS)

Definition of "Medical Visit" - any visit with a health care professional who provides routine primary care for the patient with HIV/AIDS (may be but is not limited to a primary care clinician, ob/gyn, pediatrician, infectious diseases specialist)

Note: For potent antiretroviral therapy recommendations refer to current DHHS guidelines available at www.aids.gov

Aberg JA, Kaplan JE, Libman H, Emmanuel P, Anderson JR, Stone VE, Oleske JM, Currier JS, Gallant JE; HIV Medicine Association of the Infectious Diseases Society of America. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2009 Sep 1;49(5):651-81. Available at

http://www.uphs.upenn.edu/bugdrug/antibiotic_manual/idsahivprimarycare2009.pdf. Accessed May 25, 2012.

National Center for Infectious Diseases Division of HIV/AIDS. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMRW Recomm Rep. 1992;41(RR-17):1-19.

- 2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Maternal Health
- 2a1.6 **Denominator Time Window** (*The time period in which cases are eligible for inclusion*): 12-month measurement period
- 2a1.7 **Denominator Details** (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*): ICD-9 diagnosis code: 042, V08,

AND

CPT® E/M service code: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99384, 99385, 99386, 99387, 99394, 99395, 99396, 99397, 99241, 99242, 99243, 99244, 99245,

AND

- a. CPT® Category II code for CD4 count less than or equal to 500 cells/mm3 [will be requested]
- b. CPT® Category II code: 3490F History of AIDS-defining condition, or
- c. ICD-9 Code for pregnancy: V22.0, V22.1, V22.2, V23.0, V23.1, V23.2, V23.3, V23.41, V23.42, V23.49, V23.5, V23.7, V23.81, V23.82, V23.83, V23.84, V23.85, V23.86, V23.89, V23.9

Note: The denominators for the NCQA/AMA-PCPI HIV/AIDS measures have been harmonized, where appropriate.

- 2a1.8 **Denominator Exclusions** (Brief narrative description of exclusions from the target population): None
- 2a1.9 **Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): N/A
- 2a1.10 **Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

 N/A
- 2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification 2a1.12 If "Other," please describe:
- 2a1.13 **Statistical Risk Model and Variables** (Name the statistical method e.g., logistic regression and list all the risk factor variables. Note risk model development should be addressed in 2b4.): N/A
- 2a1.14-16 **Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

- 2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Higher score
- 2a1.20 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

Measure Calculation

For performance purposes, this measure is calculated by creating a fraction with the following components: Denominator and Numerator.

- Step 1: Determine the eligible population. The eligible population is all the patients, regardless of age, with a diagnosis of HIV/AIDS.
- Step 2: Determine number of patients meeting the denominator criteria as specified in Section 2a1.7 above.
- Step 3: Determine the number of patients who meet the numerator criteria as specified in section 2a1.3 above. The numerator includes all patients in the denominator population who were prescribed potent antiretroviral therapy at least once.
- Step 4: Calculate the rate by adding all of the denominators, then dividing the total from Step 4 by the total from Step 2.
- 2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

Attachment

PCPI_Sample_Calculation_Algorithm-634768413528296324.pdf

- 2a1.24 **Sampling (Survey) Methodology**. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

 This measure is not based on a sample or survey.
- 2a1.25 **Data Source** (Check all the sources for which the measure is specified and tested). If other, please describe: Administrative claims, Electronic Clinical Data, Electronic Clinical Data; Electronic Clinical Data : Pharmacy
- 2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): N/A
- 2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:
- 2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
- 2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): Clinician: Group/Practice, Clinician: Individual
- 2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Ambulatory Care: Clinician Office/Clinic

- 2a2. **Reliability Testing**. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)
- 2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Measure Validity

The measure performance was calculated from data collected using two different methods of collection:

- -Automated electronic health record report
- -Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

The data source was electronic health records in the ambulatory care setting. The data sample came from four sites representing community health centers serving primarily low-income and uninsured patients with multiple, complex needs in the Midwest region. The sample consisted of 342 patient encounters. Visual inspection of the medical records was performed in 2009.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

As referenced in the NQF Guidance on Measure Testing (2011), separate reliability testing of the data elements is not required if empirical validity testing of the data elements is conducted (e.g., if the validity of ICD-9 codes in administrative claims data as compared to clinical diagnoses in the medical record is demonstrated, then inter-coder or inter-abstractor reliability would not be required). Consequently, we are submitting validity testing results to demonstrate reliability for this measure.

Measure Validity

Data from a performance report for the measure automatically-generated from the electronic health record (designed to collect the necessary data elements to identify eligible cases and calculate the performance score) were compared to data elements found and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included percent agreement at the denominator and numerator.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted): Measure Validity

Below are the results when comparing electronic health record automated report to visual inspection of the medical record.

Automated calculation of performance=96.6%

Manual calculation of performance=100%

Percentage Point Difference between Automated and Manual=3%

2b. VALIDITY. Validity, Testing, including all Threats to Validity:	$H \square M \square L \square I \square$
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2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (*criterion 1c*) and identify any differences from the evidence: The evidence is consistent with the focus and scope of this measure.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Measure Validity

The measure performance was calculated from data collected using two different methods of collection:

- -Automated electronic health record report
- -Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

The data source was electronic health records in the ambulatory care setting. The data sample came from four sites representing community health centers serving primarily low-income and uninsured patients with multiple, complex needs in the Midwest region. The sample consisted of 342 patient encounters. Visual inspection of the medical records was performed in 2009.

Face Validity

An expert panel was used to assess the face validity of this measure when it was re-evaluated in 2012. The full list of panel members is provided under the section Additional Information, Ad.1. Workgroup/Expert Panel Involved in Measure Development – 2012 (Measure Review) Panel.

2b2.2 **Analytic Method** (Describe method of validity testing and rationale; if face validity, describe systematic assessment): Measure Validity

Data from a performance report for the measure automatically-generated from the electronic health record (designed to collect the necessary data elements to identify eligible cases and calculate the performance score) were compared to data elements found and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included percent agreement at the denominator, numerator.

Face Validity

Face validity of the measure score as an indicator of quality was systematically assessed as follows. After the measure was fully specified, the expert panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality. Scale 1-5, where 1=Strongly Disagree; 3=Neither Agree or Disagree; 5=Strongly Agree.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):

Measure Validity

Below are the results when comparing EHR automated report to visual inspection of the medical record.

Automated calculation of performance=96.6%

Manual calculation of performance=100%

Percentage Point Difference between Automated and Manual=3%

Face Validity

The results of the expert panel rating of the validity statement were as follows: N=8; Mean rating=4.13 and 75.0% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

The results of the expert panel rating of the validity statement were as follows:

Frequency/Distribution of Ratings

- 1 (Strongly Disagree)-0 members
- 2-2 members
- 3 (Neither Agree or Disagree)-0 members
- 4-1 member
- 5 (Strongly Agree)-5 members

POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

- **2b3**. **Measure Exclusions**. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)
- 2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

There are no exclusions for this measure.

2b3.2 **Analytic Method** (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

N/A

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses): N/A

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

2b4.1 **Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

N/A

2b4.2 **Analytic Method** (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

N/A

2b4.3 Testing Results (<u>Statistical risk model</u>: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):

N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

CMS Physician Quality Reporting System:

The following information is from the 2009 and 2010 CMS Physician Quality Reporting System. In 2009, 60 eligible providers reported this measure, and in 2010, 61 eligible providers reported this measure. This represented 675 total instances in 2009, and 735 total instances in 2010.

2b5.2 **Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

For the CMS PQRI Program, the mean performance rate was calculated from 675 total instances in 2009, and 735 total instances in 2010.

2b5.3 **Results** (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

For this measure, the average performance rate per eligible professional was 90.3% in 2009 and 97.2% in 2010. These numbers are based on a small numbers of providers (60 in 2009, 61 in 2010). Data from a much larger source, the HIVQUAL-US reporting program, indicate that there is a gap in care with room for improvement.

HIVQUAL-US is a program designed to improve care for people living with HIV/AIDS through quality improvement, performance measurement, and infrastructure/capacity building. It is funded through a cooperative agreement administered by the Health Resources & Services Administration's HIV/AIDS Bureau. Ryan White HIV/AIDS Part C and Part D Programs are eligible to participate. It has several viral load control measures, including: 1) last viral load undetectable or <200, among patients on antiretroviral therapy >12 weeks, and; 2) viral load always undetectable or <200, among patients on antiretroviral therapy >12 weeks.

There were 202 facilities that reported this measure in 2009 (covering 9,153 patients). The facility means were 75.2% and 64.2%, respectively.

NQF #0406 HIV/AIDS: Adolescent and Adult Patients who are Prescribed Potent Antiretroviral Therapy, Last Updated Date: Aug 23, 2012 2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.) 2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): This measure has not been compared across data sources. 2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure): N/A 2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted): N/A 2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.) 2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): The measure is not stratified by patient groups or cohorts that could potentially be affected by disparities in care. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data is not coded in a standard manner and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, and employer) should capture and report this data. While "requiring" reporting of the data could push the field forward, it has been our position that doing so would create substantial burden without generating meaningful results. We believe that the measure specifications should not require this unless absolutely necessary since the data needed to determine disparities cannot be ascertained from the currently available sources. 2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain: N/A 2.1-2.3 Supplemental Testing Methodology Information: Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met? (Reliability and Validity must be rated moderate or high) Yes No Provide rationale based on specific subcriteria: If the Committee votes No, STOP 3. USABILITY Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria) C.1 Intended Actual/Planned Use (Check all the planned uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I (The measure is meaningful, understandable and useful for public reporting.)

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following

questions): Public Reporting, Quality Improvement (Internal to the specific organization)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.] This measure was used in the CMS PQRS program in 2009, 2010, and 2011, and will be included in 2012. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/pgrs 3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The successful use in PQRS supports the feasibility and usability of the measure specification on a national scale. Additionally, while this measure is not yet in widespread use in PQRS, we expect that with increasing incentives for reporting there will be an increase in the use of this and all the PQRS measures to leverage improvements in care. While performance data from PQRS is high, data on similar measures from a reporting program with a larger sample (the HIVQUAL-US program) indicate there remains a gap in care (average facility rate = 65% and 75% for two measures), with room for improvement. 3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure may be used in a Maintenance of Certification program. 3b. Usefulness for Quality Improvement: H M L I (The measure is meaningful, understandable and useful for quality improvement.) 3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s): **For Maintenance** – If not used for QL indicate the reasons and describe progress toward using performance results for improvement. The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) uses similar measures in its Core Clinical Performance Measure Module (PMM). This module is a reporting tool that allows providers to compare their performance regionally and nationally to other providers, and supports quality improvement. Also, the measure specifications are made freely available on the PCPI website and through the implementation efforts of medical specialty societies. 3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results: The successful use in PQRS supports the feasibility and usability of the measure specification on a national scale and the results show substantial improvement (7%) in scores from 2009 to 2010, reflecting provider's QI initiatives around HIV care. Also, similar potent ART measures are used by HAB's PMM, indicating that a measure with this focus is meaningful for quality improvement for this patient population. Overall, to what extent was the criterion, *Usability*, met? H M L I Provide rationale based on specific subcriteria: 4. FEASIBILITY Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria) 4a. Data Generated as a Byproduct of Care Processes: H M L I 4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply). Data used in the measure are: generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

NQF #0406 HIV/AIDS: Adolescent and Adult Patients who are Prescribed Potent Antiretroviral Therapy, Last Updated Date: Aug 23, 2012 4b. Electronic Sources: H M L I 4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): ALL data elements are in a combination of electronic sources 4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources: 4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I 4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results: We are not aware of any unintended consequences related to this measurement. 4d. Data Collection Strategy/Implementation: H M L L I A.2 Please check if either of the following apply (regarding proprietary measures): Proprietary measure 4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures): As a result of our current review of the measures and our experience with the measures since 2008, we have learned and subsequently changed the NCQA/AMA-PCPI HIV/AIDS measures in the following ways. We have attempted to limit the number of exclusions/exceptions in these measures due to difficulties accurately capturing them in the health record. We have combined measures that address similar clinical areas (e.g., STD screening) into one measure to support feasibility and implementation. Overall, to what extent was the criterion, *Feasibility*, met? H M L I Provide rationale based on specific subcriteria: OVERALL SUITABILITY FOR ENDORSEMENT Does the measure meet all the NQF criteria for endorsement? Yes No Rationale: If the Committee votes No. STOP. If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures. 5. COMPARISON TO RELATED AND COMPETING MEASURES If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made. 5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures: 5a. Harmonization 5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? 5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.2 Point of Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncga.org, 202-955-1728-

Co.3 Measure Developer if different from Measure Steward: National Committee for Quality Assurance, 1100 13th Street NW, Washington, District Of Columbia, 20005

Co.4 Point of Contact: Dawn, Alayon, MPH, CPH, alayon@ncqa.org, 202-955-3533-

Co.5 Submitter: Dawn, Alayon, MPH, CPH, Senior Health Care Analyst, alayon@ncqa.org, 202-955-3533-, National Committee for Quality Assurance

Co.6 Additional organizations that sponsored/participated in measure development:

Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement™ (the Consortium) and the National Committee for Quality Assurance (NCQA). The Health Resources and Services Administration (HRSA) and the Infectious Diseases Society of America also participated in the development of this measure.

Co.7 Public Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-, National Committee for Quality Assurance

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

2007-2008 (Measure Development) Panel

The measure development panel helped guide development of this measure. Staff sought member feedback on all components of the measure (including denominator, numerator, exclusions). The panel met multiple times to achieve consensus on the measures and to address questions about the measure.

Workgroup members

Judith Aberg- Bellevue Hospital Center- New York University (co-chair)

Michael Horberg- Santa Clara Medical Center (co-chair)

Bruce Agins- New York State Department of Health AIDS Institute (NYSDOH)

Steven Asch- RAND Health Communications

Larry Bryant-Housingworks- Advocacy & Organizing

Sophia Chang- California Healthcare Foundation

Laura Cheever- Health Resources and Services Administration (HRSA)

Antoine Douaihy- UPMC Mercy

Arry Deiudonne- Center for Children- University Hospital

Patricia Emmanuel- University of South Florida

Marcy Fenton- LA County Department of Public Health

Joel Gallant- Johns Hopkins University School of Medicine

Joseph Gathe- Texas Medical Center

Cyril Goshima- Hawaii AIDS Education and Training Center

Andrew Hamilton- Alliance of Chicago

Lisa Hischhorn- Harvard Medical School, JSI Research and Training Institute

Jan King-Los Angeles County Department of Health Services

W. Christopher Matthews- UC San Diego, Department of Medicine

James L. Raper- University of Alabama at Birmingham

Jennifer Read- National Institutes of Health (NIH)

Kimberly Smith- Rush University Medical Center

Alice Stek- University of Southern California

Valerie Stone- Harvard Medical School, Massachusetts General Hospital

Bob Tracy- Bob Tracy Consulting

Paul Voldberding- VAMC

Rochelle Walensky- Massachusetts General Hospital

Bruce Williams- University of New Mexico Health Sciences Center

Liaisons

Brigid Krezek- American College of Obstetricians and Gynecologists

Dan Green- Centers for Medicare & Medicaid Services (CDC)

Deborah Willis-Fillinger- Health Resources and Services Administration (HRSA)

Magda Barini-Garcia- Health Resources and Services Administration (HRSA)

Lori DeLorenzo- Health Resources and Services Administration (HRSA)

Christine Lubinski- Infectious Diseases Society of America/ HIV Medicine Association

Jennifer Padberg- Infectious Diseases Society of America/ HIV Medicine Association

2012 (Measure Review) Panel

The measure review panel reviewed the existing measure against current clinical practice guidelines to ensure it reflected current evidence.

Workgroup members

Judith Aberg- New York University School of Medicine

Bruce Agins- New York State Department of Health AIDS Institute (NYSDOH)

Allison Agwu- Johns Hopkins Medical Institutions

Marc Foca- Columbia University

Rohan Hazra- National Institutes of Health (NIH)

Lisa Hirschhorn- Harvard Medical School, JSI Research and Training Institute

Gregory Lucas- Johns Hopkins University

Michael Horberg- Mid-Atlantic Permanente Group, PC

Vicki Peters- NYC Department of Health and Mental Hygiene

Alice Stek- University of Southern California School of Medicine

Bruce Williams- University of New Mexico Health Sciences Center

Liaisons

Laura Cheever- Health Resources and Services Administration (HRSA)

Anna Huang- Health Resources and Services Administration (HRSA)

Marlene Matosky- Health Resources and Services Administration (HRSA)

John Brooks- Centers for Disease Control and Prevention (CDC)

Abigail Viall- Centers for Disease Control and Prevention (CDC)

Pascale Wortley- Centers for Disease Control and Prevention (CDC)

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for

adapting the original measure and any work with the original measure steward: N/A

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 06, 2012

Ad.5 What is your frequency for review/update of this measure? Every three years, or sooner, if clinical guidelines are updated.

Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement: This Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposed, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and American Medical Association, (on behalf of the Consortium) or NCQA. Neither the AMA, NCQA, Consortium nor its members shall be responsible for any use of the Measure.

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Ad.8 Disclaimers: These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications.

THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

Ad.9 Additional Information/Comments: While there are no currently NQF-endorsed measures that compete with this measure, we understand that HRSA will be submitting a measure that has a similar denominator and numerator. The HRSA measure will calculate a rate for all patients with HIV/AIDS who are receiving antiretroviral therapy. The NQCA measure, which supports potent antiretroviral therapy for patients with HIV/AIDS and a CD4 count =500 cells/mm3, an AIDS-defining condition, or who are pregnant, is more firmly supported by the evidence than the measure being proposed by HRSA. NCQA's measure relies on denominator populations that are based on strong recommendations in the clinical guidelines and supported by either randomized controlled trials or observational cohort studies. The HRSA measure relies on moderate recommendations supported by expert opinion. Since potent ART may have serious side effects and is expensive, we believe a more conservative measure is appropriate.

Date of Submission (MM/DD/YY): 07/02/2012

Sample PCPI Calculation Algorithm

Calculation for Performance

For performance purposes, a measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:

Number of patients meeting numerator criteria

Denominator (PD) Includes:

Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:

Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation

A (# of patients meeting numerator criteria)

PD (# patients in denominator) – C (# patients with valid denominator exclusions)

If a measure does not allow for exclusion(s), it is calculated by creating a fraction with the following components: Numerator and Denominator.

Numerator (A) Includes:

Number of patients meeting numerator criteria

Denominator (PD) Includes:

Number of patients meeting criteria for denominator inclusion

A (# of patients meeting measure criteria)

PD (# of patients in denominator)

It is also possible to calculate the percentage of patients excluded overall, or excluded by medical, patient, or system reason where applicable:

Overall Exclusion Calculation

C (# of patients with any valid exclusion)

PD (# patients in denominator)

OR

Exclusion Calculation by Type

C₁ (# patients with medical reason)

PD (# patients in denominator)

C₂ (# patients with patient reason)

PD (# patients in denominator)

C₃ (# patients with system reason)

PD (# patients in denominator)