

Pennsylvania Medicaid
Adult HIV
Clinical Practice
Guideline ©

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P.O. BOX 2675
HARRISBURG, PENNSYLVANIA 17105-2675

OFFICE OF MEDICAL
ASSISTANCE PROGRAMS

Dear Physician:

Enclosed is a copy of the updated Pennsylvania Medicaid Adult HIV Clinical Practice Guideline for 2008-2009. The guideline was developed to help practitioners care for adult Medical Assistance recipients with HIV/AIDS. It was created using currently existing national protocols and is intended to be broad enough to cover all adult members living with HIV/AIDS and allow for accepted variations in clinical treatment and pharmaceutical utilization.

This guideline was formed through a collaborative effort among all of the HealthChoices managed care organizations, Department of Public Welfare (Department) clinicians, HIV experts, community providers, behavioral health experts, and patient advocacy representatives. This guideline is to be used by practitioners as a “best practice” reference.

The 2008-2009 Pennsylvania Medicaid Adult HIV Clinical Practice Guideline has been reviewed and adopted by each of the HealthChoices health plans and ACCESS Plus program. Again this year, the guideline is being made available in electronic format on each of the HealthChoices health plans’ and ACCESS Plus Internet sites as well as the Department’s Internet site.

If you have any questions or comments, please direct them to the organization with which you are affiliated. We hope that this joint initiative helps improve the quality of HIV/AIDS care delivered to adult Medical Assistance recipients in Pennsylvania and reduces the variability of care delivered to this population. We thank you for your ongoing efforts to care for our members.

Sincerely,

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Pennsylvania Medicaid Adult HIV Clinical Practice Guideline

I. Work Group Charter

Work Group Charge:

It is the sole intent to develop a uniform clinical practice guideline for HIV care delivered to adult medical assistance recipients enrolled in Pennsylvania's Medicaid Program. The guideline will be a "best practice" that will be based upon reasonable scientific evidence. The guideline will be adopted from currently existing national protocols.

The scope of the guideline will be broad enough to cover all adult members living with HIV/AIDS and allow for accepted variations in clinical treatment and pharmaceutical utilization. This guideline is to be used by practitioners as a "best practice" reference. Recognizing that HIV/AIDS care rapidly changes; the work group will review updates of the guideline on regular intervals. Each HealthChoices managed care organization as well as the ACCESS Plus and Fee-for-Service programs will make services recommended in the Pennsylvania HIV/AIDS guideline available to their members in accordance with its individual policies and procedures.

The desired outcomes of this effort are to improve the quality of HIV/AIDS care delivered to adult Medical Assistance recipients in Pennsylvania and to reduce the variability of care delivered to this population. Each HealthChoices managed care organization as well as the ACCESS Plus and Fee-for-Service programs will be responsible for measuring compliance with this guideline in accordance with its individual policies and procedures.

Composition: Susan Hunt, MD, Medical Director, Pittsburgh AIDS Center for Treatment, University of Pittsburgh; Pedro J. Cardona, MD, MBA, Medical Director, Gateway Health Plan; Humberto Guerra-Garcia, MD, MPH, FACP, Chief Medical Officer, AmeriChoice of Pennsylvania, Inc.; Helen A. Kwakwa, MD, Director of HIV Clinical Services, Philadelphia Department of Health; David Piontkowsky, MD, Medical Director, Positive Health Clinic, Allegheny General Hospital; William R. Short, MD, Assistant Professor of Medicine, Division of Zurlo, MD, Professor of Medicine, Division of Infectious Diseases, Penn State Hershey Medical Center.

Chair:

The work group will have two co-chairpersons.

Meetings:

Meetings will occur when called by the chairs. Much of the discussion will take place via electronic mail due to the geographical distances between various work group members. (Prior Meeting Dates: **2000-** January 10th, March 12th, and May 8th; **2001-** April 30th, June 25th, **2002-** March 8th, **2003-** March 11th, and August 14th, **2005-** April 20th, 2007- July 3rd, September 26th, **2008-** January)

Quorum:

Any four members of the committee will constitute a quorum.

Staff:

The Department of Public Welfare will provide necessary meeting facilities and support staff as needed for the work group.

Voting:

All business will be transacted by simple majority of the work group members in attendance at the time of voting. The chair may give proxies.

Reporting:

The workgroup will report its final results to the Medical Directors of the participating managed care organizations and the ACCESS Plus Medical Director. There are to be no sub-work groups of the HIV Guideline Work Group.

Pennsylvania Medicaid Adult HIV Clinical Practice Guideline

II. Introduction

It is the sole intent of this Adult HIV Clinical Practice guideline to serve as a uniform, “best practice.” The guideline is intended for use with the adult Medical Assistance recipients with HIV infection enrolled in Pennsylvania’s Medicaid Program.

This guideline describes the best clinical practices based on available knowledge and a consensus of experts as of January 2008. This guideline is intended as a resource for health care providers who treat adults with HIV infection. It is recognized that not all recommendations are appropriate for all patients; these recommendations are not intended to substitute for the judgment of a physician or other health care provider who is an expert in the care of HIV-infected patients. Decisions to adopt these recommendations must be made on an individual patient basis. There is increasing evidence that outcomes are improved for HIV-infected patients under the care of physicians with extensive experience in the care of this population. When this is not possible, the physician treating the patient should have access to such expertise through consultation.

This guideline is based upon the review of published scientific literature and expert opinion, and represents the consensus of the Pennsylvania Medicaid Adult HIV Clinical Practice Guideline Work Group. The Work Group has agreed to reconvene and update these guidelines every one to two years.

Each HealthChoices managed care organization as well as the ACCESS PLUS and Fee-for-Service Programs will make services recommended in this guideline available in accordance with its individual policies and procedures. The desired outcomes of this guideline are to improve the quality of HIV care delivered to adult Medical Assistance recipients in Pennsylvania and to reduce the variability of care delivered to this population. Each HealthChoices managed care organization as well as the ACCESS PLUS and Fee-for-Service Programs will be responsible for measuring compliance with this guideline in accordance with its individual policies and procedures.

III. Pennsylvania Medicaid Adult HIV Clinical Practice Guideline

	Treatment	Frequency/Indication	Comments
1.0	General Care		Everything related to this guideline should be documented in the medical record. All lab results should be contained in the medical record.
1.1	Comprehensive Health History	First comprehensive visit and update at least twice a year	See Appendix 1.1
1.2	Comprehensive Psychosocial History	First comprehensive visit and update at least twice a year	See Appendix 1.2
1.3	Comprehensive Physical Examination	First comprehensive visit and update at least twice a year	See Appendix 1.3
1.4	Advance Directives	First comprehensive visit and as indicated	See Appendix 1.4
1.5	Adult Preventive Care	Adult Preventive Care per MCO Guidelines	
1.6	Risk Reduction Screening	First comprehensive visit, subsequent routine visits, occurrence of an STD	See Appendix 1.6
2.0	Antiretroviral Therapy	Antiretroviral therapy has many pros and cons: 1) While the benefits of prolonged life and reduced morbidity have been clearly established for patients with advanced disease, such benefits are less clear for earlier stage, asymptomatic patients; 2) The list of known or suspected drug toxicities continues to expand; 3) The choice of antiretroviral regimens used to treat the naïve patient has a great impact on future options for that patient; 4) FOR ANY REGIMEN, MEASURES TO ENSURE PATIENT ADHERENCE TO THERAPY ARE OF EQUALLY VITAL IMPORTANCE AS THE CHOICE OF AGENTS. Hence it is strongly recommended that primary care providers with limited experience in treating HIV infection become thoroughly familiar with the latest treatment guidelines (found at www.aidsinfo.nih.gov and/or consult with an expert before initiating therapy. (See Appendix 2.0)	
2.1	Laboratory evidence of HIV infection	Baseline	See Appendix 2.1
2.2	CD4 count, CBC with Differential and Platelets.	Q 3-6 months (& initial evaluation)	
2.3	HIV-1 Viral Load Assay	Two measurements during initial evaluation 1-2 weeks apart and 2-8 weeks after initiation or change in therapy and every 3-4 months thereafter.	See Appendix 2.3
2.4	HIV-1 Viral Load Target Treatment Goal	Reduction to below the level of detection (currently <50 copies/mL)	See Appendix 2.4
2.5	Treatment of the Naïve Patient	<p>Indications for combination ART:</p> <p><u>Treatment strongly recommended:</u> Patients with symptomatic HIV/AIDS at any CD4 or HIV RNA; asymptomatic patients with CD4 <200/mL</p> <p><u>Treatment should be offered:</u> Asymptomatic patients with CD4>200/mL but ≤350/mL with any HIV RNA</p> <p><u>Treatment controversial:</u> Asymptomatic patients with CD4 >350/mL and HIV RNA ≥100,000 copies/mL</p> <p><u>Treatment should be deferred:</u> Asymptomatic patients with CD4 >350/mL and HIV RNA <100,000 copies/mL</p>	<p>Recommended First Line Regimens</p> <p>1 highly active PI + 2 preferred nucleoside analogues OR 1 highly active NNRTI + 2 preferred nucleoside analogues</p> <p>See Appendix 2.5 Refer to www.aidsinfo.NIH.gov for the latest guidelines.</p>
2.6	Treatment of the Treatment-Experienced Patient	Treatment should be individualized for the patient.	The choice of antiretroviral therapy for the treatment-experienced patient needs to be made with thorough knowledge of the patient's antiretroviral history and likely adherence in association with the judicious use of resistance testing. Consultation with an expert is strongly recommended.
2.7	Treatment of the Patient with Acute HIV Infection	Since the benefits of treatment are unknown for patients identified within 6 months of seroconversion, treatment with antiretroviral therapy is considered optional. Consultation with an expert provider is strongly recommended.	Recommended treatment regimens are the same as for the naïve patient. See Appendix 2.7
2.8	Anti-Retroviral Resistance, HLA, and Trofile Testing		See Appendix 2.8
3.0	Care of Women with HIV/AIDS	Similar to national statistics, the number of women with HIV/AIDS living in Pennsylvania is increasing. Despite dramatic medical advances in HIV care, many women continue to be diagnosed late in the course of infection. Clinicians should be familiar with the unique issues associated with caring for women with HIV/AIDS. These issues include reproductive health, gynecologic care, and pharmacologic considerations.	
3.1	Gynecologic Care PAP Test; and STD screening	For STD screening, see 4.5 below.	See Appendix 3.1
3.2	Pregnancy		See Appendix 3.2

Adapted from the following references: (1) USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus, MMWR, (2) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents developed by the Panel on Clinical Practices for the Treatment of HIV Infection, Health and Human Services (3) Prevention and Treatment of Tuberculosis Among Patients Infected with HIV: Principles of Therapy and Revised Recommendations. MMWR (4) Medical Management of HIV Infection. Bartlett, John G. Johns Hopkins University. A Guide to the Clinical Care of Women with HIV. Anderson JR. USPHS health resources and Services Administration.

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4.0	HIV Related Preventative Care		
4.1	Laboratory Evaluation	Initial evaluation and repeat as clinically indicated <ul style="list-style-type: none"> Electrolytes, BUN/creatinine, liver enzymes, fasting lipid panel, fasting blood sugar, urinalysis; consider oral glucose tolerance testing as per ADA guidelines 	
4.2	Imaging	Chest radiograph - Consider during initial evaluation and repeat as clinically indicated. Bone densitometry – Consider for patients being treated for osteoporosis or who have additional risk factors for osteoporosis	See Appendix 4.2
4.3	Eye Exam <ul style="list-style-type: none"> dilated fundoscopic by ophthalmologist 	Consider initially and annually for patients with CD4 <100/mL	
4.4	CMV Serology	Consider during initial evaluation and repeat as clinically indicated.	See Appendix 4.4
4.5	STD Screening <ul style="list-style-type: none"> RPR/VDRL Consider Chlamydia, gonorrhea, and trichomonas screening 	First comprehensive visit and subsequent visits as indicated depending on the patient's risk behavior	See Appendix 1.6
4.6	Hepatitis A, B, C Serologies	Baseline and as clinically indicated: <ul style="list-style-type: none"> Anti - HAV IgG HBsAg, HBcAb, HBsAb Anti – HCV 	See Appendix 4.6 Check hepatitis C qualitative PCR to confirm active infection and check HCV genotype for patients who are HCV seropositive
4.7	Hepatitis A Vaccine	Immunization recommended for all susceptible patients at increased risk for HAV infection (e.g., illicit drug users, men who have sex with men, hemophiliacs) or with chronic liver disease, including chronic hepatitis B or hepatitis C	Hepatitis A Vaccine <ul style="list-style-type: none"> Two doses - at 0 and 6 months See Appendix 4.7
4.8	Hepatitis B Vaccine	Immunization recommended for all susceptible (HBsAg/ HBcAb/ HBsAb negative) patients.	Hepatitis B Vaccine <ul style="list-style-type: none"> Three doses – at 0, 1, and 6 months See Appendix 4.8
4.9	Influenza Vaccine	Vaccinate annually.	See Appendix 4.9
4.10	Pneumococcal Vaccination	Initially and at 5 years for patients with CD4 count \geq 200/ml.	Pneumovax 0.5 ml IM x 1 See Appendix 4.10
4.10a	Tetanus Vaccine	Vaccinate with Td (tetanus/diphtheria) every 10 years; substitute a single dose of Tdap (tetanus, diphtheria, acellular pertussis) for Td for adults aged <65 years who have not previously received a dose of Tdap.	
4.10b	HPV Vaccine	Recommended for all females \leq 26 years of age irrespective of CD4 count or history of HPV infection or known HPV complication	
4.11	<i>Mycobacterium avium</i> Complex (MAC) Prophylaxis	Indication: CD4 < 50/ml	See Appendix 4.11
4.12	PCP Prophylaxis	Indications: <ul style="list-style-type: none"> CD4 < 200/ml Prior History of PCP Oropharyngeal candidiasis 	See Appendix 4.12
4.13	Toxoplasma Serology (IgG)	Initially. For toxoplasma seronegative adults; repeat when CD4 < 100/ml	
4.14	Toxoplasma Prophylaxis	CD4 < 100/ml and (+) toxoplasma IgG	See Appendix 4.14
4.15	Tuberculosis Screening	Purified protein derivative (PPD); initially and annually	If \geq 5 mm, perform CXR.
4.16	Tuberculosis Prophylaxis	PPD reaction \geq 5 mm or prior PPD (+) without treatment or contact with active TB.	See Appendix 4.16
4.17	Varicella Zoster Virus	Varicella zoster immune globulin (VZIG) is indicated for patients with a significant exposure to chickenpox or shingles who have no history of either	VZIG <ul style="list-style-type: none"> Given as 5 vials, 1.25 ml each, intramuscularly

Adapted from the following references: (1) USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus, MMWR, (2) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents developed by the Panel on Clinical Practices for the Treatment of HIV Infection, Health and Human Services (3) Prevention and Treatment of Tuberculosis Among Patients Infected with HIV: Principles of Therapy and Revised Recommendations. MMWR (4) Medical Management of HIV Infection. Bartlett, John G. Johns Hopkins University. A Guide to the Clinical Care of Women with HIV. Anderson JR. USPHS health resources and Services Administration.

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		condition or, if available, have negative antibody to VZV.	administered < 96 hrs. after exposure (ideally within 48 hrs.)
4.18	Anal Pap Smears for MSM	While anal pap smears to screen for HPV-related anal cancer and precancerous lesions in MSM have been advocated, no clear consensus or algorithm for management are available to recommend this procedure routinely.	
5.0	Ancillary Services		
5.1	Oral Health	The comprehensive physical examination should include assessment of the patient's oral health. Patients should be referred at least annually for a routine dental examination and as needed. Referral.	
5.2	Mental Health	On an on-going basis, the practitioner should perform an assessment of the patient's need for Mental Health services. <ul style="list-style-type: none"> Referral to Behavioral Health as needed. 	See Appendix 1.2
5.3	Substance Abuse	On an on-going basis, the practitioner should perform an assessment of the patient's need for Substance Abuse services. <ul style="list-style-type: none"> Referral to Behavioral Health as needed 	See Appendix 1.2
5.4	Nutritional Health Assessment and Counseling	Initially and as needed	Referral
5.5	Smoking cessation counseling	On an on-going basis, the practitioner should perform an assessment of the patient's smoking history and offer counseling along with pharmacologic aids to help with smoking cessation.	Providers certified as a tobacco cessation counselor (TCC) by the Department of Health may enroll as a TCC and be paid for providing these services. Contact the provider enrollment area at 1-800-537-8862 with any questions

5.6 Managed Care Organization and ACCESS Plus Coordination of Services (Special Needs Unit and Case Management Services)

Within its organizational structure each HealthChoices Managed Care Organization has a dedicated Special Needs Unit to ensure that each member with special needs receives access to appropriate primary care; access to specialists trained and skilled in the needs of the member; and information about the access to a specialist as PCP if appropriate. See the appendix 5.6 for more information.

To be referred to a Managed Care Organization Special Needs Unit (SNU) contact the member services line at:

- Health Partners 1-800-553-0784
- AmeriChoice 1-800-321-4462
- Keystone Mercy Health Plan 1-800-521-6860
- AmeriHealth Mercy Health Plan 1-888-991-7200
- UPMC for You 1-800-286-4242 Option 2
- Gateway Health Plan 1-800-642-3550x1
- Unison Health Plan 1-800-414-9025

All referrals to ACCESS Plus/ Fee for Service Intense Medical Case Management Unit should be directed to:

- Jean Whitehead, RN, CCM 1-866-588- 9819 option # 5

5.7 AIDS Waiver

Services are available to adults who are not currently eligible for Medical Assistance coverage. See the appendix 5.7 for more information.

Adapted from the following references: (1) USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus, MMWR, (2) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents developed by the Panel on Clinical Practices for the Treatment of HIV Infection, Health and Human Services (3) Prevention and Treatment of Tuberculosis Among Patients Infected with HIV: Principles of Therapy and Revised Recommendations. MMWR (4) Medical Management of HIV Infection. Bartlett, John G. Johns Hopkins University. A Guide to the Clinical Care of Women with HIV. Anderson JR. USPHS health resources and Services Administration.

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IV. Appendix

- 1.1 It is important to ascertain when the patient was likely infected, by what means (if known), and when the patient was diagnosed. Patients should be questioned about their past medical history, including HIV related opportunistic infections and malignancies, STD's, chickenpox, hepatitis, gynecologic problems (particularly the past Pap test history), vaccination history, and tuberculosis history, both tuberculin skin test history and the history of possible close contacts with individuals with active TB. Additional questions should focus on common HIV-related symptoms, including fevers, night sweats, weight loss, diarrhea, cough, skin rashes or lesions, oral thrush or ulcerations, headache, and changes in neurologic function or mental status. For the patient previously diagnosed with HIV and treated with antiretroviral agents, it is vital to get a detailed antiretroviral history including start and stop dates, reasons for medication discontinuation, drug failures, and results of genotype and phenotype testing if available. Records of prior CD4 counts and viral load determinations are equally important in putting together the previous treatment profile.
- 1.2 Optimal management of HIV disease requires recognition that HIV disease occurs within a psychosocial context. Elements of the patient's psychosocial status can have a major impact on the outcome of medical treatment, while medical treatment and disease progression can lead to major changes in a patient's psychosocial status.

A psychosocial assessment includes gathering information about a patient's social system including:

- Family
- Friends
- Job
- Income
- Housing
- Other support systems such as legal and case management

The strength of these social systems can have a direct effect on the outcome of medical treatment and may need to be strengthened before medical treatment, such as adherence with complex antiretroviral regimens, can even be initiated. Conversely, disease state can directly affect these support systems; a patient's declining health status affects ability to work, income, and potentially housing.

Psychological and psychiatric status and risk factors require frequent monitoring. There is an increased lifetime incidence of psychiatric disorders including Adjustment Disorders, Major Mood Disorders, Cognitive Disorders, and Organic Brain Disorders in people with HIV. HIV infection is increasingly occurring as a co-morbid disorder in individuals with primary mental health or substance abuse disorders. In addition, HIV infection can directly cause psychiatric disorders, including dementia. Seventeen percent of people with HIV disease will develop a major depressive disorder during the course of their illness; seventy percent will develop an organic brain disorder.

Evaluation requires gathering a history of prior or current psychiatric/substance abuse treatment as well as family history of psychiatric/substance abuse disorders. Current mental status, including assessment of mood, affect, cognition, judgment, and insight should be briefly assessed. The presence of neuro-vegetative signs, including sleep and appetite disturbances, should be identified.

A risk assessment for suicidality, including the presence of ideation, intent, a plan, and a means, should be conducted with any depressed patient. Use of recreational drugs and alcohol, and misuse of prescription drugs, should be asked about.

Laboratory investigations, including RPR, thyroid-stimulating hormone (TSH), folate and B12 levels, blood chemistries, and CNS imaging in patients presenting with confusion or other symptoms of dementia should be conducted, as well as a review of current medications and side effects; many medications used in HIV treatment have side effects which present as psychiatric symptoms.

There are predictable points in the progression of HIV disease when psychiatric disorders, including mood disorders and anxiety disorders, are more frequent. First diagnosis of HIV positivity, first diagnosis of AIDS, new symptom development, occurrence of an opportunistic infection (OI), and major changes in treatment often provoke emotional responses which can progress to psychiatric symptoms or increase the likelihood of substance abuse relapse.

When presented with the likelihood of a psychiatric or substance abuse disorder, the PCP must make a determination about appropriate management. After ruling out physical causes, mild to moderate depression and anxiety can first be treated with antidepressants and/or anxiolytics. Patients more severely affected should be referred to specialists for further evaluation and treatment. Releases should be obtained in order to coordinate care between the physical and behavioral health providers. Patients should be referred to community supports, including self-help groups, AIDS support groups, AIDS service organizations, case managers, and 12-step programs, when indicated.

- 1.3 A complete physical examination should be performed, with special attention to the evaluation of lymph nodes, funduscopic examination, examination of the oropharynx and skin, abdominal examination to detect enlargement of the liver or spleen, and genital and neurological examination.
- 1.4 It is well remembered that AIDS was at one time a fatal illness. With the advent of effective antiretroviral therapy, many patients do extremely well medically. As a result, while death from AIDS still occurs, the death rate is much lower and for many individuals HIV infection has become a chronic treatable infection. Nonetheless, the issue of advance directives remains as relevant for HIV-infected individuals as for all members of society. The purpose of advance directives is to respect patients' wishes. Early on, the physician should initiate a discussion concerning a patient's understanding of his/her illness and the goals of treatment, whether he/she would ever limit treatment, state what he/she would find unacceptable, and what risks he/she is willing to take to avoid these states. When a patient states specific preferences, it is important to ask "why?" The discussion should include what the patient DOES want (e.g. to die at home). The physician should emphasize that he/she will be there and

remain actively involved regardless of the patient's goals. Discussions about end-of-life decisions are ongoing and evolve as patients gain understanding and experience of their illness. Patients should be reminded they don't have to make immediate decisions and can change their mind. Patients should be reassured that death is not believed to be imminent, if true. Discussions and preferences should be recorded in the medical record. Patients should also be asked to identify a healthcare proxy whose name, relationship to patient, and phone number is recorded in the medical record. Patients should be encouraged to discuss their preferences with their proxy. Patients should be encouraged to prepare a legal document such as a living will. Patients whose proxy is not his/her legal next-of-kin should be encouraged to obtain a legal document identifying power of attorney for healthcare. (Tulsky JA, Fischer GS, Rose MR, Arnold RM. Opening the black box: how do physicians communicate about advance directives? *Ann Intern Med* 1998; 129(6):441-49.)

1.6

Transmission of HIV infection can be reduced through attention to prevention, especially as it pertains to risky sexual and needle-sharing behaviors among people with HIV. Providers caring for patients with HIV should screen patients for risky behaviors, and for sexually transmitted diseases (STDs) at every visit and should provide appropriate treatment and follow-up. This assessment should include:

- 1) Screening for behaviors associated with HIV transmission in a non-judgmental fashion.
 - Indication of risky behavior should prompt a more thorough assessment of HIV transmission risks.
- 2) For injection-drug users
 - Encouragement should be provided to cease injecting and to enter into substance abuse treatment programs.
 - Those who continue to inject drugs should be advised to always use sterile injection equipment and to never reuse or share needles, syringes or other infection equipment.
 - Information should be provided on how to obtain new sterile needles and syringes.
- 3) Questioning about symptoms of STDs with prompt diagnostic testing and evaluation of symptoms.
- 4) Questioning women of child-bearing age to identify possible current pregnancy, interest in future pregnancy or sexual activity without contraception.
 - When indicated, appropriate assessment for current pregnancy should be performed.
 - When indicated, referral for counseling or reproductive health care should be made.
- 5) Screening for STDs among asymptomatic patients initially and at least annually including
 - For men:
 - Screening for syphilis
 - Consideration of screening all HIV-infected men for gonorrhea and Chlamydia infection
 - For women:
 - Screening for syphilis
 - Screening for trichomoniasis

- Screening for cervical Chlamydia infection for all sexually active women \leq 25 years or at increased risk
 - Consideration of screening all HIV-infected women for gonorrhea and Chlamydia infections.
- 6) Discussion about disclosure of HIV status to past, current and future sex or needle-sharing partners.
 - 7) Referral to the appropriate health department to discuss sex and needle-sharing partners who have not been informed of their exposure and to arrange for their notification and referral for HIV testing.
 - 8) Following delivery of the initial prevention messages, subsequent longer or more intensive prevention interventions/counseling should be delivered.
 - 9) Referral to appropriate services for issues related to HIV transmission that cannot be adequately addressed during the clinic visit.

Citation: Center of Disease Control and Prevention. Incorporating HIV prevention into the medical care of persons living with HIV: recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR 2003;52(No. RR-12)
www.aidsinfo.nih.gov.

2.0 The complications associated with antiretroviral therapy can be significant and even life-threatening. The provider should be thoroughly familiar with these complications, and educate patients regarding the potential adverse events involved in taking antiretroviral therapy. The provider must also be aware of drug-drug interactions in the medication regimens of patients with HIV and AIDS.

Adverse drug reactions may be drug specific or related to a class or classes of antiretroviral therapy, such as lactic acidemia (usually related to the use of nucleoside reverse transcriptase inhibitors), or lipodystrophy syndrome (associated with the use of all classes of antiretroviral therapies, but more commonly with protease inhibitors and some NRTIs). PCPs are urged to seek expert consultation when prescribing antiretrovirals and monitoring related outcomes.

Detailed guidelines for the treatment of HIV-infected adults and children have been published and are updated regularly by an expert panel funded by the Department of Health and Human Services (DHHS) and the Henry J. Kaiser Family Foundation. The latest guidelines are available from the HIV/AIDS Information website (www.aidsinfo.nih.gov). Johns Hopkins AIDS Service (<http://www.hopkins-aids.edu>) also provides comprehensive information regarding complications of antiretroviral therapies and drug-drug interactions related to antiretroviral therapy.

2.1 Record of positive HIV serology should include both the EIA and Western Blot results.

2.3 Most experts recommend at least two viral load measurements separated by a few weeks, particularly in circumstances in which the viral load result is the principal determinant as to whether antiretroviral therapy should be initiated. The viral load measurement at 2 to 8 weeks after initiation or change of an antiretroviral regimen is a means of establishing efficacy of the regimen and adherence by the patient.

2.4 The goal of antiretroviral therapy is to reduce the viral load below the level of detection (currently <50 or <75 copies/ml). An undetectable viral load at six months following the initiation of therapy is predictive of a durable antiretroviral response.

2.7 Treatment of Acute HIV Infection: Approximately 50% to 70% of individuals acutely infected with HIV experience a mononucleosis-like illness. Common clinical features include fever, lymphadenopathy, pharyngitis and skin rash. Primary care practitioners should be able to recognize and diagnose the symptom complex of acute HIV infection. Long term virologic, clinical, and immunologic benefit have not been proven. Therefore treatment of acute HIV infection is considered optional. **It is strongly advised that decisions about treatment in this setting should be made in close consultation with an expert or in the context of a clinical trial.**

2.8 Use of Resistance Testing

Consultation with an expert in HIV medicine is recommended prior to the ordering of resistance testing. Genotype and phenotype drug resistance assays may be useful in the assessment of antiretroviral therapy. Genotypic assays provide information on the types of mutations that are present and can indicate the possible cross-resistance to other agents. The reports are generally available in 1-2 weeks. Phenotypic testing actually measures the ability of HIV to grow in the presence of varying concentrations of antiretroviral drugs. Phenotypic testing involves recombining the patient's gene sequences with a laboratory HIV clone and measuring the replication of the virus in different drug concentrations. The concentrations that inhibit 50% (IC50) and 90% (IC90) are compared to a reference strain of HIV. The phenotypic assay can take 2-3 weeks for reporting the results.

1. Resistance Testing Recommended for:

- a. Virologic failure during therapy (genotype, phenotype or both – consult with an expert in HIV medicine).
- b. Inability to suppress plasma HIV RNA to undetectable levels within 4-6 months of initiating therapy (genotype, phenotype or both – consult with an expert in HIV medicine).
- c. Acute (within 6-12 months of transmission) or chronic HIV infection prior to initiating therapy (genotype recommended).

2. Resistance Testing Not Usually Recommended for:

- a. After discontinuation of antiretroviral therapy.
- b. Plasma viral load <1,000 copies/mL. In these instances, the assays may not detect the minor species of resistant virus or have enough viral copies available to adequately perform the test.

3. Some Caveats to Resistance Testing are:

- a. As mentioned, resistance testing measures only dominant species at the time the test is performed.
- b. There must be a viral load of 500-1000 c/ml to perform the test.
- c. Genotypic mutations may be difficult to interpret due to multiple mutations required for drug resistance and cross resistance.
- d. Expert interpretation improves results.

Tropism Assay

HIV tropism refers to which co-receptor the HIV virus uses to enter healthy CD4 cells. Depending on which co-receptor used, HIV is classified as one of the following:

R5 HIV (CCR5-tropic) uses CCR5 co-receptor solely

X4 HIV (CXCR4-tropic) uses CXCR4 co-receptor solely

D/M HIV (dual or mixed tropic) uses either CCR5 or CXCR4 to enter CD4 cells

Trofile assay is a diagnostic test that is performed to determine the viral tropism of HIV. It will report whether a patient has R5, X4, or D/M tropic virus. This test is required prior to commencing a patient on CCR5 inhibitors. If a patient is X4 or D/M tropic, they are not candidates for the currently approved CCR5 inhibitor, Maraviroc, which is the first in a new oral class of antiretrovirals for use in combination with other drugs in treatment experienced patients.

HLA-B* Testing

Abacavir is a commonly used in the treatment of HIV infection and very well tolerated. A major drawback has been the risk of development of hypersensitivity reaction, which usually occurs in about 5-8% of patients. The syndrome is characterized by 2 or more of the following: fever, rash, gastrointestinal, respiratory, or constitutional signs and symptoms. The reaction usually occurs within the first 6 weeks of treatment. Once Abacavir hypersensitivity reaction (HSR) is diagnosed, the drug must be discontinued and re-challenge is contraindicated.

Research has established that the presence of the major histocompatibility complex (MHC) allele HLA-B*5701 is strongly associated with the development of Abacavir hypersensitivity reaction. Studies have shown that screening with this test can result in a reduction in the incidence of Abacavir HSR.

- 3.1 The CDC recommends that a gynecological exam including pelvic exam and Pap smear be performed at baseline, six months and annually thereafter (*MMWR* 1999; 48[RR-10]:31, *MMWR* 2002; 517[RR-6]:59) for patients with normal smears.

Recommendations for Intervention Based on Results of Pap Smear*

PAP Result	Management
Severe inflammation	Evaluate for infection; repeat PAP smear, preferably within 2-3 months.
Atypia • ASC-US** • ASC-H (ASC-H is indeterminate between ASC-US and HSIL)	Consider HPV testing; if high risk type (16, 18, 31, 33, or 35) – colposcopy. Alternative without HPV testing is follow-up; f/u PAP without colposcopy every 4-6 mos. x 2 yrs. until 3 are negative; if second report of ASC-US, perform colposcopy.
Low grade squamous intraepithelial lesion (LSIL)	Colposcopy +/- biopsy or follow with PAP every 4-6 mos. as above with colposcopy and biopsy if repeat smears are abnormal.
High grade squamous intraepithelial lesion (HSIL (<i>carcinoma-in-situ</i>))	Referral for colposcopy +/- biopsy.
Invasive carcinoma	Colposcopy with biopsy or conization; treat with surgery or radiation

*From Bartlett JG & Gallant JE. Medical Management of HIV Infection.

**Atypical squamous cells of undetermined significance

Cervical specimens for detection of *N. gonorrhoea* and *Chlamydia* should be taken during each pelvic exam.

Psychosocial and Cultural Considerations. HIV infection in women is often a family issue, imposing social, psychological and economic burdens on women who care for family members while they are ill. Existing data indicate that many HIV-infected women struggle with poverty, poor self esteem and may be in abusive relationships. These situations all pose significant barriers to obtaining health care services. Clinicians caring for women with HIV/AIDS should obtain a full psychosocial history (see Appendix 1.2) and determine the need for case management and related ancillary services early in the course of clinical care.

3.2 Reproductive Issues: The comprehensive care of the HIV infected pregnant woman incorporates antiretroviral therapy to reduce the risk of perinatal transmission and to maintain the health and immune status of the mother. An experienced HIV care provider and an obstetrician familiar with issues of perinatal transmission and care should ideally manage pregnant women with HIV/AIDS. Options counseling also needs to be included in the services available to the pregnant woman. In general, the recommendations for antiretroviral therapy for the pregnant HIV infected woman will depend on several factors including: immune status as measured by the CD4 cell count, the risk of individual disease progression and vertical transmission as measured by the viral load (HIV RNA levels), current and previous experience with antiretroviral therapy and gestational age. Genotypic testing should be utilized in those instances where there is incomplete viral suppression.

Decisions about mode of delivery should be discussed between the physician and the woman in instances where viral suppression is incomplete or where other medical conditions increase the possibility of perinatal transmission of HIV. In such circumstances, caesarian section may be the recommended mode of delivery.

The details of antiretroviral therapy and safety of those medications can be found in the following guidelines: <http://www.aidsinfo.nih.gov/guidelines>

Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States – October 12, 2006.

Apart from clinical trials, information about the safety of antiretroviral therapy during pregnancy is available from the Antiretroviral Pregnancy Registry (www.APRegistry.com)

The Antiretroviral Pregnancy Registry
Research Park
1011 Ashes Drive
Wilmington, NC 28405
Tel: 1-800-258-4263
Fax: 1-800-800-1052

Health care providers are encouraged to report cases of prenatal exposure to antiretroviral drugs in order to accumulate information that will assist in refining the approach to the pregnant HIV infected woman.

- 4.2 A chest radiograph is indicated for all patients with a positive PPD (≥ 5 mm) or strong exposure history. Though not a requirement it also has been advocated to screen for occult tuberculosis in PPD negative patients. More importantly a baseline chest radiograph may become useful later owing to the high incidence of pulmonary disease in late stage HIV infection.

Osteoporosis risk factors include immobility, cigarette smoking, excessive alcohol use, chronic renal failure, hyperthyroidism, and long term corticosteroid use (CID 2004; 39:609-29).

- 4.4 CMV serology is recommended by the USPHS/IDSA guidelines for “groups with relatively low rates of seropositivity for CMV and who anticipate possible exposure to CMV” Possible uses: screening for patients who require prophylaxis (**Note: prophylaxis not currently recommended**); for seronegative patients avoiding CMV seropositive blood transfusions, if possible; diagnostic use in late stage patients with clinical disease possibly consistent with CMV.

- 4.6 Hepatitis A, B, C Serologies:

Hepatitis A and B may be preventable diseases in susceptible HIV-infected patients after vaccination. Most patients with HIV have risk such that it wise to consider screening all HIV-infected patients for Hepatitis A with a Hepatitis A IgG antibody. Hepatitis B screening is recommended for all HIV-infected patients. Although there is no vaccine available for Hepatitis C, screening for Hepatitis C with EIA alerts the provider/patient to this serious co-morbidity. In general, markers of a poor Hepatitis C outcome/contraindication to therapy include uncontrolled HIV viral RNA, IVDU, alcohol use, and/or depression. Patients infected with hepatitis C require a full work-up and referral for liver biopsy and treatment as appropriate.

- 4.7 Hepatitis A Vaccine:

Two doses of hepatitis A vaccine given intramuscularly (IM) in the deltoid muscle at time 0 and at 6-12 months are recommended for persons over age 18 years at risk for hepatitis A infection including illicit drug users, MSM, and hemophiliacs. The need for periodic booster doses of the vaccine has not been established.

- 4.8 Hepatitis B Vaccine:

The recommended regimen for the recombinant hepatitis B vaccine is to administer three doses of 10 or 20 micrograms (depending on the vaccine product) IM in the deltoid muscle at time 0 and at 1 and 6 months. Clinicians should consider testing antibody response at 1-6 months after the last dose of vaccine in HIV-infected individuals who are at very high risk for Hepatitis B. Serum levels equal or greater than 10 SRU/ml are considered protective. Non-responders may benefit from an additional 1-3 doses.

- 4.9 For patients who cannot receive either whole or split influenza virus vaccine, alternative preventive agents for influenza A include rimantadine 100 mg po BID or amantadine 100 mg po BID. Oseltamivir, 75 mg po daily also is indicated for prevention of influenza A or B.
- 4.10 Revaccination with pneumococcal vaccine earlier than 5 years should be considered if the initial immunization was given when the CD4 cell count was <200/μL and if the count increases to ≥200/μL on HAART.
- 4.11 Primary Prophylaxis for *Mycobacterium avium* complex

<i>M. avium</i> complex	First Choice	Alternatives
	<ul style="list-style-type: none"> • Azithromycin 1200 mg po q.w. • Clarithromycin 500 mg po BID 	Rifabutin 300 mg po q.d. Rifabutin 300 mg po q.d. plus Azithromycin 1200 mg po q.w.

For patients receiving primary prophylaxis for *M. avium* complex, the latest USPHS/IDSA guidelines suggest that prophylaxis can be discontinued for patients whose CD4 counts have rebounded above 100/μL for ≥ 3 mos. provided there is a sustained suppression of HIV plasma mRNA (viral load).

- 4.12 Primary Prophylaxis for *P. carinii* pneumonia

<i>P. carinii</i>	First Choice	Alternatives
	TMP/SMX ¹ 1 DS po q.d. TMP/SMX 1 SS po q.d.	Dapsone ² 50 mg po q.d. plus pyrimethamine 50 mg po q.w. plus leukovorin 25 mg po q.w. Dapsone 50 mg po BID or 100 mg po q.d. Dapsone 200 mg po plus pyrimethamine 75 mg po plus leukovorin 25 mg po q.w. Aerosolized pentamidine 300 mg q.m. Atovaquone 1500 mg po q.d. TMP/SMX 1 DS po TIW

¹TMP/SMX – Trimethoprim/sulfamethoxazole

²Screening for G6PD deficiency should be performed before starting dapsone

For patients receiving primary prophylaxis for *P. carinii* pneumonia, the latest USPHS/IDSA guidelines suggest that prophylaxis can be discontinued for patients whose CD4 counts have rebounded above 200/μL for ≥ 3 mos.

- 4.14 Primary Prophylaxis for Toxoplasmosis

<i>T. gondii</i>	First Choice	Alternatives
	TMP/SMX ¹ 1 DS po q.d.	TMP/SMX 1 SS po q.d. Dapsone ² 50 mg po q.d. plus pyrimethamine 50 mg po q.w. plus leukovorin 25 mg po q.w. Atovaquone 1500 mg po q.d. +/- pyrimethamine 25 mg po q.d. plus leukovorin 10 mg po q.d.

¹TMP/SMX – Trimethoprim/sulfamethoxazole

²Screening for G6PD deficiency should be performed before starting dapsone

For patients receiving primary prophylaxis for toxoplasmosis, the latest USPHS/IDSA guidelines suggest that prophylaxis can be discontinued for patients whose CD4 counts have rebounded above 200/ μ L for \geq 3 mos.

4.16 Chemoprophylaxis for Tuberculosis

<i>M. tuberculosis</i>	First Choice	Alternatives
All Patients- whether receiving Protease Inhibitors or NNRTI's or not;	<ul style="list-style-type: none"> • INH¹ 300 mg, daily for duration of 9 months 	<ul style="list-style-type: none"> • INH 900 mg, 2 times/week for duration of 9 months (Direct observed preventative therapy)

¹INH – isoniazid

Note: Owing to significant drug interactions between rifampin (and rifabutin) and HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTI's), any decisions concerning the use of these medications concurrently should be made only after careful consultation with an expert.

5.6 HealthChoices Managed Care Organization Special Needs Unit (SNU) and Case Management Services

Special Needs Unit (SNU):

The Special Needs Unit (SNU) serves as an additional member support service that helps the member to:

- Navigate the MCO
- Access care coordination in response to a member's special need
- Access timely and effective services

The Department of Public Welfare has been deliberately non-categorical in its definition of a "special need." Therefore, the Department and the MCOs promote the SNU as the place members should call when they believe they have a special need.

The following highlights what the SNU is and how it operates:

- SNU staff are care coordinators who personally assist special needs members in receiving health care through their MCO
- SNU staff educates other MCO staff and network providers about special needs populations. They assist members with special needs by communicating with utilization management staff for authorization of needed services
- SNU staff assist members with special needs who have circumstances which will affect their health, i.e., lack of transportation
- SNU staff provide community education about the SNU's purpose to agencies and organizations that may serve members with special needs
- PCPs, other network providers, or responsible persons may contact the SNU on the member's behalf to request assistance in providing care coordination
- Members with special needs may call the SNU directly or call Member Services where they will be transferred to the SNU.

Examples of work SNUs perform include:

- Assisting members with special needs in finding a PCP or specialist who is experienced in serving persons with similar special needs
- Instructing members and their providers how to submit adequate documentation to indicate medical necessity for a needed item or service
- Communicating with the MCO's medical director to provide comprehensive information about a particular member's social as well as medical circumstances for the purpose of appropriate authorization of needed care
- Referring providers experienced in serving persons with a particular special need to the MCO's provider services staff for recruitment to enhance the MCO's provider network
- Communicating with MCO staff to expedite prior authorization reviews for services without which a member may experience critical secondary complications.

Case Management Services:

Each physical health MCO for Medicaid beneficiaries offers Targeted Case Management Services. These are case management services targeted to the special needs of persons with symptomatic HIV infections or AIDS. The purpose of this program is to assist eligible persons access needed medical and social services to stabilize or improve their quality of life. These services are voluntary. Qualified persons can enroll and disenroll at any time, and can select another case manager if desired. Participation in the program does not change eligibility for any other services otherwise available from the MCO.

Each Medicaid beneficiary that wishes to participate selects a qualified case manager from a list maintained by each MCO. These case managers have expertise assisting persons with symptomatic HIV infections and AIDS. Each MCO offers help in identifying and selecting a case manager and monitors the activity of each case manager for quality assurance.

ACCESS Plus Intense Medical Case Management

The ACCESS Plus / Fee for Service program offers care management services to persons with symptomatic HIV infection or AIDS. A qualified nurse case manager will collaborate, coordinate and facilitate services for individuals, in all age groups, with their complex physical, emotional or social needs. The nurse case manager will make outreach calls to the individuals, providers and will make in-home visits on a case by case basis.

The nurse care manager will:

- Provide case management services, assuring continuity of care and follow up
- Provide a comprehensive assessment of medical, social and psychosocial needs
- Develop a plan of care addressing clinical care, social and psychosocial needs
- Provide assistance in coordinating multidisciplinary health care services and referral activities, to minimize duplication of services

- Provide on-going follow-up activities to ensure delivery of needed health care and social services
- Provide periodic reassessment and evaluation of the individual's needs and case management activities

5.7 AIDS Waiver

To qualify for the AIDS Waiver a recipient must:

- Be eligible for medical assistance as categorically needy or medically needy (the former blue card, green card)
- Must be age 21 or older
- Be diagnosed as having AIDS or symptomatic HIV disease
- Require an acute, a skilled nursing facility (SNF), or an intermediate care facility (ICF/ICFMR) level of care as determined by the Department of Public Welfare.
- Have exhausted any third party benefits including inpatient insurance. Effective July 1, 2003 consumers may have in-patient hospitalization, including Medicare
- May not be in a hospice program
- Be determined as likely to benefit from home and community-based waiver services (Waiver services must be part of the physician's plan of care)
- Be in outpatient status while receiving waiver services.

An individual who is not currently eligible for Medical Assistance coverage, but who qualifies for an acute, SNF, or ICF/ICFMR level of care, may apply in conjunction with the Waiver. The County Assistance Office (CAO) will use eligibility criteria similar to that used for nursing home eligibility, which includes higher income and resource levels.

V. Available HIV Resources

1. Federal Resources on HIV/AIDS research, treatment, and prevention - <http://www.aidsinfo.nih.gov> - 1-800-874-2572
2. AIDS Educational Global Information System - <http://www.aegis.com>
3. American Foundation for AIDS Research - <http://www.amfar.org> - 1-800-382-6327
4. CDC National Prevention Information Network - <http://www.cdcnpin.org>
5. HIV/AIDS Office of Special Health Issues - <http://www.fda.gov/oashi/aids/hiv.html>
6. International Association of Physicians in AIDS Care - <http://www.iapac.org>
7. JAMA HIV/AIDS Information Center Archives- <http://pubs.ama-assn.org/>
8. Johns Hopkins AIDS Service - <http://www.hopkins-aids.edu>
9. Medscape HIV/AIDS - <http://www.medscape.com/home>
10. National HIV Telephone Consultation Services - 1-800-933-3413
11. Office of Aids Research, NIH - <http://www.oar.nih.gov>
12. Zung Self Rating Depression Scale - <http://www.fpnotebook.com/Psych/Exam/ZngSlfRtngDprsnScl.htm>
13. The Quality of Life Instruments Database- www.qolid.org
14. Pennsylvania HIV/AIDS Community Resource Directory, - <http://www.stophiv.com>
15. Health Resources and Service Administration <http://www.hab.hrsa.gov/>
16. Aids Education and Training Center: www.aids-etc.org
17. Medical Outcomes Trust: <http://www.outcomes-trust.org/instruments.htm#mos-hiv>
18. Incorporating HIV prevention into the Medical care of persons living with HIV: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm>
19. Pennsylvania's Special Pharmaceutical Benefits Program (SPBP): <http://www.dpw.state.pa.us/partnersproviders/medicalassistance/advocatesstakeholders/aidscl ozarilprogram/default.htm>

Note: This program in other states is called AIDS Drug Assistance Program or ADAP